Health and Social Care Board

NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP

Protocol for Joint Investigation of Adult Safeguarding Cases

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SECTION 1

1.1 Introduction

Living a life that is free from harm and abuse is a fundamental right for every person.

There has been growing recognition that a wide range of adults may, for a variety of reasons, be at risk of harm from abuse, exploitation or neglect. This has been reflected in the continuing evolution of government thinking and policy in relation to adult safeguarding at national, regional and local levels.

In a Northern Ireland context, there has been a series of documents published in recent years that have had considerable influence in the delivery of safeguarding services.

They include The Protocol for the Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults (2003 and revised in 2009) and Achieving Best Evidence in Criminal Proceedings (Northern Ireland) (2003, revised in 2010 and again in 2012) which set out in detail how health and social care and criminal justice professionals should work together to more effectively support adult victims when harm/abuse constitutes a possible crime.

'Adult Safeguarding in Northern Ireland: Regional and Local Partnership Arrangements' (DHSSPS and DoJ) was published in 2010 and led to the establishment of the Northern Ireland Adult Safeguarding Partnership (NIASP) and the five Local Adult Safeguarding Partnerships (LASPs).

It is important to note that there have also been many developments over the last few years in terms of entitlements and support to victims of crime.

The Victim Charter (Justice Act (Northern Ireland) 2015) Order 2015 sets out requirements in relation to entitlements and supports to victims of crime and the standards of service that victims can expect to receive when they come in contact with the Criminal Justice System.

The Victim Charter - a Charter for Victims of Crime, published by the Department of Justice in September 2015, provides information on the range of entitlements aimed at supporting victims of crime and details the roles and responsibilities of relevant agencies in relation to delivering of these supports. Some of the entitlements are available to all victims of crime such as crime information leaflets and access to Victim Support Northern Ireland.

Other entitlements are targeted at the most vulnerable in our society and include, but are not limited to, Achieving Best Evidence in Criminal Proceedings, the use of Special Measures and, where appropriate, use of Registered Intermediaries.

These supports aim to assist the victim through the criminal justice process from the point of referral to PSNI, making a statement of complaint, giving evidence in Court and follow up in terms of outcome. There are other arrangements in place to support a vulnerable individual who is suspected of committing a crime.

In July 2015 the Adult Safeguarding Prevention and Protection in Partnership Policy (the Policy) was produced jointly by the Department of Health Social Services and Public Safety (DHSSPS) and Department of Justice.

The Policy sets out the future agenda for adult safeguarding in a Northern Ireland context. It extends safeguarding to encompass both prevention and protection and places a very strong emphasis on partnership working. The responsibilities of different organisations are clearly set out within the Policy which includes thresholds for referrals to adult protection services.

This Protocol for Joint Investigation of Adult Safeguarding Cases (the Joint Protocol) will provide clarity in respect of the roles and responsibilities of adult protection services where the nature of the harm to the adult in need of protection constitutes a potential criminal offence.

1.2 Background

This is the third edition of the Joint Protocol and replaces the Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults 2009. It should be read in conjunction with the regional adult safeguarding policy Adult Safeguarding: Prevention and Protection in Partnership (DHSSPS & DOJ) 2015 and Adult Safeguarding Operational Procedures (NIASP) 2016.

Health and Social Care Trusts (HSC Trusts) and the Police Service of Northern Ireland (PSNI) are identified as the lead agencies with responsibility for adult protection. The Regulation and Quality Improvement Authority (RQIA) is recognised as a key partner when the concern relates to a regulated service.

The Joint Protocol aims to provide a framework within which HSC Trusts, PSNI and RQIA can work in partnership to ensure adults at risk and in need of protection have equal access to the justice system when harm/abuse constitutes a potential crime.

It reflects the experience and learning of practitioners from a range of agencies, including HSC Trusts, PSNI, RQIA and the Public Prosecution Service (PPS). It also incorporates recommendations contained in the Joint Review by RQIA and CJINI of the Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults, 2009.

1.3 Scope of the Protocol

The Joint Protocol relates to adults who are at risk and in need of protection where the harm caused by abuse, exploitation or neglect constitutes a potential criminal offence.

It adopts the definitions of an adult at risk and in need of protection as detailed in Adult Safeguarding Prevention and Protection in Partnership 2015:

An **adult at risk of harm** is a person aged 18 or over, whose exposure to harm through abuse, exploitation or neglect may be increased by their:

i) **personal characteristics** (may include but are not limited to age, disability, special educational needs, illness, mental or physical frailty or impairment of, or disturbance in, the functioning of the mind or brain);

and/or

ii) **life circumstances** (may include, but are not limited to, isolation, socio-economic factors and environmental living conditions);

An **adult in need of protection** is an adult at risk of harm (above):

i) who is **unable to protect** their own well-being, property, assets, rights or other interests;

and

ii) where the **action or inaction of another person or persons** is causing, or is likely to cause, him/her to be harmed.

"Harm" is defined as the impact on the victim of abuse, exploitation or neglect (Appendix 1 Definitions of Abuse, Neglect, Exploitation and related definitions).

The decision as to whether the definition of an adult in need of protection is met will require the careful application of professional judgement on a case by case basis. This should take into account all the available evidence, concerns, the impact of harm, degree of risk and other matters relating to the individual and his or her circumstances. The seriousness and the degree of risk of harm are key to determining the most appropriate response and establishing whether the threshold for protective intervention has been met.

It is important to note that when harm caused by abuse, exploitation or neglect constitutes a potential crime, the PSNI have the lead role and responsibility to investigate. The adult in need of protection should be made aware of their fundamental right to make a report to the police.

The Joint Protocol recognises the dilemmas and complexities posed when an adult in need of protection withholds consent to a police referral and/or there is a lack of clarity regarding whether a concern constitutes a potential crime.

The Joint Protocol provides a framework to support the HSC Trust Designated Adult Protection Officers (DAPO) in making decisions. It is intended as a guide only and there is an expectation that the HSC Trust DAPO must ensure that a professional assessment/risk assessment is carried out for each individual. While each case is unique, this professional assessment process will begin from the perspective that any potential criminal offence should be reported to the PSNI.

The Joint Protocol sets out requirements to ensure that the welfare and protection needs of the adult in need of protection are met as fully as possible. Throughout the Joint Protocol processes, HSC Trusts and PSNI will work in partnership to take these needs into account.

Where the adult in need of protection is known to regulated services, RQIA and the Registered Provider/Manager will be expected to co-operate fully with all processes being put in place to support them.

1.4 Aim and Objectives

Aim

The aim of the Joint Protocol is to ensure that the adult in need of protection is supported in a manner which upholds his/her rights, in particular their right to equal access to the criminal justice system and to prevent further abuse through a collaborative multi-agency partnership.

Objectives

- To provide a framework for effective communication and collaboration between HSC Trusts, PSNI, RQIA and PPS in relation to Joint Protocol referrals and investigations

- To support staff in the decision making process involved in the Joint Protocol

- To provide details of the Joint Protocol processes to be followed.

1.5 Underpinning Principles

Adult safeguarding is complex and challenging and therefore should at all times be guided by a number of underpinning principles. In this context the Joint Protocol adopts the same guiding principles as the Adult Safeguarding: Prevention and Protection in Partnership regional policy:

- **a rights-based approach** which promotes and respects an adult's rights to the protection of the law; to freedom from harm and coercion; to privacy; to confidentiality; to equality of treatment, free from discrimination; and to be safe and secure

- **an empowering approach** which empowers adults to keep themselves safe and free from harm in ways that manage exposure to risk and maximise opportunities to participate in wider society

- **a person-centred approach** which promotes and facilitates full participation by the adult in all decisions affecting his or her life and take full cognisance of the views, wishes and feelings of the individual and, where safe and appropriate, the views of others who have an interest in his or her well-being

- **a consent-driven approach** which makes a presumption of the adult's decision-making capacity and ability to make informed choices; to help inform choice through the provision of information, and advocacy where needed, and the identification of options and alternatives; to have particular regard to the needs of individuals who lack the capacity to consent; and intervening in the life of an adult against his or her wishes only in very particular circumstances, for very specific purposes and always in accordance with the law

- **a partnership approach** which acknowledges that safeguarding will be most effective when it has the full support of the wider public and of safeguarding partners across the statutory, voluntary, community and private sectors working together with and for adults at risk; and is delivered in a way where roles, responsibilities and lines of accountability are clearly defined and understood.

1.6 Roles and Responsibilities of Key Agencies

Health and Social Care Trusts

There are 5 Health and Social Care (HSC) Trusts - Belfast HSC Trust, South Eastern HSC Trust, Western HSC Trust, Southern HSC Trust and Northern HSC Trust. The HSC Trusts provide integrated health and social care services across Northern Ireland. HSC Trusts manage and administer hospitals, health centres, residential homes, day centres and other health and social care facilities and they provide a wide range of health and social care services to the community. HSC Trusts have a significant role in adult safeguarding, including both prevention and protection of adults at risk.

Within each HSC Trust there are key personnel with responsibility for delivering on the requirements set out in the Joint Protocol. These are Designated Adult Protection Officers (DAPOs); Investigating Officers (IOs) and Specialist ABE Interviewers.

HSC Regional Emergency Social Work Service

The Regional Emergency Social Work Service (RESWS) provides an emergency social work service outside normal office hours including weekends and public holidays. These are 5pm to 9am Monday to Thursday and 5pm on Friday to 9am on Monday. There is 24 hour cover over public holidays. Contact details are contained in Appendix 2.

The RESWS responds to a wide range of people in crisis and deals with situations which cannot be left until the next working day. People in crisis can include older people, people with mental health issues, learning disabilities, physical disabilities and children and young people.

There are a number of situations in which the RESWS will become involved or work with other agencies to ensure the safety of an individual and others who may be at risk. Examples of emergency situations are where:

- There are immediate significant protection and welfare concerns in relation to an adult at risk and/or an adult in need of protection;
- There are immediate significant protection and welfare concerns in relation to children and young people;
- Urgent advice and/or support is required by families or carers;
- Older people are at risk;
- There is consideration that compulsory admission to hospital under the Mental Health Order (NI) 1986 is required.

Staff within RESWS will provide an adult safeguarding and adult protection service where required and staff will therefore fulfil the role of DAPOs. As DAPOs, RESWS will respond to all elements of the role in emergency situations which require an urgent response.

Police Service of Northern Ireland
The Police Service of Northern Ireland (PSNI)'s purpose is 'keeping people safe'. This goal is achieved through policing in partnership with the community. This proactive, community-driven approach sees the police and local community working together to identify and solve problems.

The Central Referral Unit (CRU) is the regional PSNI centre for all referrals made by either HSC Trusts or PSNI where harm caused by abuse, exploitation or neglect to adult in need of protection constitutes a potential crime. The CRU will, in consultation with HSC Trust DAPO determine whether a criminal investigation is appropriate and, if required, CRU will make a decision regarding which branch of the police service is best placed to conduct the criminal investigation.

In many cases the PSNI Public Protection Branch (PPB) will be appointed to conduct the criminal investigation. CRU and PPB have officers experienced in adult protection work and officers trained as specialist interviewers under Achieving Best Evidence (ABE).

Depending on the nature of the crime CRU may refer the case to other PSNI branches, for example Response Teams, the Rape Crime Unit or CID. These branches will also include specially trained officers in adult protection work and ABE.

It is the responsibility of the PSNI to investigate alleged offences and to gather evidence about what has occurred. When the police have obtained evidence that an identifiable individual may have committed an offence, a file will be prepared and forwarded to the Public Prosecution Service (PPS).

PSNI contact details can be found in Appendix 3**.**

Public Prosecution Service
The Public Prosecution Service takes prosecution decisions and conducts prosecutions on behalf of a number of Government bodies, including the PSNI. The PPS will determine whether criminal proceedings should be instituted or, where criminal proceedings have been instituted, whether they should be continued or discontinued, and also what charges should be preferred. The PPS provides the people of Northern Ireland with an independent, fair and effective prosecution service.

The PPS is wholly independent from both the police and government and its decisions are based on an impartial and professional assessment of the available evidence and the public interest. All actions are undertaken with complete impartiality, to the highest ethical and professional standards. All persons, including those accused of offences, will be treated fairly. All victims and witnesses will be treated with respect and sensitivity. All prosecution decisions are taken and every prosecution conducted in an

effective and efficient manner (Appendix 4 - Guidance in Relation to Test for Prosecution).

Regulation and Quality Improvement Authority (RQIA)

RQIA is an independent regulator with responsibility for registering, inspecting and encouraging improvement in a range of health and social care services delivered by statutory and independent providers, in accordance with The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 and its supporting regulations. The services which it regulates include residential care homes; nursing homes; supported living facilities; supporting people services; children's homes; independent health care providers; nursing agencies; adult placement agencies; domiciliary care agencies; residential family centres; day care settings; and boarding schools. RQIA also have a specific role in relation to inspections in mental health and learning disability hospitals. Other inspections or reviews can be commissioned and conducted across a range of health and personal social services. Where the service inspected is not meeting the required quality standards or where compliance issues or concerns are identified, there are a range of robust sanctions and powers available to RQIA.

RQIA's remit therefore involves prevention, safeguarding and protection of adults at risk of harm and adults in need of protection. With regard to the Joint Protocol RQIA are a key partner in relation to investigations and protection planning in all regulated services.

Contact details can be found in Appendix 5.

1.7 Reporting and Referral Arrangements

Harm to adults in need of protection can take place in any setting; in the person's own home, in the wider community, in a residential or nursing home, hospital or indeed anywhere. It can also be perpetrated by anyone - family, friends, paid staff including professional staff such as doctors, nurses, social workers, police, volunteers, clergy, etc.

Where the harm constitutes a potential criminal offence the adult in need of protection has a right to make a report to the police and should if necessary be supported to make this report.

The arrangements below set out the requirements for reporting a concern which may constitute a criminal offence to either the HSC Trust and/or the PSNI.

a) Referrals to HSC Trusts and/or PSNI by organisations that have direct contact with adults at risk:

The regional policy places a responsibility on organisations that have direct contact with adults at risk to nominate an Adult Safeguarding Champion (ASC). One of the key responsibilities of the ASC is to advise and support staff when there are concerns that an adult at risk may have been subjected to serious harm through abuse, neglect or exploitation (Appendix 6 Definitions of Harm and Serious Harm).

The ASC should ensure that a referral to HSC Trust Adult Protection Gateway Service is made. The ASC should also consider whether there is a need to make an immediate report to the PSNI where there is an imminent risk to the adult.

The adult in need of protection's views and wishes are paramount and any decisions taken should involve consultation with them. Where it is feasible to do so, the consent of the individual should be sought before a referral/report is made to the HSC Trust or PSNI.

However, if there is an adult protection concern which constitutes a possible crime the ASC must consult with the HSC Trust Adult Protection Gateway Service and/or PSNI as appropriate.

b) Referrals/Reports to HSC Trusts by PSNI

Where PSNI have a concern that the individual may be an adult in need of protection, and a crime is suspected, the individual should be advised of the support and protection role of the HSC Trust. In these situations the consent of the individual to contact the relevant HSC Trust should be sought (Appendix **7** Consent and Capacity).

Where an adult in need of protection withholds consent to a referral to the HSC Trust for support and/or protection, the police officer will need to make a professional assessment based on available information as to whether a report/referral to the HSC Trust is nonetheless appropriate.

The following factors should be considered:

- whether the individual has the capacity to make an informed decision in relation to a referral; and
- the level of risk of harm to the individual and /or others including children

Where a police officer decides that a referral to the HSC Trust against the expressed preference of the individual involved is appropriate the rationale for the decision must be clearly recorded.

Each HSC Trust has an Adult Protection Gateway Service which is the central point of contact for all new adult in need of protection referrals. (Appendix 2: HSC Trust Adult Safeguarding contact details).

If a police officer has any concerns that a child or children are in any danger or at risk of harm they should contact the local HSC Trust's Child Protection Gateway Team *(*Appendix 2 HSC Trust Child Protection contact details).

Where there is a concern regarding the safety of an adult in need of protection or a child outside of normal working hours (Monday-Friday 9am to 5pm) the HSC Regional Emergency Social Work Service (RESWS) will work with the PSNI to ensure the immediate protection of the Adult at Risk and/or a child/children.

It will be the responsibility of the RESWS to either update the relevant HSC DAPO if the person is already known to HSC, or to make a referral to the Adult Protection Gateway Service (Appendix 2 RESWS contact details).

Where PSNI identify an adult at risk and have a welfare or care concern that falls outside the Joint Protocol, consideration should be given to whether a referral to HSC Trusts might be appropriate. General referrals in relation to an adult at risk can be made to local Trust offices.

c) Referrals to PSNI by HSC Trusts

In all cases of alleged or suspected harm caused by abuse, exploitation or neglect of an adult in need of protection which constitutes a potential crime, a report to PSNI should be made **except where there is clear and compelling evidence which supports a decision not to report (**see below).

In situations where there is a potential relevant offence under Section 5 of the Criminal Law Northern Ireland Act 1967, HSC Trusts **must** report the matter to the PSNI. (See Appendix 8 Section 5 Criminal Law (Northern Ireland) Act 1967)

The adult in need of protection should always be advised of their right to have the incident reported to the PSNI for investigation. However, if they withhold consent to the referral to the PSNI, then immediate consideration should be given to the balance between the individual's human rights and the obligation to address the risks to the individual and/or others, including children.

Issues in relation to the individual's capacity to consent should be considered (Appendix 7 Human Rights Consent and Capacity) alongside the HSC Trust's legal obligation to report the matter to the PSNI.

No action should be taken until the Joint Agency Consultation (see below) takes place.

Section 2 of this document provides detailed guidance for HSC Trust DAPOs in relation to referrals to PSNI.

In all emergency cases there should be no delay in contacting PSNI via telephone using the 999 telephone number.

The central point of contact for all other reports/referrals to the PSNI is the Central Referral Unit (CRU). Referrals to PSNI CRU will be made by forwarding an AJP1 form to the CRU. This must only be done via secure email using the Criminal Justice Secure Messaging (CJSM) system. All related correspondence must be sent via the same secure system (Appendix 3 PSNI Contact Details; Appendix 14 Adult Joint Protocol Forms).

d) Referrals/Reports to HSC Trusts and/or PSNI by RQIA

RQIA have a responsibility to identify issues that may have an impact on the wellbeing and welfare of adults at risk and to address safeguarding concerns in relation to regulated services. RQIA have a range of mechanisms in place to respond to and address such issues (Appendix 5 RQIA Contact Details and list of RQIA Regulations).

Where there is a concern regarding an individual or group of individuals, RQIA should consider whether this has been caused by abuse, exploitation or neglect. In these circumstances a report to the relevant HSC Trust should be made.

In situations where there is an alleged or suspected concern which constitutes a potential crime, consideration should be given as to whether a referral to the HSC Trust should be made alongside a report to the PSNI. RQIA will make an immediate report to the PSNI if there is an imminent risk to any service user.

1.8 Escalation Arrangements

At any point of the Joint Protocol process where an adult in need of protection and/or their family have a concern regarding how the situation is being handled by any agency, that agency's arrangements for addressing such concerns should be implemented. This can include, for example, local resolution, escalation through the line management structure, or application of the relevant complaints procedure. If the concern remains unresolved, it can be referred to either the Ombudsman for HSC Trust issues or the Police Ombudsman for Northern Ireland.

In the majority of situations it is hoped that positive outcomes will be achieved for the adult in need of protection through effective joint working.

Where there is a difference of opinion between agencies regarding how a case is being managed, every effort should be made to resolve this locally.

In the event that a situation cannot be resolved at this level the following process should be followed:

Within HSC Trusts:
The process of escalating a concern regarding how a case is being managed will involve raising the matter with the following Trust officers in sequence as required:

- DAPO
- DAPO's professional supervisor
- Adult Safeguarding Lead in the relevant Programme of Care
- Trust Adult Safeguarding Specialist Manager (TASS)
- Co-director/ Assistant Director / LASP Chair
- Executive Director of Social Work.

Within the PSNI:
The process for escalating a concern regarding any aspect of the management of a case is as follows and should again be followed in sequence as required.

At point of referral to CRU:

- CRU Sergeant
- CRU Inspector
- CRU Chief Inspector.

Following allocation of a case:

- Sergeant in relevant PSNI branch, i.e. Public Protection branch, CID
- Inspector in relevant PSNI branch or nominated Adult Safeguarding PSNI Lead within Branch
- relevant Chief Inspector

- Chief Inspector with regional responsibility for Adult Safeguarding.

Within the RQIA:

- Inspector aligned to the Regulated Service Provider
- Senior Inspector
- Head of Inspection

There is an expectation that escalation within each organisation will result in senior managers linking with their equivalents, i.e. Trust Adult Safeguarding Leads in each programme would link with the relevant PSNI Inspector.

If a Joint Protocol process has been initiated or a joint agency investigation is taking place, any relevant information arising from a Review should be shared with the other agency/agencies involved.

The framework for requesting a review as detailed above does not exclude normal line management reporting responsibilities.

SECTION 2 Joint Agency Working

2.1 Thresholds for referral to PSNI

The Joint Protocol outlines the thresholds within which a report **must** be made to PSNI and also provides a framework for consideration of a decision not to report to PSNI. The thresholds are intended as a guide for the HSC Trust DAPO and are not intended to be used as exclusion criteria. In some situations a Joint Agency Consultation will be the most appropriate way forward in determining whether a criminal offence may have been committed and/or whether a criminal investigation is required.

All harm is unacceptable and will require and receive a safeguarding response. The nature of that response will be determined by a range of factors. A critical first consideration is whether or not the harm constitutes a criminal offence.

A crime is a breach of the criminal law which is contained in statute or of common law. Not all harm constitutes a crime and only when a criminal offence is suspected is the Joint Protocol applicable.

Where harm constitutes a potential criminal offence the Joint Protocol seeks to ensure that the adult in need of protection has equal access to the criminal justice system. When a report of a potential criminal offence is made PSNI and HSC Trust Adult Protection Gateway Services will work together to:

a) support the individual through the criminal justice process; and
b) collaborate to ensure their welfare and protection needs are identified are addressed.

The Joint Protocol recognises that conflict that can arise when an adult in need of protection, who has capacity to give informed consent, withholds that consent to a police referral.

The HSC Trust DAPO has a significant role and responsibility in balancing the individual's human rights, which include the right to choice, with the obligation to address the risks to the adult in need of protection and/or others including children.

The Protocol is predicated on the principle of reporting alleged or suspected criminal acts to PSNI. Any decision by a DAPO not to report an incident which may constitute a possible crime is a serious and significant decision which must always be supported by clear rationale.

2.2 Roles and Responsibilities of the HSC Trust DAPO

The role of the HSC Trust DAPO is to screen the referral and any other available information to ensure that all relevant HSC adult protection processes are implemented as applicable (Section 3 HSC Adult Protection Processes).

The safety of the person who is being abused is paramount. Appropriate action **must** be taken to safeguard the adult in need of protection. This should involve consultation with, and consent of, the individual concerned.

Where there is a concern regarding imminent danger to an adult in need of protection the HSC Trust DAPO must consider whether an immediate report to PSNI should be made.

When a potential crime has been committed, the HSC Trust DAPO will decide if there is a duty to report a relevant offence as outlined in the Criminal Law Act 1967 Section 5 (Appendix 7

Where any crime is suspected the issue of possible PSNI involvement should be discussed with the adult in need of protection. Their consent for contact with the PSNI should be sought and details of the nature and content of that contact should be provided.

The adult in need of protection should be provided with as much information as possible to assist them in making an informed decision about how they wish the situation to be handled, including information on their right to make a report to the PSNI. Details of all support available through the course of any investigation should also be provided.

Where there is a query regarding the capacity of the adult to make an informed decision regarding whether to report to the PSBI, the HSC Trust DAPO should ensure that every effort is made to maximise their capacity to make this decision.

In all situations where the individual and/or their family take the view that a report to the PSNI should be made, the HSC Trust should facilitate and assist them with this report.

The HSC Trust DAPO is responsible for ensuring that the adult in need of protection's views and all other relevant information inform professional judgements as to any further action to be taken. They must give full consideration to issues of consent and capacity in every case and in every circumstance (Appendix 8 Human Rights, Consent and Capacity).

In situations where the individual lacks capacity to make an informed decision regarding a report, the HSC Trust DAPO should ensure that, where appropriate, the individual's family are consulted.

Where the individual lacks capacity to make an informed judgement and he/she has no family, the HSC Trust DAPO should ensure that 'best interest' principles are applied. This can also apply in circumstances where the family of the adult in need of protection do not agree with a referral to the PSNI. In some situations use of an independent advocate may also need to be considered and/or legal advice sought.

Actions to protect the individual or other adults in need of protection or children should not be delayed pending any assessment of capacity.

Decisions taken to report to PSNI without the consent of the adult in need of protection are serious and significant decisions. The HSC Trust DAPO will need to consider whether undue influence or coercion have been factors influencing the individual's decision.

In making these decisions the HSC Trust DAPO must balance the individual's human rights under Article 8 (Right to Private and Family Life) within the context of possible risk to the individual or others at risk or children. A decision not to make a complaint to the PSNI may be outweighed by the need to ensure that other adults are given the full protection available to them under Article 3 (Prohibition of Torture, Inhuman or DegradingTtreatment) **OR** where the HSC legal obligation is to report a relevant offence.

In these circumstances any decision to report a concern to the PSNI against the expressed wishes of the adult in need of protection should be based on careful consideration of the exercise of both these Articles which indicates that there are reasonable grounds for such a report to be made. The referral to the PSNI should record the basis for this determination. *(*Appendix 7 Human Rights, Consent and Capacity; Appendix 8Definition of Relevant Offence)

2.3 Joint Protocol Pathways

The HSC Trust DAPO, in applying the Joint Protocol, has three possible pathways to consider. They should use the following options to achieve the best possible outcome for the adult in need of protection.

A. There is a potential crime which must be reported to PSNI

B. There is a need for a Joint Agency Consultation with PSNI CRU to determine the most appropriate course of action

C. The criteria for reporting to PSNI under the Joint Protocol are met

A. There is a potential crime which must be reported to PSNI

In the following situations there **must** be a report of the incident to the PSNI:

- An adult in need of protection is in **imminent danger** and there is a need for an immediate report to PSNI

OR

- There has been an incident which may constitute a **relevant offence** under Section 5 of the Criminal Law Act (NI) 1967 (Appendix 8)

OR

- Referral information clearly states the adult in need of protection wishes or has consented to PSNI involvement

OR

- The referral information clearly states that the adult in need of protection lacks capacity to give informed consent to PSNI involvement and family members and/or professionals involved take the view that PSNI involvement is required.

When considering the urgency of the response required the following should be used as appropriate:

- 999 call – if an imminent danger has been identified
- CRU (Central Referral Unit) via email on CJSM system (Mon-Fri 8am-9pm; Sat & Sun 9am-5pm)
- Outside the CRU hours call 101 if required (non-emergency)

Incidents which may constitute a relevant reportable offence and which must be referred to the PSNI

In some situations it will be evident from the outset that a relevant offence has occurred. In other situations, assessment, professional judgement and joint agency consultation will be required to properly determine this. For example a situation where both adults at risk lack capacity and are found in bed together does not necessarily mean that a sexual offence has been committed. A professional assessment should take place to decide the most appropriate response.

- **Physical assault**
  Any form of assault is unacceptable. There are a range of potential offences which include common assault, assault occasioning actual bodily harm, grievous bodily harm, and grievous bodily harm with intent, attempted murder, manslaughter and murder. However in terms of relevant offences, common assault is not a relevant

offence under section 5 of the Criminal Law (Northern Ireland) Act 1967 (as it attracts a sentence of less than 5 years).

- **Sexual offences**
  Most sexual offences will be relevant offences under section 5 of Criminal Law Act (Northern Ireland) 1967. The DAPO as part of the professional assessment should ascertain whether any non-consensual sexual activity has occurred and taking into consideration the views of the alleged victim and/or their next of kin determine whether harm has taken place.

- **Domestic abuse incidents**
  The definition of domestic violence and abuse incorporates issues such as forced marriage, female genital mutilation and honour based violence, as well as abuse of adult in need of protection within the family or by an intimate partner.

  However not all acts which may amount to domestic abuse constitute criminal offences. For example psychological abuse, name calling or controlling behaviour are not criminal offences per se but may still require an alternative safeguarding response.

  Whether a criminal offence has been committed will depend on the circumstances of each individual case. In all domestic violence cases the CAADA/DASH/RIC form **must** be completed to determine whether a referral to MARAC is required and/or serious harm has been caused which requires a report to the PSNI.

- **Financial abuse incidents**
  Where there are reasonable grounds to suspect that a crime has been committed or there is an allegation of fraud, theft and/or misuse of finances.

- **All cases of Human Trafficking and Modern Slavery**
  Most cases of human trafficking and modern slavery will be complex in nature and may involve serious organised crime where the risk to victims and /or others can be significant. Therefore consultation with the victim and PSNI should take place and the wider public interests must be taken into consideration. The HSC Trust DAPO should seek further advice from the HSC Trust Lead officer for cases of human trafficking and modern slavery.

- **All cases where the person alleged to have caused the harm is a paid employee or a volunteer in a position of trust and there is a reasonable suspicion that a crime has been committed.** Where poor practice may constitute ill-treatment or wilful neglect, consideration may need to be given to Article 121 of the Mental Health (Northern Ireland) Order 1986. (Appendix 9)

  Not all incidents of poor practice constitute serious harm and/or an offence but may still require an alternative safeguarding response.

- **Institutional abuse** can take many forms, ranging from issues associated with poor practice to situations where serious harm may have been caused and/or a criminal offence may have been committed.

- **Historical abuse** can relate both to childhood abuse or past abuse in adulthood. The main forms of historical abuse to date have been sexual, physical, financial and institutional abuse. In cases of alleged historical childhood abuse, the lead agency will be the PSNI.

  However if the adult is considered to be an adult at risk, HSC Trusts should consider whether the individual would benefit from the support offered through the Joint Protocol process. In these cases it is essential that there is robust joint agency consultation between PSNI CRU and the Adult Protection Gateway Service. Child Protection Gateway Services should be involved as appropriate.

  In cases of historical child abuse, a PJI1 form (Appendix 14) should be completed and forwarded to the PSNI using the secure email CJSM system. Where the professional assessment indicates that the adult in need of protection will require the support mechanisms offered via the Protocol process, this should be recorded on the PJI1 form clearly stating that the Pre-Interview Assessment and Achieving Best Evidence processes should be followed.

Where there are reasonable grounds to suspect that a relevant offence has been committed, the HSC Trust has a legal obligation to report the matter to the PSNI. However this does not negate the HSC Trust responsibility to ensure that all human rights obligations are fully considered.

In order to meet these obligations there is a clear and explicit requirement for the DAPO to ensure that the HSC Investigating Officer (IO), where it is safe to do so, engages with the adult in need of protection to discuss the incident and their view on any action to be taken.

Where the individual does not want to make a report to the PSNI and the professional view is that a relevant crime may have been committed, there must be evidence of the rationale for any decisions to report the matter to the PSNI. This rationale should be recorded on the Regional ASP and Joint Protocol AJP forms (Appendix 14 AJP Forms).

B. There is a need for a Joint Agency Consultation with PSNI CRU to determine the most appropriate course of action

Where there are reasonable grounds to suspect that an adult in need of protection may be a victim of a potential criminal offence and there is uncertainty regarding the

most appropriate course of action, a Joint Agency Consultation should be considered. The views and wishes of the individual should be sought and a full explanation of the process provided.

Where the individual withholds consent to a Joint Agency Consultation, the HSC Trust DAPO may need to consider seeking legal advice on the appropriate way to proceed.

The purpose of a Joint Agency Consultation is for the HSC Trusts and PSNI to work together to reach an informed decision regarding the best possible outcome for the adult in need of protection. It ensures and facilitates an early exchange of relevant information.

This consultation should involve the relevant HSC Trust DAPO and the PSNI CRU officer and should determine whether a PSNI investigation is required and if so whether this should be a joint agency investigation.

Referrals for a Joint Agency Consultation should be made using the AJP1 form (Appendix 14). This form must be forwarded via the CJSM secure email system. On completion and forwarding of the AJP1, the referrer should make contact with the PSNI CRU and the process of Joint Agency Consultation will begin.

Not all consultations will automatically result in a police investigation. However they will be treated as a potential crime and as such will be issued a crime reference number.

Careful consideration will need to be given to all available information including active consideration of the views and wishes of the adult in need of protection and/or their family and relevant others as appropriate.

PSNI, as the lead agency in relation to criminal matters, will have a pivotal role in determining whether a criminal investigation needs to take place. Nevertheless, it is anticipated that there will be joint agency discussion and decision making.

PSNI CRU, like the HSC Trust DAPO, will need to consider issues of consent, capacity and human rights when deciding what action needs to be taken. Where a criminal investigation is to proceed against the expressed wishes of an adult in need of protection, there should be clear evidence and record of the balancing of rights and a rationale to support any decision taken.

The detail of any decision and rationale should be recorded by PSNI CRU on the AJP1 form (Section 3 and Appendix 14), along with details of agreed actions to be taken. The Joint Agency Consultation must agree a decision as to the way forward. This should not preclude an interim protection plan being implemented if required. The AJP1 outcome will be forwarded to the DAPO by PSNI.

Outcome of an Initial Joint Agency Consultation

There are a number of possible outcomes from a Joint Agency Consultation:

1. There is insufficient information available to make a decision.

In such cases the PSNI/CRU must provide detailed instructions regarding any additional preliminary information to be gathered by the HSCTrust. It will be for the PSNI to ensure that an effective balance is drawn between seeking sufficient information from the HSC Trust to make an informed judgement and not jeopardising a possible PSNI investigation.

2. Single agency HSC Trust adult protection investigation

Where a single agency HSC Trust investigation is considered to be the appropriate response, HSC Trust staff should refer to the Adult Safeguarding Operational Procedures (2016) for detailed guidance on conducting a single agency HSC Trust adult protection investigation. The decision to conduct a single agency investigation should be kept under review as new information may indicate a need to reconsider the decision in relation to the Joint Protocol.

3. Single agency PSNI investigation
Where a single agency PSNI investigation is considered to be the appropriate response, PSNI officers should refer to Police Service Procedures.

During a single agency PSNI investigation, where appropriate the HSC Trust will respond to any adult safeguarding or protection issues identified. Strategy discussions/meetings provide a forum in which any potential conflict between safeguarding adults in need of protection and criminal investigations can be discussed and resolutions agreed.

The PSNI should continue to liaise with the relevant HSC Trust DAPO in relation to any adult safeguarding or protection issues. The HSC Trust will co-operate with any PSNI request to provide a Specialist Interviewer.

4. Joint Agency collaborative working

In some cases both the PSNI and the HSC Trust will have a role. In these circumstances close liaison and communication between the two agencies and an agreed action/strategic plan will be required. This plan should, at a minimum, include:

- Clarification of the roles and responsibilities of the two agencies including details of nominated officers
- Details of the communication strategy between the two agencies

- The communication strategies with victims, carers and families and when applicable with RQIA and service providers. This should include agreed time scales and details of the named staff responsible for this
- Details of the agreed actions and sequencing of actions with associated timescales
- Arrangements for ongoing adjustments and review of the action plan

Outcomes should be formally agreed and joint agency decisions taken regarding closure.

PSNI must inform the HSCTrust DAPO of the outcome of any single agency investigation. This will allow the HSCTrust to consider if there are any additional actions and/or protective measures required.

5. Joint Agency investigation involving the PSNI and HSC Trust.
In some cases where the PSNI are taking the lead investigative role but the HSC Trust continue to be involved with the adult(s) in need of protection; joint agency collaborative working will be required.

In joint agency investigative interviews involving the HSCTrust and PSNI, the requirements in relation to collaborative working will apply (See Section 2.3).

6. No further action under the Joint Protocol.
PSNI, HSC Trusts and/or RQIA will need to consider possible alternative responses or support mechanisms, e.g. enforcement action by RQIA.

C. Criteria for NOT reporting to the PSNI using the Protocol for Joint Investigation of Adult Safeguarding Cases

There is always a need for a balanced and proportionate response to concerns. In some instances it will be clear from the outset that the harm or likelihood of harm caused by abuse, exploitation or neglect does not meet the threshold of criminality and that a single agency response under adult protection procedures is more appropriate.

In other situations referral information can be limited and where there is insufficient information to determine what is the appropriate course of action careful consideration must be given to how to proceed. (See section 3.2)

Where the threshold for a potential criminal offence is met the HSC Trust position is that reports to PSNI should be made.

In circumstances where the adult in need of protection has the capacity to make an informed decision and withholds consent to a report being made to the police, attention must be paid to the individual's right to respect, dignity and choice.

A first consideration for the DAPO will be whether there is a legal obligation to report to the police under Section 5 of the Criminal Law Act (NI) 1967 (Appendix 8).

Where there is no legal obligation to report the matter, the DAPO will need to balance the HSC Trust's broad position of reporting to the PSNI with the individual's human rights and, if applicable, the rights of others. The nature of the incident, its impact on the individual and/or others and likelihood of reoccurrence are among a number of factors which must be taken into consideration. Full consideration of all legal obligations will be required when determining the actions to be taken. The DAPO should ensure that a comprehensive risk assessment is conducted to support decision making.

A decision not to report an incident to the PSNI is a serious and significant decision and therefore only HSC Trust DAPOs who have conducted or co-ordinated an initial professional assessment will have the authority to make these decisions.

In making the decision **NOT** to report to the PSNI, the HSC Trust DAPO must as a minimum demonstrate consideration of the following:

- The adult in Need of protection has capacity to make an informed decision and does not want to make a complaint to PSNI. Full consideration will need to be given to all elements of consent, capacity and human rights, including issues of undue influence and possible coercion (Appendix 7 Consent/Capacity/Human Rights).

AND

- The Trust is not required by law to make a referral to PSNI (if the potential offence committed is not a relevant offence under Section 5 of the Criminal Law Act (NI) 1967 (Appendix 8 Section 5 Criminal Law (Northern Ireland) Act 1967)

AND

- It is a minor incident. A comprehensive assessment of all the factors **MUST** be completed to evidence a through risk assessment of these cases. This will include consideration of whether repeat incidents have occurred and/or whether other adults at risk or children have been or are likely to be at risk of harm (Appendix 6 Factors to be considered in the assessment of the seriousness of Harm and Risk of Harm)

AND

- The situation is being managed through an adult safeguarding process and/or there are other protective measures in place

The HSC Trust DAPO must ensure that **all** the above criteria are met and take into consideration any other relevant information. The rationale for a decision not to report an incident to PSNI must be clearly evidenced and recorded on the Regional Adult Joint Protocol forms (Appendix 14)**.**

Where the individual lacks capacity to give informed consent and their next of kin take the view that a report should not be made to the PSNI, this should be adhered to, provided all other above criteria are met and this decision is consistent with best interest principles.

Under NO circumstances should any adult in need of protection's request for a report to be made to PSNI be refused. The entitlement of all individuals to equal access to the justice system is absolute and begins with a report to PSNI.

2.4 Factors to be considered when the person alleged to have caused harm is themselves an Adult at Risk

The HSC Trust will have responsibility in situations where the person alleged to have caused the harm is also an adult at risk. The HSC Trust should take into consideration the human rights and need for protection for this individual. The HSC Trust responsibility in relation to protection remains a constant, irrespective of which pathway the investigation takes i.e. adult safeguarding, adult Protection, PSNI only or joint investigation.

The HSC Trust DAPO should consider the likelihood that the person causing the harm may present an ongoing risk to the victim and/or others including children

In situations where the victim or the victim's family decide not to make a complaint to the PSNI the HSC Trust DAPO should consider:

- The criteria for not reporting to PSNI
- The need for a Joint Agency Consultation

Obligations to report serious harm which may constitute a relevant offence to the PSNI continue to apply.

In all situations where a report is being made to the PSNI, the fact that the person causing harm is also an adult at risk should be clearly highlighted. The PSNI should also be advised if there is a concern that the adult at risk and/or the individual who is

alleged to have caused harm, may not have the capacity to engage in a PSNI interview and to give legal instruction.

There should be no assumptions made about an individual's capacity, even in situations where there is an existing diagnosis affecting cognitive functioning such as dementia or learning disability. Each case should be assessed on an individual basis to determine the person's level of cognitive functioning, whether the harm caused was intentional or unintentional and whether the person can be reasonably held accountable for their actions (Appendix 7 Human Rights, Consent and Capacity).

Capacity assessments should be carried out by an appropriately trained professional. In cases where the person alleged to have caused harm is themselves an adult in need of protection and is already known to specialist services the professional involved may be able to provide an informed opinion in relation to the individual's capacity.

Capacity assessments/reassessment should consider as a minimum:-

- The extent to which the person causing harm is able to understand his/her actions and whether there is an awareness of or intent to cause harm; and

- Whether the behaviours of the person causing harm may be associated with learning disability, mental ill-health or dementia.

In situations where the adult at risk has allegedly caused harm and is deemed to lack capacity to understand his/her actions, the harm was unintentional and does not constitute serious harm or a relevant offence, then consideration should be given to whether a single agency HSC Trust investigation may be a more appropriate response than a PSNI investigation.

In all cases where serious harm has occurred or where the potential offence reaches the threshold of a serious relevant crime, a Joint Agency Consultation with PSNI CRU must take place.

The Public Prosecution Service (PPS) will provide early direction to PSNI in relation to whether a fast track disposal can be considered (Appendix 4 PPS Test for Prosecution). In all cases where PSNI are involved a case file should be prepared by the PSNI.

In certain types of offences the PSNI can consider Discretionary Disposal. In these instances the decision regarding Discretionary Disposal is for the adult in need of protection and/or their family the detail regarding resolution is reliant on the person alleged to have caused the harm acknowledging wrong-doing and complying with the protection plan and any sanctions agreed.

In cases which require the PSNI to submit a case file to the PPS, the PSNI should liaise at an early stage with the PPS to ascertain whether a full investigation file is required to be submitted for consideration or whether a streamline file would suffice.

In any event the file submitted should provide a comprehensive record of all the relevant information and actions taken. The case file should also clearly identify if the person alleged to have caused the harm is an adult at risk and has been assessed as lacking capacity to understand the consequences of his/her actions.

In some situations the adult at risk who is allegedly causing harm will already be known to the HSC Trust and may be resident in a care setting (Residential/Nursing Home, specialist hospital or specialist facility) or in receipt of community services. In light of any identified concerns a full reassessment of this adult at risk's needs should always be conducted.

Where the victim and person alleged to have caused the harm are both considered to be adults at risk and are in the same environment, effective risk management is critical. The likelihood that the person causing the harm will present an ongoing risk to the victim and/or others including children must be considered by the HSC Trust DAPO under both the Adult Protection Operational Procedures and the Joint Protocol.

In situations where the PSNI are the first responders and have concerns that the person allegedly causing harm is an adult at risk, it is their responsibility to make a professional judgement as to whether a referral should be made to the appropriate HSC Trust.

At a minimum this judgement should consider the needs, capacity and consent of the individual and whether there are wider protection issues in relation to other Adults at Risk or children.

SECTION 3

3.1 HSC Trust Adult Protection Processes

The following grid outlines the HSC Trust Adult Protection Processes to be followed in cases where there is a concern that harm caused to an adult in need of protection which may constitute a potential criminal offence.

Stages in Joint Protocol Process	Decision	Action	Decision Process	Forms
Stage 1 DAPO screens referral to determine if Adult Protection criteria is met	a) Criteria not met	Refer to appropriate service/agency	Complete appropriate referral	Record decision on Regional Adult Protection forms
	b) Criteria met	Proceed to **Stage 2**		Record decision on Regional Adult Protection forms
Stage 2 DAPO assesses referral information to determine if a potential crime has been committed	a) Where the referral information clearly states that the adult in need of protection and/or their next of kin wants to make a complaint to the PSNI (section 2.2)	DAPO will ensure that the individual is supported in making a report to the PSNI	DAPO ensures that an immediate report is made to PSNI: - 999 if there is imminent danger to a person. - In all other cases report to CRU (Mon-Fri 8am-9pm; Sat & Sun 9am-5pm) - 101 at all other times PSNI and the DAPO will consult with the person and decide what level of response is required	Record decision on Regional Adult Protection forms DAPO completes AJP1 section 1 & 2 and forwards to CRU without undue delay
	b) Insufficient information to make decision	DAPO considers follow up actions required (section 3.2)	The DAPO will consider the additional information and decide whether a potential crime has or has not been committed and follow either (b), (c) or (d)	Record on Regional Adult Protection forms
	c) Potential crime **NOT** identified	Proceed to Regional Adult Protection Procedures	DAPO initiates single agency Adult Protection investigation	Record on Regional Adult Protection forms
	d) Potential crime identified	Trust DAPO applies threshold criteria (see section 2)	The DAPO should also consider potential additional factors e.g. - the person alleged to have caused harm is themselves an adult at risk. DAPO also needs to consider the needs of this person (see section 2.4) - the case may constitute organised or multiple abuse (see section 6) Proceed to **Stage 3**	Record decision on Regional Adult Protection forms

Stages in Joint Protocol Process	Decision	Action	Decision Process	Forms
Stage 3 Trust DAPO applies threshold criteria to the specifics of referral and considers which of the three options should be implemented (section 2)	<u>Option 1</u> Potential Crime which must be reported to the PSNI (see section 2)	DAPO ensures that the adult in need of protection is informed of requirement to make report to the PSNI	DAPO ensures that in completion of the AJP1 all the individuals and/or others human rights are considered. The rationale for decisions should be recorded (section 2 & Appendix 8)	DAPO completes AJP1 form sections 1 & 2 and forwards to CRU without undue delay via CJSM system DAPO contacts CRU to discuss referral and agree action plan. CRU officer completes AJP1 section 3 and forwards to DAPO on same day
		Where criteria for relevant offence / reportable crime are met, DAPO proceeds to report to PSNI. (see section 2)	DAPO should consider whether there is a need for an immediate report to PSNI via 999 (if there is imminent danger to a person). In all other cases report to CRU (Mon-Fri 8am-9pm; Sat & Sun 9am-5pm) and 101 at all other times (see Stage 4)	Recorded on Regional Adult Protection and AJP forms
	<u>Option 2</u> Joint Agency Consultation	Where the HSC Trust DAPO requires clarification on whether there is a need for a Police investigation, the joint agency consultation process should be initiated. HSC Trust DAPO must provide information on views and wishes of the individual and/or family if applicable. This should be central to the decision making for both agencies. The PSNI expertise in criminal offences will inform this decision (see section 2)	The joint agency consultation should agree a decision as to which option is most appropriate and any actions which are required. There are a range of options which can be considered (see section 2). The decisions regarding which option is agreed should be clearly recorded. If the decision is for joint agency collaborative working, proceed to **Stage 4.** Single Agency Trust investigations follow the Regional Adult Safeguarding Operational Procedures – Adults in Need of Protection.	CRU completes AJP1 section 3 and forwards to HSC Trust DAPO on same day
	<u>Option 3</u> **NOT** reporting case to PSNI	HSC Trust DAPO applies criteria for **NOT** reporting potential crime to PSNI (see section 2)	Where the criteria for **NOT** reporting is met HSC Trust DAPO follows Regional Single Agency adult protection procedures. Decision not to report must be kept under ongoing review	The rationale for a decision **NOT** to report an incident to PSNI must be clearly evidenced and recorded on the Regional Adult Protection Procedures forms by the HSC Trust DAPO.

Stages in Joint Protocol Process	Decision	Action	Decision Process	Forms
Stage 4 Joint Agency Collaborative Working	Joint Agency strategy discussion / meeting following CRU allocation of case to appropriate PSNI Sergeant	HSC Trust DAPO co-ordinates Joint Agency Strategy discussion / meeting Contact made between PSNI Sergeant and agrees Interim Protection Plan All immediate protection measures required should be taken in liaison with the PSNI HSC Trust DAPO ensures that adult in need of protection is informed of the report to the PSNI and their views are considered and recorded on Regional Adult Protection forms and the AJP forms	HSC Trust DAPO agrees interim protection measures as part of strategy discussion / meeting with PSNI Investigating Officer Joint agency agreement in relation to: - lead agency in investigation - Clarify roles and responsibilities - Identify key PSNI and Trust Investigating Officers - Agreed investigation plan - Agreed communication strategy	HSC Trust DAPO records decision in both the Regional Adult Protection forms and the AJP2 form
PIA and ABE				
Joint Agency Investigation Process PIA and ABE Planning	Joint Agency investigation planning	HSC Trust DAPO and PSNI agree to proceed to PIA Specialist Interviewers identified Where appropriate, ABE arranged PSNI consider referral for Registered Intermediary	Joint Agency consideration of need for PIA and ABE interview (Section 5)	AJP3 completed if PIA agreed AJP4 and AJP4(a) if ABE interview required

Closure				
Stage 5 Exit Joint Protocol Investigation	No further action under Protocol	Agreed by all agencies involved in investigation		Decisions recorded on AJP5
	PSNI single Agency Investigation	PSNI responsibility		Decisions recorded on AJP5
	PSNI progresses file to PPS	PSNI responsibility		Decisions recorded on AJP5
	Trust Single Agency Investigation	Trust continues single agency protection planning / agreed actions as appropriate		Decisions recorded on AJP5
	RQIA single agency	RQIA continues to consider regulatory issues and enforcement options as appropriate		Decisions recorded on AJP5

3.2 Initial Decision Making by HSC DAPO where there is insufficient information

Where the HSC Trust DAPO is unable to make an informed decision as to whether a report to the PSNI is appropriate, the following range of options can be considered as part of the preliminary information gathering under the adult protection process:

- Further clarification to be sought from referrer and/or relevant others as part of a preliminary screening process;

- Allocation of the case to an HSC Trust IO for an initial assessment and/or implementation of an Interim Protection Plan

Rationale for Initial Decision Making

The HSC Trust DAPO may decide that an initial Trust single agency assessment or intervention is required. There should be a clear rationale to support this decision which may include:

- There is insufficient information regarding whether serious harm has been caused

or

- There is no indication from the information currently available that a relevant crime and/or a reportable offence has been committed

or

- There are safety concerns regarding the adult in need of protection and the HSC Trust considers that it is best placed to take immediate action to assess and/or manage this risk. The safety of any adult at risk/in need of protection or children will always be paramount in any investigation process. (The DAPO must also consider whether there are any safety issues for staff)

or

- There is insufficient information to determine if the adult in need of protection has the ability to give informed consent and there are no immediate protective actions required or actions under relevant offences.

or

- There are queries regarding the reliability of the information and further checks need to be carried out.

The list above is not exhaustive. Decisions need to be taken on a case by case basis and the application of professional judgement will be critical.

However there should be no delay in establishing whether there is a protection issue to be addressed.

The HSC Trust DAPO is required to consider whether an early referral to the PSNI is appropriate. The HSC Trust DAPO needs to be mindful not to jeopardise a potential PSNI investigation and all actions taken must be considered in this context. If there is the potential to secure forensic evidence and/or possible investigative opportunities, there should be no delay in making a report to the PSNI.

If the HSC Trust DAPO takes the decision that there a need for an initial HSC Trust single agency risk assessment, the HSC Trust DAPO will appoint an IO and give explicit instructions in relation to what actions are to be taken. The HSC Trust DAPO will determine what level of information and assessment is required in order to make an informed decision regarding the nature and level of intervention.

The agreed actions should be recorded on the Regional Adult Safeguarding forms (Appendix 14)**.**

Initial Assessment by HSC Investigating Officer

IOs conducting interviews with the adult in need of protection should be mindful not to jeopardise any potential police investigations and be aware that information obtained may be used as part of any subsequent police investigation.

An initial assessment should, as a minimum, include:

- meeting with the adult in need of protection to establish the facts of the allegation to determine whether there are reasonable grounds to suspect that a crime may have occurred;

- advising the adult in need of protection of the options available to them in terms of making an informed decision regarding their wishes;

- where the concerns constitute a possible crime, advising the adult in need of protection of their right to a referral to the PSNI and providing them with an outline of the Protocol process;

- ascertaining what course of action the adult wishes to take;

- where a **relevant offence** or other reportable offences has taken place the adult in need of protection should be advised of the HSC Trust's legal obligation to report the matter to the PSNI. At this stage particular focus should

be given to the individual's human rights and if contravention of these rights is deemed necessary the rational for this decision should be explained to the individual and recorded using the Regional Adult Safeguarding forms.

Every effort should be made to maximise the adult's capacity to make informed decisions. However if there are issues in relation to the adult's capacity then best interests principles should be applied and, where appropriate, their carer/family should be consulted.

The rights of the adult in need of protection are of paramount importance. However when the investigation and/or protection plan have the potential to infringe on the human rights of others, focused consideration needs to be given to this issue.

Critical Factors to be considered by the HSC Trust DAPO in the assessment process

When there is sufficient information to make a professional judgement regarding whether the harm constitutes a potential crime, it is the role and responsibility of the HSC Trust DAPO to fully apply the guidance provided in Section 2.

In addition the following factors should be considered:

- where the person alleged to have caused harm is themselves an Adult at risk, consideration should be given to how best to proceed. This will include a requirement to review at the needs of the person who is alleged to have caused harm (see Section 2.4)

- where the information provided indicates that there are reasonable grounds to suspect that more than one person has been harmed or there are potentially more than one person alleged to have caused the harm, consideration should be given to whether the criteria for Organised or Multiple Abuse has been met.

  While a number of cases may meet the criteria of organised or multiple abuse, it will be for the professionals involved to determine on a case by case basis whether the additional structures and supports available in these types of cases are required. Any decision not to avail of this should be agreed with senior managers and should be kept under review (Section 6 Large Scale or Complex Investigations).

- where the person under investigation is a member of staff or a paid carer there are potentially a number of investigative processes which will be required. These include a PSNI investigation, an investigation by the employing organisation, an adult safeguarding investigation and a referral to professional or regulatory body.

The interface between these investigative processes and the timescales for investigation should take into consideration the rights of the adult in need of protection and **also** the rights of the person under investigation. Any decision to delay an adult safeguarding or an agency investigation pending the outcome of a PSNI investigation should be kept under active review.

3.3 Application of Joint Protocol Threshold by HSC Trust DAPO

The HSC Trust DAPO, having made a decision based on the available information and/or the initial assessment outcome of the specific case, will determine which of the following thresholds for intervention is deemed to be the most appropriate (see Section 2)

a) Relevant crime and/or reportable crime referred to PSNI for joint agency investigation
b) Joint Agency Consultation with PSNI to determine most appropriate option
c) Criteria for not reporting to PSNI are met, in which case regional Adult Safeguarding Procedures should be followed

(Appendix 10 Joint Protocol flow charts)

3.4 Joint Agency Working

In most situations it is expected that a level of joint agency collaborative working required. The nature of this will depend on the individual case and can include the HSC Trust, PSNI, RQIA and any other relevant organisations. The HSC Trust DAPO will have the lead role in co-ordinating any joint agency meetings required.

Joint Agency Collaborative Working

In cases where the PSNI are taking the lead investigative role but the HSC Trust continue to be involved with the adult(s) in need of protection, joint agency collaborative working will apply. This requires close liaison and communication between the key agencies. It is essential that all key agencies engage in strategy discussions or meetings to facilitate close communication and coordination and effective action plan.
Where the concern relates to an individual or group of individuals known to regulated services, RQIA will be a key partner in terms of joint agency working. Clarification of roles and responsibilities specific to the case and the development of an agreed action plan will be required.

Joint Agency Investigations

It is critical that in joint agency investigations the two key agencies (PSNI and HSC Trust DAPO) work together to ensure that the adult in need of protection is supported in a manner which enables them to have equal access to the justice system. This begins with a process of joint agency strategy planning.

Joint Agency Strategy Planning

The purpose of strategy planning is to:

- share and assess available information
- agree roles and responsibilities in conducting the investigation
- agree /review the interim protection plan
- gather additional information
- formulate a multi-agency plan for the assessment of risk
- address any protection issues
- address any investigation requirements
- consider referral to other agencies or services as required
- decide whether the ABE process may be applicable
- agree a communication strategy

A number of factors will determine which method is used for strategy planning, such as the urgency of the situation, the nature of the allegation, the type of investigation required and so on.

While initial strategy discussions can take place by telephone, a comprehensive planning session can only be achieved when all key personnel are present and can contribute to the risk management process. It is recommended that in most situations where joint agency working is required, a strategy planning meeting should take place.

It is essential that the PSNI and HSC Trust are present at any strategy planning meeting. Decisions regarding the need for PSNI investigation will be reviewed in light of the information provided during the course of the meeting.

Where an allegation relates to a regulated service RQIA should be invited to attend the strategy planning meeting.

Joint Agency closure of case

It is acknowledged that the closure process can be lengthy, particularly in circumstances where a file has been sent to the PPS for a decision on whether a case will be taken forward to prosecution. Therefore it is essential that the agencies involved agree a strategy of closure including communication arrangements with adults in need of protection and relevant others when appropriate. Agreed actions should be recorded by all agencies involved and communicated by the identified lead agency, with clear arrangements in place for any ongoing work.

SECTION 4

PSNI CRU Procedures when HSC Trust DAPOs make a referral and/or seek a joint agency consultation

The HSC Trust DAPO should initially provide information on the AJP1 form via CJSM. Contact can then be made to discuss the details of the case.

The PSNI CRU Constable should establish from the information and discussion whether this relates to a report of a crime to be actioned or if this is a joint agency consultation to determine whether a criminal investigation is appropriate. Record checks should be carried out to inform the decision making process. Particular attention needs to be paid to the views and wishes of the adult in need of protection where they have the capacity to make informed decisions.

Officers need to consider issues of consent, capacity and human rights. A decision to proceed with an investigation against the expressed wishes of an adult in Need of protection is a breach of human rights and therefore any decision to do so must be supported by a clear rationale.

PSNI CRU will have the lead role in determining the most appropriate course of action, however joint agency discussion and decision making should take place where possible. In complex referrals where a joint agency strategy meeting is required, PSNI CRU will not be in a position to attend. Therefore referral information will be passed to the relevant Public Protection Branch and an officer from there will attend.

Section 3 of the AJP1 form should be completed by PSNI CRU, detailing the rationale for any decisions taken and agreed actions. The completed form should be shared between the HSC Trust and PSNI. Where a decision cannot be reached regarding this matter it should be raised immediately with the PSNI CRU Sergeant before any action is taken. If the case is to be allocated for investigation by PSNI, CRU will do this in line with the PSNI Crime Allocation Policy.

Collaborative working should be a feature throughout the Joint Protocol process, both at the point of referral and on allocation. This should ensure an agreed structure in terms of the investigation and protection planning (see Section 3.3 & 3.4).

See Appendix 11 PSNI and CRU Process Flow Chart.

Internal Reporting to PSNI CRU of Adult in Need of Protection referrals

Where PSNI become aware of an Adult in Need of Protection case which meets the threshold for the Protocol they should report this to PSNI CRU without undue delay.

PSNI CRU will then complete the AJP1 form and share with the relevant HSC Trust, emailing via CJSM.

PSNI CRU will then contact the HSC Trust by telephone to discuss the referral and the normal process of liaison will take place with the appropriate HSC Trust DAPO to discuss and agree actions. Section 3 of the AJP1 will be completed and shared between PSNI and Trust to evidence this process.

Adult in Need of Protection Referred by the Public

Where a member of the public rings the PSNI, existing call handling procedures will apply. Full details should be obtained and the occurrence tasked to the PSNI CRU whiteboard. If a call of this nature is received outside PSNI CRU operating hours, consideration should be given to the urgency and seriousness of the incident. In some situations there may be a need to maximise early investigative opportunities. If an immediate police response is required an appropriate call-sign/resource should be tasked as per existing practice. In all other circumstances the matter should be tasked to the PSNI CRU whiteboard as outlined above.

On Allocation

Where matters have been agreed as a joint investigation or police only Investigation, the PSNI will allocate the case to the relevant Public Protection Unit, local policing team or Reactive & Organised Crime Unit for further investigation (Appendix 11 flow chart re PSNI and CRU Processes).

Where a strategy meeting is required the relevant PSNI Investigating Officer will be expected to attend this meeting and any other related meetings required to ensure that a co-ordinated joint agency approach which supports the adult in need of protection is taken. In joint agency investigations close communication and co-ordination in relation to the investigation will be required. It is however important to note that in a single agency police investigation there will also be a need for ongoing communication to ensure that protection needs and/or any other actions can be progressed.

In complex cases PSNI may be asked to attend to provide advice and may be required to be members of the Strategic Management Group *(*see Section 6, Investigation of Organised or Multiple Abuse Cases).

For full details of procedures to be followed by PSNI, Officers should refer to Service Procedure ‘Adults at Risk of Harm and Safeguarding Procedures’ produced by Crime Operations, Public Protection Branch.

SECTION 5

Special Measures Investigative Interviews

The Criminal Evidence (NI) Order 1999 makes special provision for the gathering of evidence from adults in need of protection or intimidated witnesses.

Detailed guidance on interviewing adults as either adults in need of protection and/or intimidated witnesses, including victims, and the use of special measures in order to enable them to give their best evidence in criminal proceedings, is contained in "Achieving Best Evidence in Criminal Proceedings: Guidance on interviewing victims and witnesses, the use of special measures and the provision of pre-trial therapy (2012)".

Pre-Interview Assessment

In all situations where a decision has been taken to conduct a joint agency investigation PSNI and HSC Trust Specialist Interviewers should meet with the adult in need of protection and complete the AJP 3 form.

Only those staff that have completed specialist training will be eligible to conduct a pre-interview assessment (PIA).

The purpose of the PIA is to:

- establish with the individual whether they are willing to make a statement of complaint;
- discuss with the individual the options regarding how this statement may be made: video or ABE statement;
- discuss in full the investigative process and the possible use of Special Measures, including the use of a Registered Intermediary (RI) (Appendix 13). This discussion should highlight to the individual that the decision regarding whether the case goes forward to Court is a decision for the PPS. The decision regarding whether the video and/or statement or other form of Special Measures are used in Court is a decision for the trial Judge;
- discuss and agree the practical arrangements regarding conducting the ABE interview and complete the AJP4 and AJP4(a) forms (Appendix 14).

Achieving Best Evidence Interviews

Only those staff that have completed further specialist training will be eligible to undertake the role of Interviewer and Second Interviewer in special measures investigative interviews.

The purpose of an investigative interview is to ascertain the witness's account of the alleged event(s) and any other information that would assist the investigation. A well conducted interview will only occur if appropriate planning has taken place. Interviews should be planned and carried out in accordance with Achieving Best Evidence Part 3A – Planning and Preparing for Interviews. The planning of the interview should be recorded using the AJP 4 form.

NB: Interviewers must be given sufficient time prior to a special measures investigative interview to carry out this planning process.

Information obtained in the planning process should be used to:

- set the aim and objectives for the interview
- determine the techniques used within the phased interview
- agree the means by which the interview is to be recorded
- who should conduct the interview and if anyone else should be present (including support for the witness such as an Interpreter or RI)
- if anybody should monitor the interview
- who will operate the equipment
- the location of the interview
- the timing of the interview
- the duration of the interview (including pace, breaks and the possibility of more than one session
- what is likely to happen after the interview

Consideration should also be given to who is best qualified to lead the interview. The lead Interviewer should be a person who has or is likely to establish rapport with the adult in need of protection, who understands how to communicate effectively with witnesses who might become distressed and who has a proper grasp of the rules of evidence and criminal offences. The lead Interviewer must have a good knowledge of information important to the investigation, including the points needed to prove particular offences.

The presence of a Second Interviewer is desirable because they can help to ensure that the interview is conducted in a professional manner, can assist in identifying any gaps that emerge in the witness's account and can ensure that the witness's needs are kept paramount.

Statements of Evidence (PSNI Form 38/36) recorded in special measures investigative interviews will be retained by the PSNI for evidential purposes. A copy may be provided to the HSC Trust, provided that the adult in need of protection or their representative agrees.

Where an interview has been video-recorded, the original will be labelled and secured for court purposes by the PSNI. The working copy will be available for viewing by HSC Trusts by prior arrangement only. A log will be completed on each occasion that the tape is viewed by anyone which details the reason for viewing. This will be retained with the working copy of the tape.

Arrangements for viewing the tape by persons other than the HSC Trusts, or at any subsequent court hearing, will be the responsibility of the PSNI. PSNI General Order C(c) 70/96 must be complied with.

The police officer in charge of the case will be responsible as the prime keeper of all exhibits, including any drawings, letters, notes etc. made in the course of the special measures investigative interview. The disclosure of third party material which may be relevant to an investigation must only be made in compliance with the Criminal Procedures Investigation Act 1996.

SECTION 6

Investigation of Large Scale and Complex Abuse Cases

Complex (organised or multiple) abuse may be defined as abuse involving one or more abusers and a number of related or non-related adults at risk. The alleged abusers concerned may be acting in concert to abuse adults at risk, may be acting in isolation, or may be using an institutional framework or position of authority to access adults at risk.

Such abuse occurs both as part of a network across a family or community and within institutions such as residential or nursing homes, supported living facilities, day support settings and in other provisions such as voluntary groups. There may also be cases of adults at risk being abused through the use of the internet. Such abuse is profoundly traumatic for the adults at risk who become involved. Its investigation is time-consuming and demanding work which requires specialist skills from PSNI and HSC Trust staff.

Each investigation of organised or multiple abuse will be different, according to the characteristics of each situation and the scale and complexity of the investigation. However, every investigation will require careful and thorough planning, effective inter-agency working and attention to the needs of the adult(s) in need of protection and the adult(s) at risk involved.

Some investigations become extremely complex because of the number of people or places involved and the timescale over which the abuse is alleged to have occurred.

Process for Investigation of Large Scale and Complex Abuse Cases

On receipt of information which may indicate organised or multiple abuse, the HSC Trust DAPO should immediately consider whether a report to the PSNI is appropriate. A Joint Agency Strategy Meeting with representatives from the key agencies should then take place as a matter of urgency to discuss and agree roles, responsibilities and an interim action plan.

Where the strategy meeting confirms that the investigation relates to organised or multiple abuse, a multi-agency Strategic Management Group will be appointed to oversee the process.

Strategic Management Group

The Strategic Management Group (SMG) will manage and support the investigation and provide the necessary response to the needs of both the adult(s) in need of

protection and the adults at risk. The SMG is comprised of the following core representatives:

- PSNI;
- HSC Trust DAPO;
- a senior manager from the relevant HSC Trust adult Programme of Care; and
- RQIA (where the allegation relates to a regulated service).

The SMG will be convened and chaired by the appropriate agency. SMG representatives may co-opt representation from relevant other disciplines or agencies, dependant on the type of alleged abuse under investigation.

Appropriate legal advice will be necessary and should be sought through PSNI and HSC Trust legal advisers.

Functions of the SMG

The SMG will:

- establish the principles and practice of the investigation and ensure regular review of progress against that plan;
- prioritise and allocate expedient resources to establish an Investigative Team within their respective agencies;
- ensure co-ordination between the key agencies and the Investigative Team within the HSC Trusts and PSNI. This includes resolving any interagency operational interface challenges between various established processes;
- ensure decisions of the strategy planning group are actioned in a timely manner.
- act in a consultative capacity to those professionals who are involved in the investigation;
- draw up a media strategy to respond to public interest issues and agree who will take responsibility for responding to media enquiries;
- have oversight of the agreed communication strategy/liaison with adults in need of protection/families and carers involved in the investigation;
- at the conclusion of the investigation, discuss salient features of the investigation with a view to making recommendations for improvements either in policy or in practice.
- The closing process must be signed off by the SMG in the case of a serious/complex Adult Protection situation.

Following agreement between the PSNI and HSC Trust that referral meets the criterion for organised or multiple abuse, the SMG will meet within 2 working days. Thereafter the SMG will meet as required to discuss and review the progress of the

investigation. The frequency will be determined by the complexity of the case. Managerial representation of the Investigative team will be present at each meeting of the SMG.

The aim of these meetings is to:

- Review all aspects of the strategy for investigation
- Provide advice on the appropriate strategic direction
- Ensure the continuing active co-operation of all relevant agencies
- Agree a response to victims, families and carers if appropriate
- Agree a joint media response
- Produce an accurate record of all meetings held.

At the conclusion of the investigation, the Joint Investigative Team should meet with the SMG to discuss salient features of the investigation with a view to making recommendations for improvements either in policy or in practice.

SECTION 7

Information Management / Information Sharing / Records Management

Adult Safeguarding: Prevention and Protection in Partnership Policy provides detailed information regarding requirements in relation to information management and information sharing. All organisations must comply with these requirements including PSNI, HSC Trusts and RQIA. It will be for each organisation to ensure they are meeting the requirements as detailed in this Policy. The Protocol must be considered within this context with agencies understanding their obligations within this.

In terms of record management it is important for all professionals involved in this process to keep factual, contemporaneous records and understand that these records are critical to the investigation. As records of investigations are likely to be subject to some level of review, judicial or otherwise and are also discoverable, accurate and timely record keeping is essential.

Manual/electronic record keeping should include a detailed rationale for decision making at all stages of the adult safeguarding process. This is particularly important when there are potential contraventions of an individual's Human Rights. Use of CJSM is considered an absolute requirement in this context.

SECTION 8

REFERENCES

- Safeguarding Vulnerable Adults: Regional Adult Protection Policy and Procedural Guidance
  Regional Adult Protection Forum (2006)

- The Protocol for the Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults (2003 and revised in 2009)
  Regional Adult Protection Forum (2006)

- Achieving Best Evidence in Criminal Proceedings (Northern Ireland)
  Department of Justice (2003, revised in 2010 and again in 2012)

- Safeguarding Vulnerable Adults: A Shared Responsibility
  Volunteer Now (2010),

- Adult Safeguarding in Northern Ireland: Regional and Local Partnership Arrangements
  Department of Health Social Services and Public Safety (DHSSPS) and the Northern Ireland Office (now Department of Justice) 2010

- The Victim Charter (Justice Act (Northern Ireland) 2015) Order 2015;

- The Victim Charter – a Charter for Victims of Crime, published by DOJ in September 2015

- MARAC – Operating Protocol for Northern Ireland Multi-agency Risk Assessment Conferences (August 2014);

- Guidance to Agencies on Public Protection Arrangements (PPANI) Article 50, Criminal Justice (Northern Ireland) Order 2008;

- Working Arrangements for the Welfare and Protection of Adult Victims of Human Trafficking (October 2012);

- The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.

SECTION 9

GLOSSARY OF TERMS

Abuse is 'a single or repeated act, or lack of appropriate action, occurring within any relationship where there is an expectation of trust, which causes harm or distress to another individual or violates their human or civil rights' Abuse is the misuse of power and control that one person has over another. It can involve direct and indirect contact and can include online abuse.

ABE (Achieving Best Evidence) Interviewer – The Specialist Achieving Best Evidence Interviewer must be a professionally qualified Social Worker. The Specialist Interviewer will be responsible for planning and conducting interviews with service users who may have been the victim of a crime. These interviews will be undertaken jointly with the PSNI and in accordance with the guidance laid out in "Protocol for Joint Investigation of Adult Safeguarding cases" and "Achieving Best Evidence in Criminal Proceedings."

Adult Protection Gateway Service – is the central referral point within the HSC Trust for all concerns about an adult who is, or may be, at risk.

Adult Safeguarding - encompasses both activity which **prevents** harm from occurring in the first place and activity which **protects** adults at risk where harm has occurred or is likely to occur without intervention.

Adult at risk of harm – A person aged 18 or over, whose exposure to harm through abuse, exploitation or neglect may be increased by their:

iii) **personal characteristics** (*may include but are not limited to age, disability, special educational needs, illness, mental or physical frailty or impairment of, or disturbance in, the functioning of the mind or brain*);

and/or

iv) **life circumstances** *(may include, but are not limited to, isolation, socio-economic factors and environmental living conditions);*

Adult in need of protection - An adult at risk of harm (above):
iii) who is **unable to protect** their own well-being, property, assets, rights or other interests;
and
iv) where the **action or inaction of another person or persons** is causing, or is likely to cause, him/her to be harmed.

ASC (Adult Safeguarding Champion) - The ASC should be within a senior position within the organisation and should be suitably skilled and experienced to

carry out the role. The ASC provides strategic and operational leadership and oversight in relation to adult safeguarding for an organisation or group and is responsible for implementing its adult safeguarding policy statement. The ASC is also the main point of contact with HSC Trusts and the PSNI for all adult safeguarding matters.

Case Conference - The purpose of the case conference is to evaluate the available evidence and to determine an outcome based on balance of probability

CRU (Central referral Unit) – The central point of referral to PSNI in relation to adult protection is based in Belfast.

CJINI (Criminal Justice Inspection Northern Ireland) - an independent legal inspectorate with responsibility for inspecting all aspects of the criminal justice system in Northern Ireland apart from the judiciary. It also inspects a number of other agencies and organisations that link into the criminal justice system

Domestic Abuse - Domestic violence and abuse is threatening behaviour, violence or abuse (psychological, physical, verbal, sexual, financial or emotional) inflicted on one person by another where they are or have been intimate partners or family members, irrespective of gender or sexual orientation. Domestic violence and abuse is essentially a pattern of behaviour which is characterised by the exercise of control and the misuse of power by one person over another. It is usually frequent and persistent. It can include violence by a son, daughter, mother, father, husband, wife, life partner or any other person who has a close relationship with the victim. It occurs right across society, regardless of age, gender, race, ethnic or religious group, sexual orientation, wealth, disability or geography.

Designated Adult Protection Officer (DAPO) – the person responsible for the management of each referral received by a HSC Trust. DAPOs will be in place both within the Adult Protection Gateway Service, and within core service teams. The DPAO will provide formal / informal support and debriefing to the Investigating Officer / ABE interviewer; analyse the adult safeguarding data within their service area and contribute to the governance arrangements as appropriate; and ensure that the connections are made with related interagency mechanisms.

DBS (Disclosure and Barring Service - helps employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups, including children. It replaces the Criminal Records Bureau (CRB) and Independent Safeguarding Authority (ISA).

Exploitation - the deliberate maltreatment, manipulation or abuse of power and control over another person; to take advantage of another person or situation usually, but not always, for personal gain from using them as a commodity. It may manifest itself in many forms including slavery, servitude, forced or compulsory labour, domestic violence and abuse, sexual violence and abuse, or human

trafficking.

FGC (Family Group Conferencing) - A family group conference is a process led by family members to plan and make decisions for a person who is at risk. People are normally involved in their own family group conference, although often with support from an advocate. It is a voluntary process and families cannot be forced to have a family group conference.

Hate Crime - Hate crime is any incident which constitutes a criminal offence perceived by the victim or any other person as being motivated by prejudice, discrimination or hate towards a person's actual or perceived race, religious belief, sexual orientation, disability, political opinion or gender identity.

Harm - the impact on the victim of abuse, exploitation or neglect. It is the result of any action whether by commission or omission, deliberate, or as the result of a lack of knowledge or awareness which may result in the impairment of physical, intellectual, emotional, or mental health or well-being.

Investigating Officer (IO) - is a HSC Trust professionally qualified practitioner. Their role is to establish matters of fact, how best to protect the adult in need of protection and/or others, to explore alternatives available and to provide advice and support. The Investigating Officer alongside relevant professionals will be responsible for direct contact with the adult in need of protection, their carers and relevant others.

The Protocol – (Protocol for Joint Investigation of Adult Safeguarding Cases) - - The Protocol sets out a framework for joint working in a complex area of practice and emphasises the need to involve all other relevant agencies in information sharing, early assessment and the planning process. The overall aim of the Protocol is to prevent abuse by promoting a multi-agency approach to the protection of vulnerable adults, and to ensure that they receive equitable access to justice in a way that promotes their rights and well-being.

LASP (Local Adult Safeguarding Partnerships) - The five local multi-agency, multi-disciplinary partnerships located within their respective HSC Trusts.

MARAC (Multi Agency risk Assessment Conference) - It is a forum for local agencies to meet with the aim of sharing information about the highest risk cases of domestic violence and abuse and to agree a safety plan around victims.

Modern Slavery - Human trafficking involves the acquisition and movement of people by improper means, such as force, threat or deception, for the purposes of exploiting them. It can take many forms, such as domestic servitude, forced criminality, forced labour, sexual exploitation and organ harvesting. Victims of human trafficking can come from all walks of life; they can be male or female, children or adults, and they may come from migrant or indigenous communities.

NIASP (Northern Ireland Adult Safeguarding Partnership) – The regional multi-agency, multi-disciplinary partnership that brings together representatives from organisations and communities of interest who have a significant contribution to make to adult safeguarding.

NISCC (Northern Ireland Social Care Council) – is the independent regulatory body for the NISC workforce, established to increase public protection aby improving and regulating standards of training and practice for social care workers.

NMC (Nursing and Midwifery Council) – is the independent regulator for nurses and midwives in England, Wales, Scotland and Northern Ireland. NMC sets standards of education, training, conduct and performance so that nurses and midwives can deliver high quality healthcare throughout their careers.

Protection Plan - A plan agreed with the adult at risk (or the person representing them or their best interests) detailing the actions to be taken, with timescales and responsibilities, to support and protect the person from harm.

Registered Intermediary - RIs have a range of responsibilities intended to help adult witnesses who are in need of protection, defendants and criminal justice practitioners at every stage of the criminal process, from investigation to trial.

RQIA (Regulation and Quality Improvement Authority) - Northern Ireland's independent health and social care regulator, responsible for monitoring and inspecting the availability and quality of health and social care services in Northern Ireland, and encouraging improvements in the quality of those services.

SAI (Serious Adverse Incident) - An adverse incident is an event which causes, or has the potential to cause, unexpected or unwanted effects that will involve the safety of patients, staff, users and other people.

Serious Harm – is a professional decision considering the impact, extent, degree, duration and frequency of harm; the perception of the person and their preferred outcome.

Single Agency Investigation – A single agency adult protection investigation is a **professional assessment** which analyses the risk of harm and serious harm, the impact of that harm on the adult in need and determines if this may have led to abuse. Such assessment requires experienced professional judgement to ensure outcomes are proportionate, necessary and lawful.

Special Measures - The measures specified in the Criminal Evidence (NI) Order 1999, as amended, which may be ordered in respect of some or all categories of eligible witnesses by means of a special measures direction. The special measures are the use of screens; the giving of evidence by live link; the giving of evidence in private; the removal of wigs and gowns; the showing of video recorded evidence in chief, and aids to communication.

SMG (Strategic Management Group) – has responsibility to oversee the process of investigation. Core representatives of SMG are PSNI; HSC Trust nominated Adult protection Gateway DAPO; a senior manager from the relevant adult programme of care; and RQIA (where the allegation relates to a regulated service).

Strategy Meeting - In complex situations the strategy discussion is normally a meeting of key people to decide the process to be followed after considering the initial available facts.

APPENDICES

Appendix 1

Definitions of Abuse, Neglect, Exploitation and Related Definitions

Abuse is 'a single or repeated act, or lack of appropriate action, occurring within any relationship where there is an expectation of trust, which causes harm or distress to another individual or violates their human or civil rights'.

Abuse is the misuse of power and control that one person has over another. Abuse may be perpetrated by a wide range of people who are usually physically and/ or emotionally close to the individual and on whom the individual may depend and trust. This may include but is not limited to, a partner, relative or other family member, a person entrusted to act on behalf of the adult in some aspect of their affairs, a service or care provider, a neighbour, a health or social care worker or professional, an employer, a volunteer, another service user. It may also be perpetrated by those who have no previous connection to the victim. All forms of abuse may constitute a crime.

The main forms of abuse are:

Physical abuse
Physical abuse is the use of physical force or mistreatment of one person by another
which may or may not result in actual physical injury. This may include hitting, pushing, rough handling, exposure to heat or cold, force feeding, improper administration of medication, denial of treatment, misuse or illegal use of restraint and deprivation of liberty.

Sexual violence and abuse
Sexual abuse is any behaviour perceived to be of a sexual nature which is unwanted or takes place without consent or understanding[6]. Sexual violence and abuse can take many forms and may include non-contact sexual activities, such as indecent exposure, stalking, grooming, being made to look at or be involved in the production of sexually abusive material, or being made to watch sexual activities. It may involve physical contact, including but not limited to non-consensual penetrative sexual activities or non-penetrative sexual activities, such as intentional touching (known as groping). Sexual violence can be found across all sections of society, irrelevant of gender, age, ability, religion, race, ethnicity, personal circumstances, financial background or sexual orientation.

Psychological / emotional abuse
Psychological / emotional abuse is behaviour that is psychologically harmful or inflicts mental distress by threat, humiliation or other verbal/non-verbal conduct. This may include threats, humiliation or ridicule, provoking fear of violence, shouting, yelling and swearing, blaming, controlling, intimidation and coercion.

Financial abuse
Financial abuse is actual or attempted theft, fraud or burglary. It is the misappropriation or misuse of money, property, benefits, material goods or other asset transactions which the person did not or could not consent to, or which were invalidated by intimidation, coercion or deception. This may include exploitation, embezzlement, withholding pension or benefits or pressure exerted around wills, property or inheritance.

Institutional abuse
Institutional abuse is the mistreatment or neglect of an adult by a regime or individuals in settings which adults who may be at risk reside in or use. This can occur in any organisation, within and outside the HSC sector. Institutional abuse may occur when the routines, systems and regimes result in poor standards of care, poor practice and behaviours, inflexible regimes and rigid routines which violate the dignity and human rights of the adults and place them at risk of harm. Institutional abuse may occur within a culture that denies, restricts or curtails privacy, dignity, choice and independence. It involves the collective failure of a service provider or an organisation to provide safe and appropriate services, and includes a failure to ensure that the necessary preventative and/or protective measures are in place.

Neglect occurs when a person deliberately withholds, or fails to provide, appropriate and adequate care and support which is required by another adult. It may be through a lack of knowledge or awareness, or through a failure to take reasonable action given the information and facts available to them at the time. It may include physical neglect to the extent that health or well-being is impaired, administering too much or too little medication, failure to provide access to appropriate health or social care, withholding the necessities of life, such as adequate nutrition, heating or clothing, or failure to intervene in situations that are dangerous to the person concerned or to others particularly when the person lacks the capacity to assess risk. This policy does not include self-harm or self-neglect within the definition of an ‘adult in need of protection’. Each case will require a professional Health and Social Care (HSC) assessment to determine the appropriate response and consider if any underlying factors require a protection

response. For example self-harm may be the manifestation of harm which has been perpetrated by a third party and which the adult feels unable to disclose.

Exploitation is the deliberate maltreatment, manipulation or abuse of power and control over another person; to take advantage of another person or situation usually, but not always, for personal gain from using them as a commodity. It may manifest itself in many forms including slavery, servitude, forced or compulsory labour, domestic violence and abuse, sexual violence and abuse, or human trafficking. This list of types of harmful conduct is neither exhaustive, nor listed here in any order of priority. There are other indicators which should not be ignored. It is also possible that if a person is being harmed in one way, he/ she may very well be experiencing harm in other ways.

Domestic violence and abuse

Domestic violence and abuse is threatening behaviour, violence or abuse (psychological, physical, verbal, sexual, financial or emotional) inflicted on one person by another where they are or have been intimate partners or family members, irrespective of gender or sexual orientation. Domestic violence and abuse is essentially a pattern of behaviour which is characterised by the exercise of control and the misuse of power by one person over another. It is usually frequent and persistent. It can include violence by a son, daughter, mother, father, husband, wife, life partner or any other person who has a close relationship with the victim. It occurs right across society, regardless of age, gender, race, ethnic or religious group, sexual orientation, wealth, disability or geography.

Human trafficking

Human trafficking involves the acquisition and movement of people by improper means, such as force, threat or deception, for the purposes of exploiting them. It can take many forms, such as domestic servitude, forced criminality, forced labour, sexual exploitation and organ harvesting. Victims of human trafficking can come from all walks of life; they can be male or female, children or adults, and they may come from migrant or indigenous communities.

Hate crime

Hate crime is any incident which constitutes a criminal offence perceived by the victim or any other person as being motivated by prejudice, discrimination or hate towards a person's actual or perceived race, religious belief, sexual orientation, disability, political opinion or gender identity. Victims of domestic violence and abuse, sexual violence and abuse, human trafficking and hate crime are regarded as adults in need of protection. There are specific strategies and mechanisms in

place designed to meet the particular care and protection needs of these adults and to promote access to justice through the criminal justice system. It is essential that there is an interface between these existing justice-led mechanisms and the HSC Trust adult protection arrangements described in this policy.

Appendix 2

HSC Trust contact details

HSC Trust	Adult Safeguarding Number
Belfast	028 9504 1744
Northern	028 2563 5512
Western	028 7161 1366
South Eastern	028 9250 1227
Southern	028 3741 2015/2354

Regional Emergency Social Work Service (RESWS)

Tel: 028 9504 9999 (Mon-Fri 5pm-9am; Saturday & Sunday)

HSC Trust Child Protection Contact Details

HSC Trust	Child Protection Gateway Number
Belfast	028 9050 7000
Northern	0300 1234 333
Western	028 7131 4090
South Eastern	0300 1000 300
Southern	0800 7837 745

Appendix 3

PSNI Contact Details

Immediate report to if there is imminent danger to a person.	PSNI via 999	Completed AJP1 form should be emailed via CJSM secure email system to: **CRU@psni.pnn.police.uk.cjsm.net**
PSNI Central Referral Unit (CRU) CRU Hours	Contact Number 02890259299 Mon-Fri 8am-9pm; Sat & Sun 9am-5pm	
At all other times	101	

In historical child abuse cases, completed PJI1 form should be emailed via CJSM secure email to:

CRU@psni.pnn.police.uk.cjsm.net

Appendix 4

Public Prosecution Service (PPS) – The Test for Prosecution

The Code for Prosecutors provides guidance on how the Public Prosecution Service makes decisions about whether or not to prosecute. It is a public document and is available upon request or can be found on the PPS website at www.ppsni.gov.uk.

Prosecutions are initiated or continued by the Public Prosecution Service only where it is satisfied that the Test for Prosecution is met. This is a two stage test as follows;

i. The Evidential Test - the evidence which can be adduced in court is sufficient to provide a reasonable prospect of conviction; and

ii The Public Interest Test - prosecution is required in the public interest.

The Public Prosecutor will analyse and evaluate all of the material submitted in a thorough and critical manner. The Evidential Test must be passed before the Public Interest Test can be considered. Each of these Tests must be separately considered and passed before a decision to prosecute can be taken.

The Evidential Test

Public Prosecutors determine whether there is sufficient evidence to provide a reasonable prospect of conviction against each defendant on each charge.

A reasonable prospect of conviction exists if, in relation to an identifiable individual, there is credible evidence which can be adduced before a court upon which evidence an impartial jury or judge properly directed in accordance with the law, may reasonably be expected to find proved beyond reasonable doubt the commission of a criminal offence by the person who is prosecuted. It is necessary that each element of this definition is fully examined when considering the Evidential Test for each particular case.

The police will gather all available evidence and report the case to the PPS. The Public Prosecutor will consider the evidence carefully and make a decision as quickly as possible. If necessary the Public Prosecutor may have to seek further information from police to enable a decision to be made. The PPS will also try to ensure that cases progress through the court without unnecessary delay.

The Public Interest Test

If a case passes the Evidential Test, the Public Prosecutor must decide if a prosecution is required in the public interest.

Prosecutors must exercise their discretion as to whether a prosecution is required in the public interest. The granting of such discretion to the prosecutor is consistent with the prosecution process in similar legal jurisdictions. In taking decisions as to prosecution the prosecutor is taking decisions for the benefit to society as a whole.

Broadly, the presumption is that the public interest requires prosecution where there has been a contravention of the criminal law. This presumption provides the starting point for consideration in each individual case. A prosecution will usually take place unless there are public interest factors tending against prosecution which clearly outweigh those tending in favour. However, there are circumstances in which, although the evidence is sufficient to provide a reasonable prospect of conviction, a court based outcome is not required in the public interest. For example, Public Prosecutors should positively consider the appropriateness of prosecuting by way of a diversionary disposal, particularly where the defendant is a young person or a vulnerable adult.

In deciding whether a prosecution is required in the public interest, prosecutors should take into account the views expressed by the victim and the impact of the offence on a victim and, in appropriate cases, their family, where such views are available. However PPS does not represent victims or their families in the same way as solicitors act for their clients. It is the duty of Public Prosecutors to form an overall view of the public interest.

Appendix 5

RQIA Contact details

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower
5 Lanyon Place
BELFAST BT1 3BT
info@rqia.org.uk
028 9051 7500 - telephone
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List of Regulations Relating To Regulated Services

Potential Articles relating to RQIA Enforcement Procedures for Regulated Services:

- Improvement Notice - *Article 39 of the 2003 Order*
- Failure to Comply Notice – *Article 15 of the 2003 Order*
- Notice of Proposal to Cancel, Refuse, Vary, and Remove or Impose Conditions in Relation to Registration – *Article 18 of the 2003 Order*
- Issuing of a Notice of Decision – under *Articles 18 & 20 of the 2003 Order*
- Urgent Procedure for Cancellation of Registration or to Vary, Remove or Impost a Condition of Registration – *Article 21 of the 2003 Order*
- Appeals to the Care Tribunal – *outlined under Article 22 of the 2003 Order*

The Residential Care Homes Regulations (Northern Ireland) 2005
The Children's Homes Regulations (Northern Ireland) 2005
The Nursing Homes Regulations (Northern Ireland) 2005
The Nursing Agencies Regulations (Northern Ireland) 2005
The Independent Health Care Regulations (Northern Ireland) 2005
The Day Care Setting Regulations (Northern Ireland) 2007
The Residential Family Centres Regulations (Northern Ireland) 2007
The Domiciliary Care Agencies Regulations (Northern Ireland) 2007
The Adult Placement Agencies Regulations (Northern Ireland) 2007
The Voluntary Adoption Agencies Regulations (Northern Ireland) 2010

Appendix 6

Definitions of Harm and Serious Harm and factors to be considered in the assessment of the seriousness of harm and risk of harm

What is meant by harm?

Adult Safeguarding – Prevention and Protection in Partnership 2015 notes that harm resulting from abuse, exploitation or neglect can be experienced by adults in a range of circumstances, regardless of age, class or ethnicity. Harm is the impact on the victim of abuse, exploitation or neglect. It is the result of any action whether by commission or omission, deliberate or as the result of a lack of knowledge or awareness, which may result in the impairment of physical, intellectual, emotional, or mental health and well-being. This includes:

(i) **Conduct which causes physical harm**, i.e. physical mistreatment of one person by another which may or may not result in physical injury. This may include, among other things, hitting; slapping; pushing or pulling; kicking; rough handling; shaking; exposure to heat and cold; not giving adequate food or drink; force-feeding; unreasonable confinement (e.g. locked in, tied to a bed or chair); the improper administration of drugs or treatments or the denial of prescribed medication; misuse of medication; misuse or illegal use of restraint, or physical interventions and/or deprivation of liberty; misuse of manual handling techniques; or inappropriate sanctions (e.g. controlling access to personal resources or withholding basic necessities of life such as food and drink).

(ii) **Conduct which causes sexual harm**, i.e. the involvement of a person in sexual activities or relationships that either he or she does not want and has not consented to or cannot consent to. This may include, among other things, use of offensive, suggestive or sexual language; indecent exposure; inappropriate touching; not allowing expression of sexuality; withholding appropriate educational information; sexual harassment; sexual assault; rape; 'grooming'; 'stalking'; or human trafficking.

(iii) **Conduct which causes psychological harm**, i.e. behaviour that is psychologically harmful or inflicting mental distress by threat, humiliation or other verbal/non-verbal conduct. This may include, among other things, threats of harm or abandonment; withholding of security, affection, care or support; deprivation of contact; provoking fear of violence; threat of institutional care; humiliation or ridicule; denial of the opportunity for privacy; shouting, yelling and swearing; blaming; controlling; intimidation; coercion; harassment; isolation or withdrawal from services supportive networks or cyber bullying/threats

(iv) **Conduct which causes financial, property or material harm**, i.e. misappropriation or misuse of money, material goods or other assets; transactions to which the person did not consent to, could not consent to, or which were invalidated by intimidation or deception. This may include, among other things, theft; fraud; exploitation; embezzlement; withholding pension; not spending allowances on the individual; denying the person access to his or her money; misuse of benefits; mismanagement of bank accounts; pressure in connection with wills, property, inheritance or financial transactions; unreasonable restriction of a person's right to control his or her life in financial/material terms.

(v) **Neglect** is the deliberate withholding, or failure through a lack of knowledge or awareness, to provide appropriate and adequate care and support, which is necessary for the adult to carry out daily living activities. It may include, among other things, the physical neglect of someone to such an extent that health, development and/or well-being is impaired; administering too much or too little medication; failure to provide access to appropriate health, social care or educational services; withholding the provision of the necessities of life such as adequate nutrition, heating or clothing; failure to intervene in situations that are assessed as being dangerous to the person concerned or to others, particularly when the person lacks the capacity to assess risk.

(vi) **Institutional harm**, which can occur in care settings and services as a result of poor standards, practices and behaviours, inflexible regimes and rigid routines, that place adults at risk and which violate their human rights. It involves the collective failure of an organisation to provide safe and appropriate services, and includes a failure to ensure that the necessary preventive and/or protective measures are in place; failure to maintain good standards of care in accordance with individual needs; failure to properly train, manage and supervise staff; poor record keeping; an inability or unwillingness to implement best practice guidelines; poor liaison with other providers of care; a culture that denies, restricts or curtails the dignity, privacy, choice, independence or fulfilment of adults at risk.

Generally, harm falls into one or more of the six categories listed above. However, it is important to recognise its manifestation in other ways, including

(i) **Domestic violence and abuse** is essentially a pattern of behaviour which is characterised by the exercise of control and the misuse of power by one person over another within an intimate relationship or a family. It is usually frequent and persistent. It can include violence by a son, daughter or any other person who has a close or blood relationship with the victim. It can occur right across society and is not bound by age, gender, race, ethnic or religious group, sexual orientation, wealth, disability or geography. **Forced marriage** of an adult, who may be unwilling or lack the capacity to agree to getting married is an abuse of human rights and is a form of domestic abuse, and should be treated as such. A clear distinction must be made between a forced marriage and an arranged marriage.

In arranged marriages, the families of both spouses take a leading role in arranging the marriage but the choice whether or not to accept the arrangements remains with the adult or young person. In forced marriage one or both spouses do not consent to the marriage and some element of duress is involved. Duress may include conduct which causes physical and or emotional harm. **Honour-based violence or honour crime** are also forms of domestic abuse and encompass a variety of crimes of violence (mainly but not exclusively against women), including assault, imprisonment and murder, where the person is being punished by their family or their community for actually, or allegedly, undermining what the family or community believes to be the correct code of behaviour.

(ii) **Hate crime** is any incident which constitutes a criminal offence, perceived by the victim or any other person as being motivated by prejudice or hate towards a person's actual or perceived race; faith or religion; sexual orientation; disability; political opinion or gender identity. The legislative provisions underpinning hate crime offences and penalties in Northern Ireland are set out in the Public Order (Northern Ireland) Order 1987 and the Criminal Justice (No2) (Northern Ireland) Order 2004.

(iii) **Human trafficking** involves the recruitment, transportation, transfer, harbouring or receipt of persons, by means of threat or use of force or other forms of coercion, abduction, fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving or receiving of payments or benefits to achieve the consent of a person, or have control over another person for the purpose of exploitation. There are many forms of exploitation, including prostitution or other types of sexual exploitation, forced labour, slavery, domestic servitude or the removal of organs. Human trafficking should be differentiated from 'people smuggling' which is normally defined as the facilitation of entry to the UK either secretly or by deception (whether for profit or otherwise). The immigrants concerned are normally complicit in the offence so that they can remain in the UK illegally. There is normally little coercion/violence involved or required from those assisting in the smuggling.

(iv) **Harm through discrimination** may manifest itself as any of the other categories of harm previously set out. What is distinctive, however, is that it is motivated by oppressive and discriminatory attitudes towards a person's disability; mental disorder; physical and/or mental infirmity; race; gender; age; religious belief; political opinion; cultural background; appearance; marital status; sexual orientation; whether or not he/she is a carer; or any other aspect of a person's individuality.

(v) **Harm by a professional/staff member** is the misuse of power and abuse of trust by professionals/staff members; the failure to adhere to best practice guidelines and professional codes of conduct/practice; the failure of professionals/staff members to act on suspected abuse/crimes, poor care practice

or neglect in services, resource shortfalls or service pressures that lead to service failure and culpability as a result of poor management systems.

The examples listed in each of the categories above are not exhaustive nor should they be taken as definitive proof that harm has taken place. There may be other indicators which should not be ignored. Also, some indicators may point to more than one form of harm; often if a person is being harmed in one way, he or she is being harmed in other ways. Any suggestion that all is not well should be seen as an indicator of possible harm of one form or another. It is important that any safeguarding concern is acted upon to ensure that the appropriate preventive or protective response is made.

All harm caused to adults in need of protection adult should be responded to in the context of safeguarding. It is recognised that the level of response needs to be sensitive and proportionate to the specific harm caused.

Factors to be considered in the assessment of the seriousness of harm and risk of potential harm

Consideration of the seriousness of harm and risk are central to determining which response is the most appropriate and key to establishing whether the threshold for a protective investigation/intervention has been met.

The criteria of what constitutes serious harm is imprecise and demands a careful application of professional judgment along with consideration of the available evidence, concerns raised, degree of risk and other matters relating to the individual and his or her context. Sometimes, a single traumatic event may constitute serious harm, e.g. a violent assault, sexual assault, suffocation or poisoning. More often, it is a series of events, both acute and long-standing, which interrupt, change or damage the individual's physical and/or psychological well-being. Also, it is important to note that harm does not need to be deliberate, that is, intent does not always have to be present to elevate harm to a level of seriousness, which might trigger a protective investigation/intervention. Any assessment of seriousness and risk should include

(a) the impact on the adult at risk, e.g. what is the degree of distress experienced; how resilient is the individual and his/her support networks;

(b) the reactions, perceptions, wishes and feelings of the adult at risk, e.g. how has the person responded; is he/she: shocked/resigned/cowed; aware of the harm caused;

(c) the frailty or vulnerability of the adult at risk, e.g. any special needs, such as a medical condition, communication impairment or disability that may affect care and support within the family;

(d) the ability of the adult at risk to consent, e.g. does he or she understand the nature of the concerns raised and the choices he or she faces;

(e) the illegality of the act or acts, e.g. has a criminal offence taken place;

(f) the nature, degree and extent of the harm, e.g. has it caused injury to the person's physical, sexual, psychological or financial wellbeing or property;
(g) the pattern of the harm causing behaviour, e.g. its intensity and frequency; one-off event or part of a long-standing pattern; have there been previous concerns (consider this in the widest sense, i.e. not just previous safeguarding referrals, but also whether the adult at risk has been a victim of anti-social behaviour, etc.);
(h) the level of threat to the individual's right to independence, e.g. the extent of support the person usually needs, and whether, and how much of, that support is normally provided by the alleged perpetrator;
(i) the intent of the person alleged to have caused the harm and extent of premeditation, and the presence or degree of threat, coercion, sadism, and bizarre or unusual elements, e.g. was this a deliberate act or a lack of awareness; was it a serious unprofessional response to difficulties in care giving; what is the attitude of the person alleged to have caused the harm now regarding the incident;
(j) the relationship between the person alleged to have caused the harm and the adult at risk, e.g. a balanced consideration of any positive benefits which the person may get from the relationship with the person alleged to have caused the harm/abusive situation;
(k) the context in which the alleged harm takes place, e.g. in a relationship; at home or in a care setting; in the context of a duty of care or trust that has been breached;
(l) the risk of repetition or escalation of harm involving increasingly serious acts relating to this individual or other adults at risk, to children under the age of 18 who may be at risk, or to the wider public, e.g. is there a risk that serious harm could result if no action is taken; is immediate protective action required; and
(m) the factors which mitigate the risk (protective factors), e.g. support services in place; awareness of what constitutes harm; awareness of how to raise concerns/seek help.

Consideration should also have to be given to the vulnerability of the person alleged to have caused the harm, e.g. are they an adult in need of protection or a child under the age of 18? If so, what actions are needed to support and safeguard them? Making a judgement here may mean having regard to some or all of the factors listed to inform the appropriate course of action.

The list of factors set out above is not exhaustive, and does not imply a hierarchy of importance; their analysis may point to a particular kind of response. In this context, it will also be necessary to:

- evaluate the reliability of the evidence upon which an assessment is made;
- consider any disparity between the strength of conviction of the person reporting the safeguarding concern (e.g. what was the basis of his/her concern or purpose in raising it), and the outcome of the assessment; and
- determine the need for further information gathering.

The safeguarding response made, however, should not undermine the risks identified and the outcomes sought.

Where an adult in need of protection has the ability to consent, appears to be able to make informed choices and is not being unduly intimidated, the available options should be explored with him/her and his/her wishes respected, unless these conflict with a statutory duty to intervene, or unless another person(s) is considered to be at risk.

Appendix 7

Human Rights, Consent and Capacity, The European Convention for the Protection of Human Rights and Fundamental Freedoms (Human Rights Act 1998)

Human Rights - Consent & Capacity

The Human Rights Act 1998 has been fully effective from 2nd October 2000. It incorporates the European Convention for the Protection of Human Rights and Fundamental Freedoms into United Kingdom Domestic Law. This makes it unlawful for public authorities to act in a manner which is incompatible with the rights and freedoms guaranteed by the Convention sets out the main Convention Rights enshrined in the 1998 Act.

Decisions taken not to comply with the wishes of the adults in need of protection adult/adult at risk may constitute a breach of Human Rights legislation. Where consideration is being given not to comply with the wishes of the adults in need of protection adult/adult at risk, the decision taken must be lawful, proportionate and in keeping with what is in the public interest.

Public authorities can interfere with an individual's rights providing it is lawful, proportionate and necessary in a democratic society.

Lawful means 'prescribed by law' and the legal basis for any restriction on rights and freedoms must be established and identified Reporting a relevant offence as defined in the Criminal Law Northern Ireland Order 1967, is not only lawful but a legal requirement on public authorities.

Proportionate means that the proposed action is viewed by any reasonable person as fair, necessary and the least restrictive in order to benefit the individual.

Necessary in a Democratic Society means
(1) Does it fulfil a pressing social need?
(2) Does it pursue a legitimate aim? And
(3) is the proposed action in the public interest taking into consideration whether other Adults at risk or children may be at risk of harm?

The Decision Making Process

In applying the key principles of lawfulness, proportionality and whether it is necessary in a democratic society, a public authority representative must ask the following questions:

- Is there a legal basis for my actions?

- Is it proportionate and necessary in a democratic society?
- Is the procedure involved in the decision-making process fair and does it contain safeguards against abuse?
- Was there an alternative and less restrictive course of action available? (The intervention should be strictly limited to what is required to achieve the objective).
- Is the restriction required for legitimate purposes?
- If I fail to interfere with this individual's rights could there be a more serious outcome in not affording the individual adequate protection in fulfilment of their human rights

Decisions to interfere with an individual's rights may be subject to scrutiny by the Courts. However, if public authorities can show that they applied the relevant Human Rights principles when making their decision, they are less likely to be over-ruled. It is very important to keep notes and decisions should be recorded in full.

Consent

The wishes of the adult in need of protection are of paramount importance in all cases of alleged or suspected abuse. Where a crime is suspected the issue of possible PSNI involvement should be discussed with the adult in need of protection.

The consent of the adult in need of protection for contact with the PSNI should be sought as a first step and details of whether this relates to a referral to PSNI or a Joint Agency consultation should be provided.

The adult in need of protection should be provided with as much information as possible to assist them in making an informed decision regarding how they wish the situation to be handled They should be fully advised by the Trust Investigating Officer of the Joint Protocol process and of their right to have a referral made to the PSNI. Details of all supports available to assist in the JP process should also be provided, i.e. ABE 2012 document.

The adult in need of protection should be advised that agreeing to a joint agency consultation does not in its self-constitute their agreement to a full PSNI investigation. The benefits of a joint agency consultation in terms of information gathering (cross referral to ensure a comprehensive assessment of all available information) should be explained to the adult in need of protection. Their entitlement to full consultation and involvement at each stage in the joint protocol process should also be explained. All staff involved must ensure that this person centred approach is strictly adhered to. The Joint Protocol should make a

significant contribution to ensuring that the individual's human rights are upheld, protected and delivered on.

In the majority of cases where the adult in need of protection is deemed to have capacity, the PSNI will only proceed to a full investigation with the consent of the adult in need of protection. In practice this will mean that the adult in need of protection should be willing to make a complaint to the PSNI. However there are some exceptions to this.

Dispensing with Consent

In exceptional circumstances the DAPO may need to consider over riding the wishes of an adult in need of protection if they do not consent to a joint agency consultation with the PSNI. These include situations where:

1. there is reasonable evidence or information to indicate that a possible relevant offence has been committed and the Trust have a legal obligation to report to the PSNI
2. there is a significant query regarding the individual capacity to make an informed decision and therefore their ability to give or withhold consent is in question. Actions taken must be proportionate to the level of concern and the views of substitute decision makers.
3. information available clearly demonstrates that the individual is subject to undue influence or coercion (must be substantial)
4. there is a significant risk to other adults at risk and/or children
5. the likelihood of further harm is high and there is a substantial opportunity to prevent further crime.

The PSNI also have the authority to investigate alleged or suspected criminal abuse where this is agreed to be in the best interests of the adult in need of protection and or others.

The above list indicates possible situations where the DAPO may need to consider overriding the wishes of an adult in need of protection adult. The list is not exhaustive. Cases will need to be assessed on a case by case basis and requirements in relation to making decisions which are lawful, proportionate and necessary in the public interests are applicable.

Acting without Consent in Emergency Situation

In situations where the adult in need of protection is in imminent danger it may not be possible to discuss with them their wishes and obtaining a valid consent may not be achievable. Trust staff, under these circumstances, should take whatever action they feel is appropriate to protect the adult in need of protection, including seeking medical and/or PSNI intervention.

Where there is no information and/or clarity regarding the wishes of the adult in need of protection and it is safe to do so, consideration should be given to deferring a decision re a joint agency consultation until such time as the adult in need of protection's views and permission can be sought. The DAPO will need to consider this on a case by case basis, mindful that a number of factors will need to be taken into account. Where a decision is taken to consult with the PSNI and the adult in need of protection has not consented to this, a detailed rationale for this decision should be recorded.

Capacity

There should be no assumptions made regarding an individual's capacity or incapacity and in the first instance unless there is contrary information, every individual should be viewed as having the capacity to make decisions about their own situation. However, if an issue is raised in relation to any individual's cognitive ability to make an informed decision about their safety, a capacity assessment should be sought.

Capacity assessments should be carried out by an appropriately trained professional. In cases where the adults in need of protection is already known to specialist services the professional involved may be able to provide an informed opinion in relation to the individual's capacity.

Capacity assessments/reassessment should determine:

a. the extent to which the adults in need of protection adult/adult at risk is able to make informed decisions about their safety and protection

b. whether the adults in need of protection adult/adult at risk is able to make a complaint to the PSNI and/or give legal instruction

c. whether the adults in need of protection adult/adult at risk has the capacity to be interviewed by the PSNI

d. the needs of the adults in need of protection adult/adult at risk.

It is important to note that any and all information provided by an adult in need of protection adult is relevant and should be considered in a safeguarding context

THE EUROPEAN CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND FUNDAMENTAL FREEDOMS

The Human Rights Act 1998

Main Convention Rights

Article 2 - Right to life

Article 3 - Prohibition of torture

Article 4 - Prohibition of slavery and forced labour

Article 5 - Right to liberty and security of person

Article 6 - Right to a fair trial

Article 7 - No punishment without law

Article 8 - Right to respect for private and family life

Article 9 - Freedom of thought, conscience and religion

Article 10- Freedom of expression

Article 11- Freedom of assembly and association

Article 12- Right to marry

Article 14- Prohibition of abuse of rights

Article 16- Restrictions on political activity of aliens

Article 17- Prohibition of abuse of rights

Article 18- Limitation of use of restriction of rights

Article 1, 1st protocol Protection of property

Article 2, 1st protocol Right to education

Article 3, 1st protocol Right to free elections

Article 1, 6th protocol Abolition of the death penalty

Appendix 8

Section 5 Criminal Law (Northern Ireland) Act 1967

A crime is a breach of the criminal law which is contained in statute or common law. Not all harm, abuse or exploitation of an adult in need of protection constitutes a possible crime.

However where an adult in need of protection and/or a relative or other professional (if the individual lacks capacity) makes a decision to access the Criminal Justice system, HSC Trusts in keeping with the principles of the Joint Protocol will support and assist in this process.

In cases of ill-treatment or wilful neglect by a staff member Article 121 of the Mental Health Order may need to be considered to determine if a possible offence has been committed.

The Criminal Law Act (NI) 1967

Section 5 of the Criminal Law Act (NI) 1967 states that where a person has committed a relevant offence, it shall be the duty of every other person, who knows or believes:-

(a)that the offence or some other **relevant offence** has been committed; and

(b)that he has information which is likely to secure, or to be of material assistance in securing, the apprehension, prosecution or conviction of any person for that offence,

to give that information, within a reasonable time, to a constable and if, without reasonable excuse, he fails to do so he shall be guilty of an offence and shall be liable on conviction on indictment to imprisonment according to the gravity of the offence about which he does not give that information, as follows:-

(i) if that offence is one for which the court is required by law to sentence an offender to death or to imprisonment for life or to detention during the pleasure of the Governor of Northern Ireland, he shall be liable to imprisonment for not more than ten years [or a fine or both];

(ii) if it is one for which a person (of full age and capacity and not previously convicted) may be sentenced to imprisonment for a term of fourteen years, he shall be liable to imprisonment for not more than seven years [or a fine or both];

(iii) if it is not one included above but is one for which a person (of full age and capacity and not previously convicted) may be sentenced to imprisonment for a term of ten years, he shall be liable to imprisonment for not more than five years [or a fine or both];

(iv) in any other case, he shall be liable to imprisonment for not more than three years [or a fine or both].

(2) It shall not be an offence under this section for the person suffering loss or injury by reason of the commission of the offence (in this section referred to as "the injured person") or some other person acting on his behalf not to disclose information upon that loss or injury being made good to the injured person or upon the injured person being reasonably recompensed therefore so long as no further or other consideration is received for or on account of such non-disclosure.

Relevant offence is defined in Section 4(1A) of the Act:

4(1A) In this section and section 5, "*relevant offence*" means—

(a) an offence for which the sentence is fixed by law,

(b) an offence for which a person of 21 years or over (not previously convicted) may be sentenced to imprisonment for a term of five years (or might be so sentenced but for the restrictions imposed by Article 46(4) of the Magistrates' Courts (Northern Ireland) Order 1981),

but in section 5(1) "relevant offence" does not include an offence under Article 20 of the Sexual Offences (Northern Ireland) Order 2008 (Article 20 of the Sexual Offences (NI) Order 2008 relates to certain sexual offences committed by persons under 18 years of age)

Basically this includes any offence for which a person may be sentenced to 5 years or more in prison.

Examples of some offences which attract a sentence of 5 years or more imprisonment would include;

Offences against the person

- Murder
- Attempted murder
- Grievous bodily harm with intent
- Grievous bodily harm
- Assault occasioning actual bodily harm
- Threats to kill

Sexual offences

- Rape
- Attempted rape
- Assault by penetration
- Sexual assault
- Causing or inciting a person to engage in sexual activity without consent

- Sexual activity with a person with a mental disorder impeding choice
- Engaging in sexual activity in the presence of a person with a mental disorder impeding choice
- Causing a person with a mental disorder to engage or agree to engage in sexual activity by inducement, threats or deception

Dishonesty offences

- Theft
- Attempted theft
- Burglary with intent to steal
- Burglary with intent to cause criminal damage
- Fraud
- Conspiracy to defraud

In relation to dishonesty offences section 5(2) would be relevant i.e.-

“It shall not be an offence under this section for the person suffering loss or injury by reason of the commission of the offence (in this section referred to as “the injured person”) or some other person acting on his behalf not to disclose information upon that loss or injury being made good to the injured person or upon the injured person being reasonably recompensed therefore so long as no further or other consideration is received for or on account of such non-disclosure”.

Appendix 9

Article 121 of the Mental Health NI Order (1986)

Ill-treatment of patients

121. (1) Any person who, being an officer on the staff of or otherwise employed in a hospital, private hospital or nursing home or being a member of the**[F1** Board or a director of the **[F2**HSC trust**]** managing**]** a hospital, or a person carrying on a private hospital or nursing home—

(a)ill-treats or wilfully neglects a patient for the time being receiving treatment for mental disorder as an in-patient in that hospital or nursing home; or

(b) ill-treats or wilfully neglects, on the premises of which the hospital or nursing home forms part, a patient for the time being receiving such treatment there as an out-patient, shall be guilty of an offence.

(2) Any individual who ill-treats or wilfully neglects a patient who is for the time being subject to his guardianship under this Order or otherwise in his custody or care (whether by virtue of any legal or moral obligation or otherwise) shall be guilty of an offence.

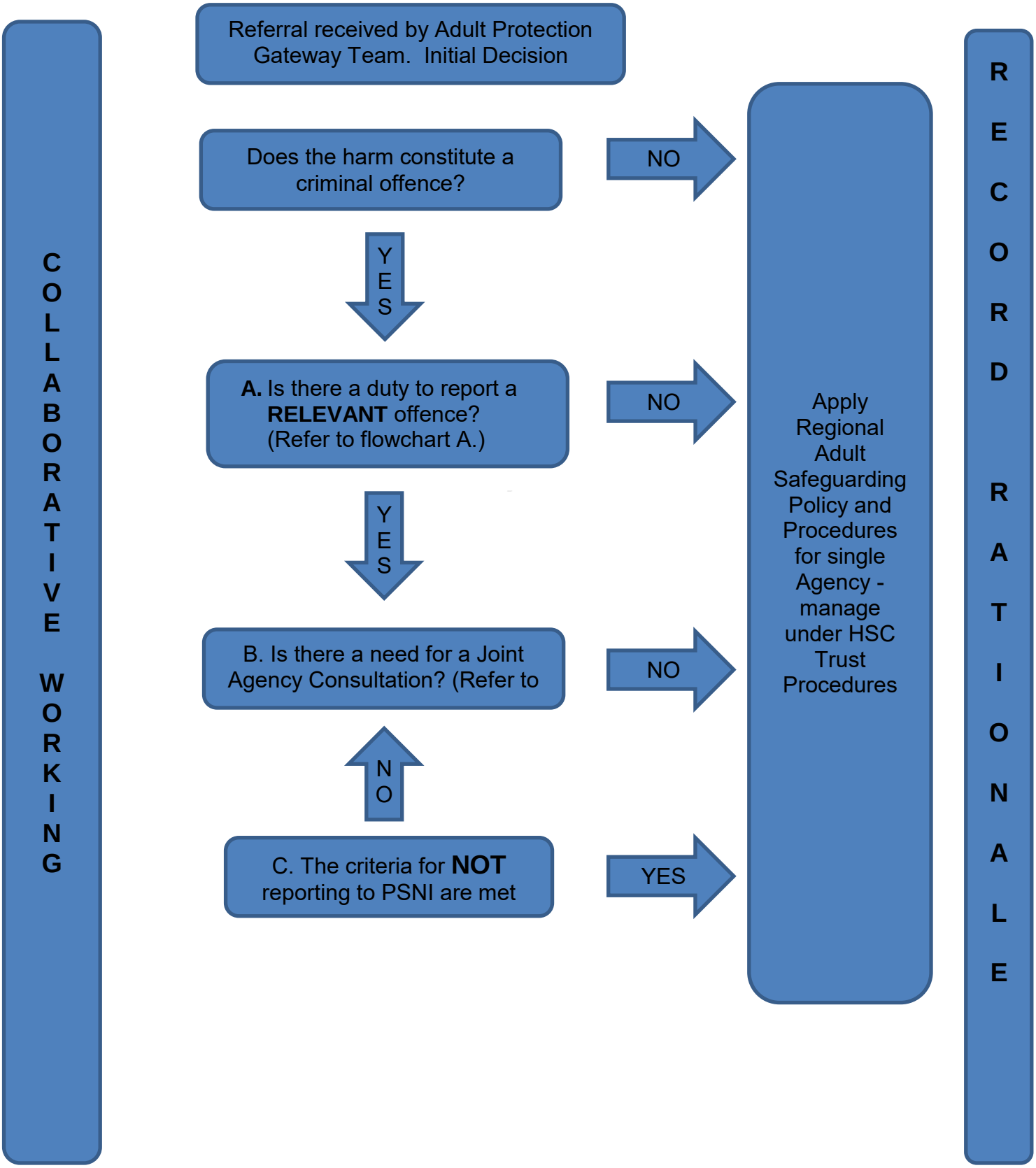
(3) Any person guilty of an offence under this Article shall be liable—

(a)on summary conviction, to imprisonment for a term not exceeding six months or to a fine not exceeding the statutory maximum, or to both;

(b)on conviction on indictment, to imprisonment for a term not exceeding two years, or to a fine of any amount, or to both.

Appendix 10

HSC Trust Flowchart for decision making and referral to PSNI CRU



A. Relevant crime and/or reportable crime referred to PSNI CRU for consideration of Joint Agency investigation

An adult in need of protection is in **imminent danger** and there is a need for an immediate report to PSNI CRU

OR

Where there has been an incident which may constitute a **relevant offence** under Section 5 of the Criminal Law Act (NI) 1967 (***Appendix 7***)

OR

Referral information clearly states the adult in need of protection **wishes** or has consented to PSNI involvement ***(Appendix 8 Human Rights)***

OR

If the referral information clearly states that the adult in need of protection lacks capacity to give informed consent to PSNI involvement and **the next of kin and/or professionals involved take the view that PSNI involvement is required.**

RECORD RATIONALE

Relevant offences include

- Sexual offences
- Domestic abuse incidents which constitute a criminal offence
- Financial abuse incidents
- Human Trafficking
- All cases where alleged offender is a paid employee / volunteer or in a position of trust
- Institutional abuse
- Historical abuse

B. Joint Agency Consultation with PSNI CRU and HSC Trust

- AJP1 completed and forwarded to CRU via CJSM

COLLABORATIVE WORKING

Follow up discussion by referrer with recipient of AJP1 to determine the most appropriate action from the following

1. There is insufficient information available to make a decision. Conduct HSC Trust single agency initial risk assessment.

OR

2. Single Agency HSC Trust Investigation

OR

3. Single Agency PSNI Investigation

OR

4. Joint Agency collaborative working

OR

5. Joint Agency Investigation involving HSC Trust and PSNI

- Strategy Planning Meeting AJP2 completed
- PIA- AJP3 completed
- ABE if required AJP4 and 4
- Investigation

Decision to end Joint Protocol Investigation – AJP5

OR

6. NFA under Joint Protocol

Apply Regional Adult Safeguarding Policy and Procedures for single Agency - manage under HSC Trust Procedures

RECORD RATIONALE

MAHI - STM - 097 - 8877

C. Criteria for NOT reporting to PSNI

DAPO must as a minimum demonstrate consideration of the following:

The adult in need of protection has capacity to make an informed decision and does not want to make a complaint to PSNI. Full consideration will need to be given to all elements of consent, capacity and human rights, including issues of undue influence and possible

AND

The Trust is not required by law to make a referral to PSNI (if the incident does not meet the threshold of **relevant offence** under section 5 of the Criminal Law Act (NI) 1967 (***Appendix 7*** Definition of Relevant Offence)

AND

It is a minor incident. A comprehensive assessment of all the factors **MUST** be completed to evidence a through risk assessment of these cases. This will include consideration of whether repeat incidents have occurred and/or whether other adults at risk or children have been or are likely to be at risk of harm (*Appendix 10 Factors to be considered in the assessment of the seriousness of Harm and Risk of Harm*)

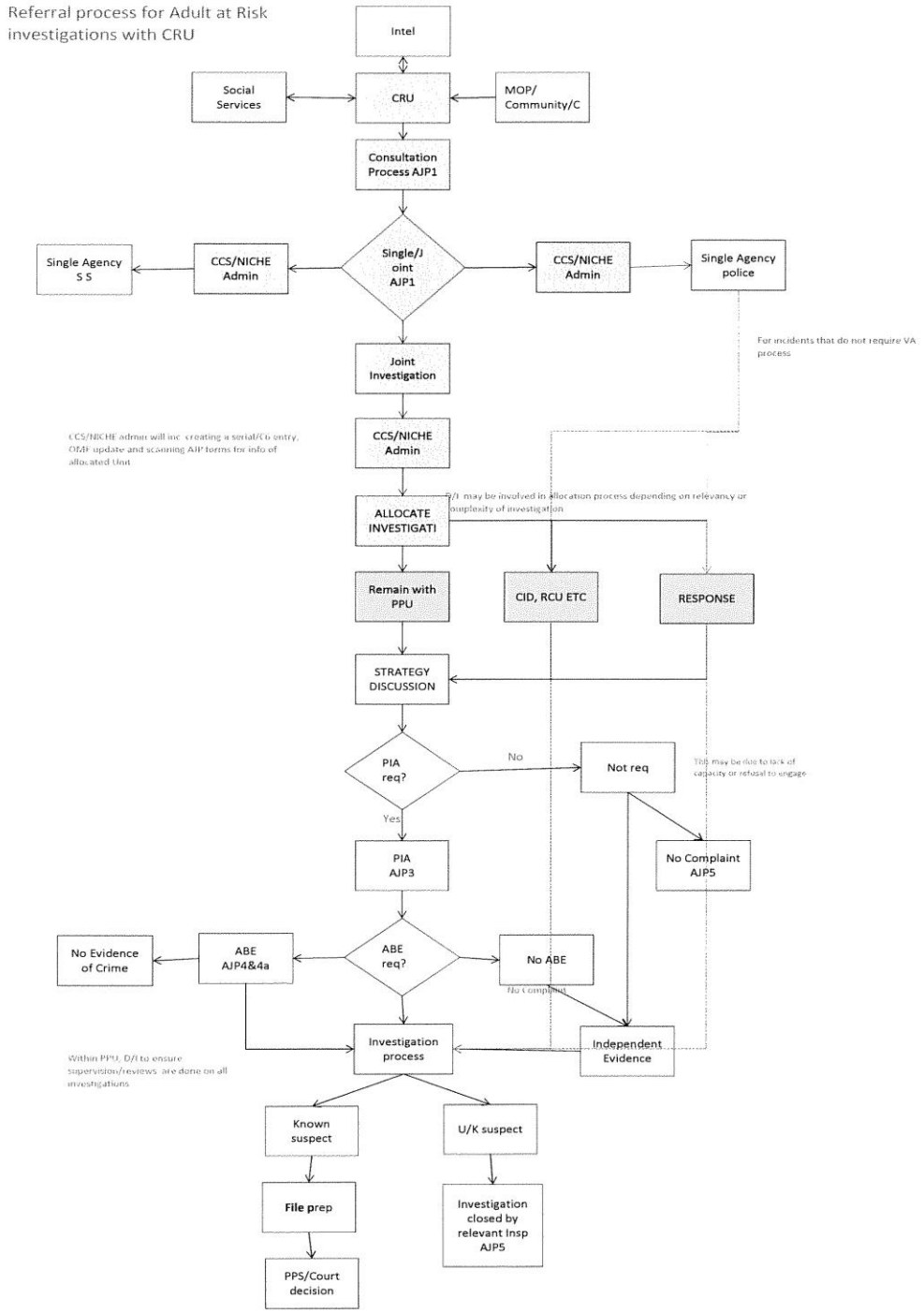
AND

The situation is being managed through an Adult Safeguarding process and/or there are other protective measures in place

RECORD RATIONALE FOR DECISIONS

Appendix 11

Referral Process for Adult at Risk Investigations with CRU



Appendix 12

Regulation and Quality Improvement Authority

Adult Safeguarding Processes

Where there is a breach of regulations RQIA have the statutory authority to issue requirements in relation to a Quality Improvement Plan, Enforcement Orders or to de-register facilities depending on nature and seriousness of the concern.

In all regulated facilities where an alleged or suspected criminal offence has occurred, RQIA should ensure that this is reported to the relevant HSC Trust Gateway Team/ DAPO and PSNI/nominated officer within Public Protection Unit. Where an incident relates to a regulated service RQIA will attend adult protection strategy meetings and case discussions to contribute to joint agency information sharing and joint agency action planning.

HSC Trusts should also ensure that RQIA are notified of these incidents *(**Appendix 6** RQIA contact details).* Where an incident occurs outside normal working hours, it is the responsibility of the Registered Manager or Senior Manager on duty to contact the Regional Out of Hours Service and if applicable the PSNI. If reports are made directly to PSNI from regulated facilities, the PSNI should contact the Regional HSC Regional Emergency Social Work Service.

Appendix 13

Registered Intermediaries

The Criminal Evidence (NI) Order 1999 provides for a number of special measures, such as video recorded evidence-in-chief and giving evidence by live link, to assist vulnerable and intimidated witnesses (both for the prosecution and the defence) give their best possible evidence in criminal proceedings.

Article 17 of the 1999 Order provides for the examination of a witness through an intermediary.

Article 21BA of the 1999 Order, as inserted by section 12 of the Justice Act (NI) 2011, provides for the examination of a vulnerable defendant when they are giving oral evidence.

The creation of the Registered Intermediary (RI) role represents a statutory recognition that adults in need of protection witnesses and defendants with communication needs may require help and facilitation with giving evidence. RIs have a range of responsibilities intended to help adults in need of protection witnesses, defendants and criminal justice practitioners at every stage of the criminal process, from investigation to trial.

It is the responsibility of the DOJ- PPU, PSNI, and PPS, to request an assessment from a Registered Intermediary.

RI's come from a number of professional backgrounds. It is a highly specialised role and requires expertise in dealing with the communication needs of individuals with the following types of conditions

- Aphasia/Dysphasia
- Autistic Spectrum Disorder
- Brain and/or Head Injury
- Deafness/hearing Impairment
- Dementia
- Dysarthria/Dyspraxia
- Fluency Difficulties
- Language Delay/Disorder
- Learning disability
- Mental health Issues
- Neurological and other Progressive Disorders
- Phonological Delay/Disorder
- Physical Disability
- Selective/Elective Mutism
- Voice Disorders (including laryngectomy)

The above list is intended to be illustrative rather than exhaustive and whether someone should be provided with RI assistance will need to be determined on a case-by-case basis, based on the particular needs of the individual witness or defendant. It is also important to note that not all witnesses or defendants with the conditions listed above will necessarily require assistance, if their disability does not affect their ability to communicate effectively.

For police interviews, the RIs duty is to assess and facilitate effective communication and understanding between the police and the witness or defendant. In terms of the court stage, the RIs duty is to the court. RIs are there to ensure the court has access to the best possible evidence and that this can be properly examined so that justice can be done.

How the RI role is exercised

An RI will carry out an assessment of a witness or defendant's communication abilities and needs. In this assessment the RI will

- Evaluate the abilities and needs of the witness/defendant, including whether they have the ability to communicate their evidence during a police interview and at court;
- Ascertain if the witness/defendant needs an RI;
- Consider if the witness/defendant would be able to give evidence at all, even with the assistance of an RI;
- Indicate whether, in the absence of an intermediary, the quality of a witness's evidence would be diminished or a defendant would not receive a fair trial; and
- Make recommendations as to special measures to enable the best communication with and evidence from, the witness.

An RI also directly assists in the communication process – helping a witness or defendant understand the questions during an investigative interview or testimony at the trial and helping them communicate their answers. Effective means of communication may include speech, symbols, communication aids, drawing and writing.

Appendix 14

AJP Forms

AJP1 Referral Information

AJP2 Record of Joint Agency Strategy Decision Making and Investigation Planning

AJP2 (a) Amendments to Strategy For Investigation

AJP3 Pre- Interview Assessment (PIA)

AJP4 Planning the Joint Investigation Interview (ABE)

AJP4 (a) Joint Protocol ABE Interview

AJP5 Decision to End Joint Protocol Investigation

In addition PJI1 form to be used in relation to adults at risk when disclosures of historical abuse have been made. There is a requirement to clearly state whether this needs to be addressed under Adult Safeguarding Joint Protocol procedures

PJI1 Referrals to PSNI of Historical Child Abuse

MAHI - STM - 097 - 8883

AJP1

JOINT PROTOCOL – ADULT PROTECTION

Referral Information

PSNI Reference Number: _____

Date of Referral: _____

Referred To: _____ Designation: _____

Referred By: _____ Designation: _____

Referrer's Address: _____

Referrer's Telephone Number: _____ Referrer's Email: _____

SECTION ONE ***(Please ensure Sections 1 & 2 are fully completed by referrer)***

DETAILS OF ALLEGED VICTIM		
Name:	Date of birth or approximate age:	Gender: Male ☐ Female ☐
Address and Postcode:	Contact No:	Programme of care if known: Information system no:
Present Location: (*if different from above)* Incident Location:		
Nature of vulnerability: *(please tick all relevant boxes)* ☐ Frail Older Person ☐ People experiencing dementia or memory impairment ☐ Learning Disability ☐ Physical/Sensory Disability ☐ Mental Health Difficulties ☐ Other *(give details)* _____		

Relevant Contacts		
	Name	**Address & Tel. No.**
Key Worker		
Care Manager		
G.P		
Other Professionals		
Next of Kin		
Significant other		

***Who Was The First Person To Note Concern*:**	
Name & Tel No:	Date:

Does This Referral Originate From:			
☐ Acute Hospital Name:	☐Adult Mental Health Unit Name:	☐Learning Disability Unit Name:	☐ Regulated Facilities Name:
☐ Community	☐ MARAC	☐ Other *(give details)*	

SECTION 2

DETAILS OF REFERRAL
Incident Report – *(Please give exact details of what has been reported and if appropriate, note injuries on the attached body chart ONLY if witnessed or observed)*
Date / Time Of Incident: Location:
Details:
Have There Been Previous Concerns Or Evidence Of Abuse To Your Knowledge? ☐ Yes ☐ No ☐ Not Known If yes, what was the nature of the concern and the outcome:

The Service User's Usual Living Arrangements:	
Does service user live alone? *(if No give details)*	☐ Yes ☐ No
Does the service user live with the person whom has allegedly caused the abuse?	☐ Yes ☐ No
Are there any support services in place? *(if yes give details)*	☐ Yes ☐ No
Are there any current court orders in place? *(if yes give details)*	☐ Yes ☐ No
Are there any concerns regarding risk to a child/children? (*if yes give details*)	☐ Yes ☐ No
Are there any concerns regarding risk to other adults in need of protection? (*if yes give details)*	☐ Yes ☐ No
Service User's Knowledge Of Referral	

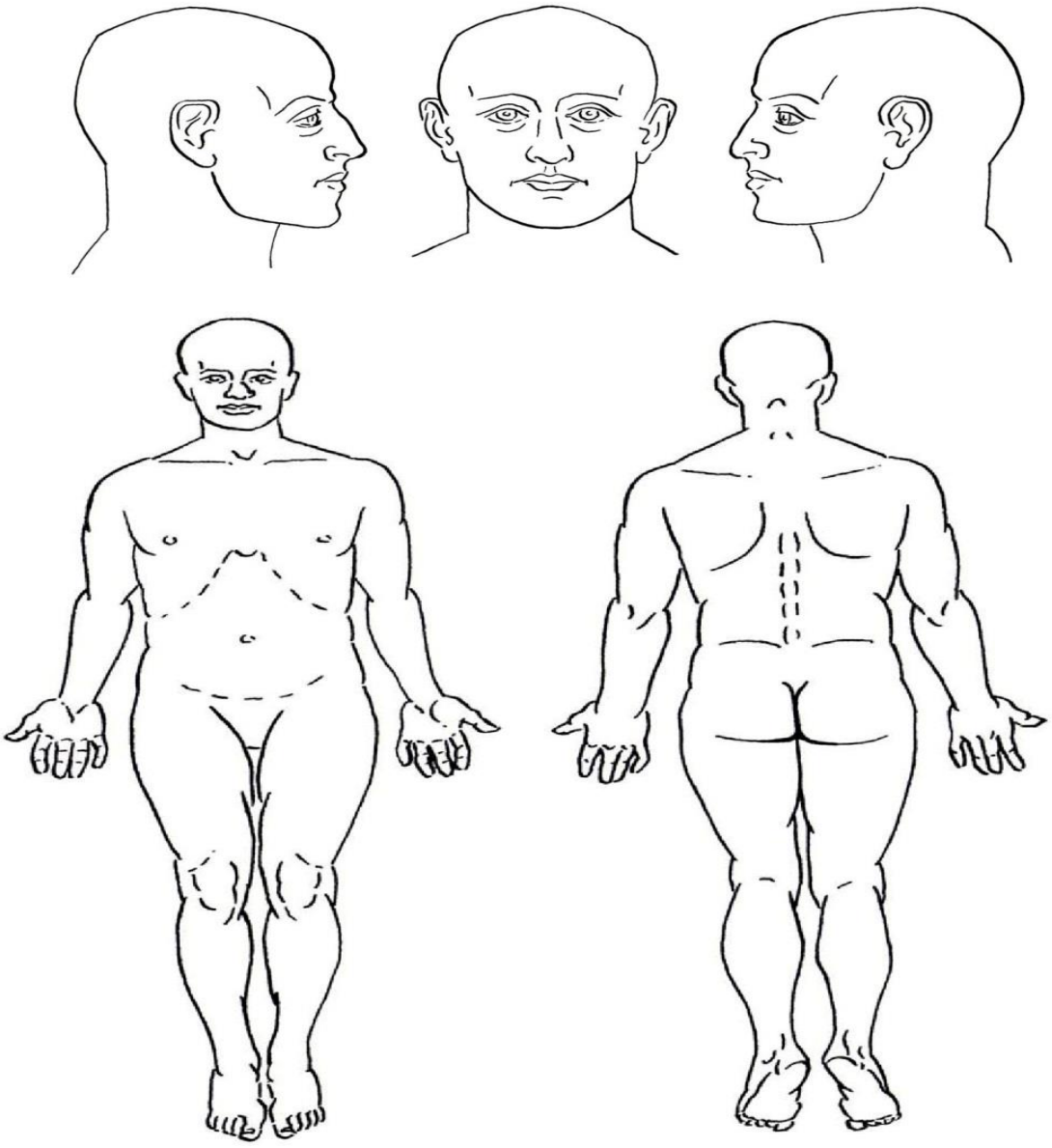
Does person know that a referral may be made?	☐ Yes ☐ No ☐ Not Known
Has the relevant explanation/information been provided in an appropriate manner? (*for example Easy Read Leaflets*)	☐ Yes ☐ No
In your view has the person capacity to make an informed decision about the referral/report?	☐ Yes ☐ No
Has the person consented to a referral? *If no give details* _____ _____	☐ Yes ☐ No
If the person lacks capacity what are the views of the next of kin about the referral? *If yes:* Name: _____ Address: _____ Contact No: _____ Date: _____	☐ Yes ☐ No
Is there a need to consider any immediate Human Rights issues? (**If yes identify which human rights have been considered and rationale for the decision**)	☐ Yes ☐ No

DETAILS OF PERSON/S ALLEGED TO HAVE CAUSED HARM *(If known)*		
Name provided by:	Date:	
Name:	Date of birth:	☐ M ☐ F
Address:		
Does the person alleged to have caused harm know that an allegation has been made against them?		☐ Yes ☐ No ☐ Not Known
Has the person alleged to have caused harm any known vulnerabilities? *If yes please specify:*		☐ Yes ☐ No ☐ Not Known
Is the person alleged to have caused harm known to service user? *If yes please specify below:*		☐ Yes ☐ No ☐ Not Known
☐ Family member	☐ Another service user	☐ Paid carer
☐ Trust employee	☐ Other	

BODY CHART

PLEASE USE THE BELOW IMAGE TO MARK ANY:

- **SCRATCH**
- **SKIN ABRASION**
- **CUT**
- **BRUISE**
- **BURN**
- **BITE**
- **FRACTURE**



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SECTION 3 *(To be completed and shared following Joint Agency Consultation)*

PSNI Reference Number _____

OUTCOME OF CONSULTATION	
☐ Single agency investigation by PSNI	Allocated to: _____
☐ Single agency investigation by Trust	Allocated to: _____
☐ Joint Protocol investigation	Allocated to: _____
☐ Referral to RQIA	
☐ No further action	
☐ Other *(give detail below)*	

RATIONALE

Agreed By

Designated Adult Protection Officer: _____

PSNI CRU Officer: _____

Approved By PSNI Sergeant: _____

Date: _____

Completed form to be emailed via CJSM secure email system to cru@psni.pnn.police.uk.cjsm.net
Joint consultation will take place on receipt of this form and outcome to be recorded and shared by PSNI CRU contact number 028 9025 9299

MAHI - STM - 097 - 8888

AJP2 Record of Joint Agency Strategy Decision Making and Investigation Planning

DETAILS OF ALLEGED VICTIM		
Name:	Date of Birth: *(if not known, please give approximate age)*	Gender: Male ☐ Female ☐
Address and Postcode:	Contact No:	Service Group:
Present Location: (*if different from above)*		PSNI Reference Number: *(If known)*

STRATEGY DISCUSSION	
Date & time of consultation:	☐ Telephone ☐ Meeting
Names of persons involved: 1._____ 2._____ 3._____ 4._____ 5._____	Designation: _____ _____ _____ _____ _____

DETAILS OF DISCUSSION

AGREED ACTIONS

Forensic Considerations
Need for medical, secure possible forensic evidence

Communication Strategy
Record agreed level of information sharing and with whom

Name of:	Contact number
PSNI Investigating Unit _____	_____
Name of PSNI Investigating Officer _____	_____
Name of PSNI Line Manager _____	_____
Name of Trust Investigating Officer _____	_____
Name of Trust Designated Adult Protection Officer _____	_____
Name of RQIA Inspector(if appropriate) _____	

Please provide details below:

Media Considerations
Record agreed level of information sharing and with whom

Interviews
(Provide name, address, contact number and nature of vulnerability (if applicable) of person(s) to be interviewed)

Victim(s):		Type of interview and by whom *(If known)*
1. _____ _____ _____	☐ None ☐ Frail Older Person ☐Physical/Sensory ☐Learning Disability ☐ Mental Health ☐ Dementia or memory impairment ☐Other*(give details)*	☐ PSNI ☐ PIA/ABE ☐ Trust PSNI _____ Trust _____
2. _____ _____ _____	☐ None ☐ Frail Older Person ☐ Physical/Sensory ☐ Learning Disability ☐ Mental Health ☐ Dementia or memory impairment ☐Other*(give details)*	☐ PSNI ☐ PIA/ABE ☐ Trust PSNI _____ Trust _____

Witnesses: 1._____ _____ _____ 2._____ _____ _____	☐ None ☐ Frail Older Person ☐ Physical/Sensory ☐ Learning Disability ☐ Mental Health ☐ Dementia or memory impairment ☐Other*(give details)* ☐ None ☐ Frail Older Person ☐ Physical/Sensory ☐ Learning Disability ☐ Mental Health ☐ Dementia or memory impairment ☐Other*(give details)*	Who will conduct interview: ☐ PSNI ☐ Trust PSNI _____ Trust _____ ☐ PSNI ☐ Trust PSNI _____ Trust _____
Person/s alleged to have caused harm : *(as provided by Trust or other agencies)* 1._____ _____ _____ 2._____ _____ _____	☐ None ☐ Frail Older Person ☐ Physical/Sensory ☐ Learning Disability ☐ Mental Health ☐ Dementia or memory impairment ☐Other*(give details)* ☐ None ☐ Frail Older Person ☐ Physical/Sensory ☐ Learning Disability ☐ Mental Health ☐ Dementia or memory impairment ☐Other*(give details)*	Who will conduct interview:
Joint Agency Interim Protection Plan		
Adult Safeguarding Investigation Strategy and Protection Plan		

Signature of DAPO _____

Signature PSNI Officer: _____

Date: _____

AJP2a **AMENDMENTS TO STRATEGY FOR INVESTIGATION**

Completed form to be emailed via CJSM secure email system

DETAILS OF VICTIM		
Name:	Date Of Birth or Approximate Age:	Gender: Male ☐ Female ☐
Address and Postcode:	Contact No:	Service Group:
Present Location: (*if different from above)*		PSNI Reference Number: *(If known)*

INFORMATION UPDATE
AGREED AMENDMENTS TO INVESTIGATION PLAN
AGREED AMENDMENTS TO PROTECTION PLAN

Agreed by:

Police Officer: _____

DAPO: _____

Date: _____

MAHI - STM - 097 - 8892

AJP3 **PRE- INTERVIEW ASSESSMENT (PIA)**

To be completed and shared by PSNI

DETAILS OF VICTIM		
Name:	Date Of Birth or Approximate Age:	Gender: Male ☐ Female ☐
Address and Postcode:	Contact No:	Service Group:
Present Location: (*if different from above)*		PSNI Reference Number: *(If known)*

PIA PLANNING	
Date &Time Of Interview:	Venue
Names Of Interviewers: _____ _____	Designation _____ _____
Names of any other persons who will be present: _____ _____	Role: _____ _____
NOTE ANY SPECIAL REQUIREMENTS *(please give relevant details)*	

DETAILS OF PIA	
Has the purpose of the interview been explained to the adult? Comment:	☐ Yes ☐ No
Have any capacity issues been identified? Comment:	☐ Yes ☐ No
Have the types of formats for the interview been explained to the adult? Comment:	☐ Yes ☐ No
Has the adult stated a preference for which format is most suitable for him/her? Comment:	☐ Yes ☐ No
Has the adult any specific needs in relation to the interview? Comment:	☐ Yes ☐ No

Is the adult willing to engage in an interview? ☐ Yes ☐ No Comment:	
Has a need for a Registered Intermediary been identified? ☐ Yes ☐ No Comment:	

OUTCOME OF PIA

☐ **Registered Intermediary required**

☐ **Video interview** Venue:_____

☐ **Written interview** Venue: _____

☐ **Victim declines criminal investigation**

MAHI - STM - 097 - 8894

AJP4 PLANNING THE JOINT INVESTIGATION INTERVIEW (ABE)

DETAILS OF VICTIM		
Name:	Date Of Birth or Approximate Age:	Gender: Male ☐ Female ☐
Address and Postcode:	Contact No:	Service Group:
Present Location: (*if different from above)*		PSNI Reference Number: *(If known)*

ABE INTERVIEW PLANNING	
Date &Time Of Interview:	Venue
Names Of Interviewers: _____ _____	Designation _____ _____
Names of any other persons who will be present: _____ _____	Role/Relationship: _____ _____

DETAILS OF PIA PLANNING *(please give relevant details)*

Do any special considerations apply? ☐ Yes ☐ No

(*If yes give details)*

Will a Registered Intermediary/ Interpreter attend? ☐ Yes ☐ No

(*If yes give details)*

Name:_____

Grade/Qualification: _____

DETAIL SPECIFIC ARRANGEMENTS PLANNED FOR INTERVIEW *(Who? What? When? Where? How?)*

SIGNATURES OF JOINT INVESTIGATIVE INTERVIEWERS:

Police Officer: _____

Social Worker: _____

Date: _____

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AJP4a **JOINT PROTOCOL ABE INTERVIEW**

To be completed by PSNI

Name of Adult: _____ **Date of Interview:** _____

Page No: _____

MAHI - STM - 097 - 8897

AJP5 DECISION TO END JOINT PROTOCOL INVESTIGATION

To be completed and shared by the responsible DAPO/PSNI Officer

DETAILS OF VICTIM		
Name:	Date Of Birth or Approximate Age:	Gender: Male ☐ Female ☐
Address and Postcode:	Contact No:	Service Group:
Present Location: (*if different from above)*		PSNI Reference Number:

OUTLINE THE REASONS FOR ENDING JOINT PROTOCOL INVESTIGATION	
AGREED BY WHOM (*Record the names of any persons/agencies involved in decision)*	
Names of persons consulted:	Designation:

Signature of DAPO: _____

Signature of PSNI Officer: _____

Date: _____

RESTRICTED WHEN COMPLETE

PJI1

CC

(please use this number on all future correspondence)

CONFIRMATION OF REFERRAL

Referral on Date: _____ Time: _____

To: _____ Designation: _____

From: _____ Designation: _____

Referrer's Telephone Number: _____

Referrer's Address: _____

Referrer's Email Address: _____

Child's Name: _____ DOB: _____

Home Address: _____

Present Location: _____

Person with parental responsibility: _____ DOB: _____

Address: _____

Telephone Number: _____

Alleged Perpetrator: _____ DOB: _____

Telephone Number: _____

Address: _____

Address where alleged incident(s) has taken place, if known/suspected:

_____

RESTRICTED WHEN COMPLETE

Nature of Referral – Comment
(include background of involvement with Social Services or Police)

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RESTRICTED WHEN COMPLETE

Joint Assessment

(Considerations, concerning child/sibling, might include assessment of current placement; the CP Register; child protection concern/referral/investigation; missing episodes; attempted suicide/self-harm; misuse of drugs/alcohol; CSE indicators; or if significant person(s) in the child/young person's life is a suspected domestic /sexual abuser, misuses drugs/alcohol etc.)

HAVING REVIEWED THE AVAILABLE MATERIAL/EVIDENCE/HISTORY THE AGREED OUTCOME OF INITIAL JOINT ASSESSMENT IS:

JOINT INVESTIGATION (2.18): ☐ **YES** ☐ **NO**

If 'NO' note outcome decided, as below:

☐	No Further Action	**Rationale:**
☐	Family Support	
☐	Police Only Investigation	
☐	Duty to Investigate (Article 66)	

Agreed by: _____ (Social Worker) and _____ (Police Officer)

Completed by: _____ Date: _____

Referrer to complete Pages 1 and 2, PO to complete Pages 2 and 3.
Completed form to be emailed asap via CJSM to HSCT/CRU.

Department of Justice
www.dojni.gov.uk

cjsni
CRIMINAL JUSTICE SYSTEM NORTHERN IRELAND

Achieving Best Evidence in Criminal Proceedings

Guidance on interviewing victims and witnesses, the use of special measures, and the provision of pre-trial therapy.

January 2012

MAHI - STM - 097 - 8902

Contents

Part 2B: Interviewing child witnesses

3 Planning and conducting interviews with vulnerable adult witnesses

Part 3A: Planning and preparing for interviews

Part 3B: Interviewing vulnerable adult witnesses

Part 4B: Interviewing intimidated witnesses

5 Witness support and preparation

6 Witnesses in court

7 Provision of therapy for child witnesses prior to a criminal trial - practice guidance

8 Provision of therapy for adult witnesses prior to a criminal trial - practice guidance

Appendices

1 Overview

Introduction

1.1 This guidance, which replaces that published in May 2011, describes good practice in interviewing witnesses, including victims, and using special measures in order to enable them to give their best evidence in criminal proceedings. It also contains advice in relation to pre-trial therapy. The guidance applies to both prosecution and defence witnesses and is intended for all persons involved in the criminal justice process, including the police, health and/or social care workers, legal profession and victim support organisations.

1.2 It is recognised that the guidance is challenging in terms of time (for example, it may take more than one attempt to interview a person with dementia) and resources, especially with the necessary delivery of training. However, the guidance set out in this document is intended to support the Northern Ireland Criminal Justice System's commitment to improve the quality of treatment for victims and witnesses in the criminal justice system so that they have an opportunity to access justice and provide their best evidence. It is complemented by the Code of Practice for Victims of Crime and should be viewed in the context of other criminal justice policies in relation to improving the quality of service to victims and witnesses (see Appendix T for a list of relevant publications).

Scope

1.3 Achieving Best Evidence in England and Wales includes guidance in relation to section 137 Criminal Justice Act 2003 witnesses and 'significant witnesses', including 'reluctant' and 'hostile' witnesses. As the equivalent legislation (Article 39 of the Criminal Justice (Evidence) (NI) Order 2004) has not yet been commenced, guidance on Article 39 witnesses has not been included. It is particularly important that interviewers are aware of this difference between the jurisdictions as guidance from the Association of Chief Police Officers often reflects the current position in England and Wales - this has the potential to lead to video recordings being made that cannot be used in Northern Ireland courts.

Children

1.4 References to 'very young children' in this guidance mean children of nursery school age (i.e. up to 5 years of age), the term 'young children' refers to children of primary school age (i.e. up to 11 years of age) and 'older children' denotes those of secondary school age (i.e. over 11 years of age). The unqualified terms 'child', 'children' or 'young witness' refer generally to children of all ages up to 18 years of age. This guidance applies to the broad range of children in these age groups and as such will not necessarily apply to an individual child witness. Practitioners should always take account of the level of cognitive, social and emotional development of the individual child when applying this general guidance.

Defence witnesses

1.5 This guidance applies to defence, as well as prosecution, witnesses and the provisions contained in Part II of the Criminal Evidence (Northern Ireland) Order 1999 (the 1999 Order), as amended by the Justice Act (Northern Ireland) 2011, are available to both prosecution and defence witnesses if the court is satisfied that they meet the criteria.

1.6 While some of the guidance is drafted with the particular needs and concerns of the prosecution in mind, in general it applies to those involved in working with all vulnerable and intimidated witnesses.

Status of the guidance

1.7 This document describes good practice in interviewing victims and witnesses, and in preparing them to give their best evidence in court. While it is advisory and does not constitute a legally enforceable code of conduct, practitioners should bear in mind that significant departures from the good practice advocated in it may have to be justified in the courts.

1.8 The guidance is generic: it cannot ever cater for every possible set of circumstances that might arise. Each witness is unique and the manner in which they are interviewed, prepared for their court appearance and supported throughout the criminal justice process must be tailored to their particular needs and circumstances.

Training

1.9 Training should take account of the curriculum that has been developed in support of the National Investigative Interviewing Strategy (Association of Chief Police Officers 2009). It is recommended that this guidance is used, in conjunction with other relevant guidance, as a key resource in the training of police officers and social workers involved in the investigative interviewing of vulnerable or intimidated witnesses. It should also be used as a resource by those concerned with providing pre-trial support and preparation, and those involved in the criminal justice process generally.

1.10 Programmes will need to deliver and maintain skills, and their content regularly reviewed in the light of practice developments and evolving legislation. As much of the guidance requires co-operation between agencies on a professional and personal level, joint training initiatives are beneficial.

1.11 Specialist training is required to interview witnesses with particular needs, for example young witnesses, traumatised witnesses and witnesses with a mental disorder, learning disability or physical disability which impacts on communication. Specialist interview training is also required in respect of the use of the techniques in the cognitive interview.

1.12 It is important to note, however, that training alone is unlikely to deliver effective performance in the workplace. Training needs to be set in the context of a developmental assessment regime. Such a regime should deliver a means of quality assuring interviews, while developing, maintaining and enhancing the skills of interviewers. The regime should be supported by an agreed assessment protocol. In the case of police interviewers, such a protocol should take account of the National Occupational Standards for interviews with witnesses. Agencies regularly involved in conducting interviews with witnesses should have the necessary policies, procedures and management structures in place to quality assure interviews on an ongoing basis.

1.13 Training is also relevant for those providing support to victims and witnesses, and this should conform to agreed standards.

Gathering physical evidence

1.14 At the investigative stage (Chapters 2- 4), the guidance focuses on how to interview vulnerable and intimidated witnesses. In preparing for and conducting such interviews, investigating police officers should remember the importance of gathering physical evidence. The analysis of physical evidence may need to be completed before an interview can take place so that the planning for interview is properly informed. Physical evidence may or may not support the testimony of a witness and it can also guide the interviewer in their interview with the witness, as well as opening up new lines of enquiry. Additionally, the interview itself may guide further recovery or direct testing of physical evidence. In preparing for interviews with vulnerable and intimidated witnesses, investigating officers must ensure that their approach does not unwittingly compromise the recovery and protection of physical evidence. The recovery of physical evidence for subsequent analysis and interpretation by forensic scientists is potentially susceptible to contamination which may compromise later prosecutions. Contamination control procedures need to be robust, not only in terms of body fluids and DNA, but also fibres etc. The advice of a forensic scientist, competent in this field, should be sought when establishing, monitoring or reviewing such procedures.

Vulnerable witnesses

1.15 'Vulnerable' witnesses are defined by Article 4 of the 1999 Order, as amended, as:

- all child witnesses (under 18 years of age); and
- any witness whose quality of evidence is likely to be diminished because they have a:
    - mental disorder (as defined by the Mental Health (NI) Order 1986); or
    - significant impairment of intelligence and social functioning (witnesses who have a learning disability); or
    - physical disability or are suffering from a physical disorder.

1.16 Early identification of the individual abilities, as well as disabilities, of each vulnerable witness is important in order to guide subsequent planning. An exclusive emphasis on disability ignores the strengths and positive abilities that a vulnerable individual possesses. Vulnerable witnesses may have had social experiences that could have implications for the investigation and any subsequent court proceedings. For example, if the vulnerable adult has spent a long time in an institutional environment, they may have learned to be compliant or acquiescent. However, such characteristics are not universal and can be ameliorated through appropriate preparation and the use of special measures. The Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adult and the Protocol for Joint Investigation

by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – Northern Ireland both set out a framework for joint working in this complex area of practice and emphasise the need to involve all other relevant agencies in information sharing, early assessment and the planning process.

1.17 Not all people with disabilities will necessarily be vulnerable as witnesses and would not wish to be treated as such. It is therefore important that the views of individual witnesses who might fall into this category are taken into account.

Intimidated witnesses

1.18 'Intimidated' witnesses are defined by Article 5 of the 1999 Order, as those whose quality of evidence is likely to be diminished by reason of fear or distress at the prospect of giving evidence.

1.19 In determining whether a witness falls into this category, the court should take account of:

- the nature and alleged circumstances of the offence;
- the age of the witness;
- where relevant:
  - the social and cultural background, and ethnic origins of the witness;
  - the domestic and employment circumstances of the witness; or
  - any religious beliefs or political opinions of the witness; and
- any behaviour towards the witness by:
  - the accused;
  - members of the accused person's family or associates; or
  - any other person who is likely to be either an accused person or a witness in the proceedings.

1.20 Fear and distress for victims and witnesses may be increased by factors relating to their gender, age, marital status, family circumstances, sexual orientation, race, ethnicity, culture, religion, political opinions and/or disability. Training in equality and diversity including section 75 obligations under the Northern Ireland Act 1998 are likely to complement practice and decision making in this area.

1.21 Particular groups of victims and witnesses who are likely to benefit from the provisions under this Article include:

- those who have experienced domestic violence;
- complainants in cases of sexual assault (as defined by Article 5(4) of the 1999 Order);

- victims of, and witnesses to, homophobic crime, racially motivated crime and crime motivated by reasons relating to religion;
- those who have experienced past or repeat harassment, stalking and bullying, or repeat victimisation;
- those who self-neglect and self-harm;
- frail older persons;
- witnesses to murder and the families of murder and manslaughter victims; and
- those who are making allegations against professionals or carers.

1.22 Research suggests that sexual offences, assaults and those offences where the victim knew the offender are particularly likely to lead to the intimidation of witnesses. In addition, crimes which involve repeated victimisation, such as racial harassment and stalking, are also particularly likely to lead to intimidation.

1.23 While the legislation distinguishes between vulnerable and intimidated witnesses, in respect of the criteria for their eligibility for special measures it is important to recognise that:

- some witnesses may be vulnerable as well as intimidated (e.g. an elderly victim of vandalism who has dementia on a housing estate);
- other witnesses may be vulnerable but not subject to intimidation (e.g. a child who witnesses a robbery in the street); and
- some witnesses may not be vulnerable but may be subject to possible intimidation (e.g. a young woman who fears violence from her current or former partner, or someone who has been the subject of a racial attack).

1.24 While these examples provide illustrations of the application of the legislation, it is important not to attempt to categorise witnesses too rigidly.

Special measures

1.25 It has long been recognised that many people who are the victims of, or witnesses to, crimes find the ensuing process of investigation and trial difficult and stressful. This affects the quantity and quality of the witness's communication. The 1999 Order, as amended, introduced a range of measures that can be used to facilitate the gathering and giving of evidence by vulnerable and intimidated witnesses. These are collectively referred to as 'special measures' and are briefly outlined in Box 1.1 below and are described in detail in Chapter 6.

Box 1.1 Special measures available to vulnerable and intimidated witnesses by order of the court under the 1999 Order, as amended

Article 11: Screens may be used to stop the witness seeing the defendant.

Article 12: A live link can enable the witness to give evidence during the trial from outside the court through a live televised link (live link) to the courtroom. The witness may be either accommodated within the court building or in a suitable location outside the court. A direction for evidence to be given via live link may also provide for a supporter.

Article 13: Evidence given in private. Exclusion from the court of members of the public and the press (except for one named person to represent the press) may be considered in cases involving sexual offences or intimidation.

A**rticle 14:** Removal of wigs and gowns by judges and barristers in the Crown Court to make the courtroom appear less formal.

Article 15: The police interview can be visually recorded and played at the trial as the witness's evidence in chief.

Article 16: Cross-examination and re-examination may be recorded in advance of the trial and then played at the trial. [Please note: this special measure is not yet available.]

Article 17: Examination of a witness through an intermediary. An intermediary may assist a witness, who has difficulty understanding questions and/or framing answers coherently, to give their evidence to the police and at court. This measure is available only to vulnerable witnesses. [Please note: this special measure is not yet available.]

Article 18: Aids to communication may be permitted to enable a witness to give best evidence whether through a communicator or interpreter, or through a communication aid or technique, provided that the communication can be independently verified and understood by the court. This measure is only available to vulnerable witnesses.

1.26 Pending the implementation of Article 17 (examination of witness through intermediary), the courts under their inherent jurisdiction can still grant the use of an intermediary. Appendix B provides details of an unreported judgment in Northern Ireland which would be of assistance to legal representatives and judges considering the need for and use of an intermediary prior to the commencement of Article 17.

1.27 The special measures for use at court are subject to application to the judge by the prosecution or defence before the trial. Special measures are not automatically available and are subject to the discretion of the court. In reaching a decision on whether the special measures application should be granted, the courts must take account of all of the circumstances of the case, including the wishes of the witness and whether or not the special measure in question is likely to inhibit the evidence being effectively tested by any party to the proceedings. In effect, three tests are applied as follows:

- whether the witness is vulnerable or intimidated;
- whether any of the special measures or any combination of them are likely to improve the quality of the witness's evidence; and
- which of the available special measures are most likely to maximise the quality of the witness's evidence.

1.28 Where a reference is made in the legislation to the 'quality of a witness's evidence' for the purposes of defining a witness as vulnerable or intimidated, and in terms of access to special measures, it refers to the "completeness, coherence and accuracy" of the evidence and "coherence" refers to a witness's ability in giving evidence to give answers which address the questions put to the witness and can be understood both individually and collectively.

1.29 Investigators should establish at an early stage whether the witness is likely to qualify for a special measures direction and, if so, what particular measures, if any, will assist the witness to maximise the quality of their evidence. It should be noted that it does not necessarily follow that playing a video recorded interview as evidence in chief is going to be the best way for the witness to achieve their best evidence. In some cases, other special measures, such as live evidence in chief from behind a screen, may be of more assistance to the witness. It is essential that the police, social care agencies, the prosecution and defence, and also court officials, take account of the individual circumstances of each witness, together with their expressed needs and wishes, in order to provide support sufficient to enable witnesses to give their best evidence.

1.30 While it is important to establish at an early stage whether the witness is likely to qualify for special measures, it should be noted that the need for such measures may change from the time of the investigation to the time of the trial. The effect of this is that witnesses might be eligible for more or less support as time goes on, depending on changes in their circumstances. For example, in some circumstances, effective witness preparation might reduce the witness's anxiety, therefore reducing the need for some or all of the special measures previously thought necessary. In other circumstances, the witness's anxiety might increase

as the time of the trial approaches, particularly where intimidation or harassment occurs or is anticipated, therefore increasing the need for special measures. It is, therefore, important that all those involved in maintaining contact with the witness and preparing them to give evidence continue to liaise with the prosecution or the defence, as appropriate, to ensure that any changes of circumstance are carefully considered and taken into account as necessary.

1.31 The legislation also provides that if a witness gave video recorded evidence in chief on the grounds that they were under 18 years of age but subsequently turned 18, the video recording is still admissible as evidence.

Additional protection

1.32 As well as special measures provisions, the 1999 Order contains additional protection as follows:

- Articles 22 and 23: Mandatory protection of witness from cross-examination by the accused in person. An exception has been created which prohibits the unrepresented defendant from cross-examining vulnerable child and adult victims in certain classes of cases involving sexual offences.
- Article 24: Discretionary protection of witness from cross-examination by the accused in person. In other types of offences, the court has discretion to prohibit an unrepresented defendant from cross-examining the victim in person.
- Article 28: Restrictions on evidence and questions about the complainant's sexual behaviour. The 1999 Order restricts the circumstances in which the defence can bring evidence about the sexual behaviour of a complainant in cases of rape and other sexual offences.

Reporting restrictions

1.33 Provisions for reporting restrictions are covered in sections 44 to 52 of the Youth Justice and Criminal Evidence Act 1999 (the 1999 Act). The 1999 Act covers England, Wales and Northern Ireland in this regard and provides for restrictions on the reporting by the media of information likely to lead to the identification of children under 18 and certain adult witnesses in criminal proceedings. Sections 46 to 52 in relation to adults have been commenced but sections 44 and 45 in relation to children under 18 have not been commenced.

1.34 The 1999 Act is not the only provision for reporting restrictions and it is important to remember that they may be available and appropriate in other circumstances, for example in relation to specific offences. For example, section 1 of the Sexual Offences (Amendment) Act 1992 imposes a mandatory reporting restriction for a

complainant's lifetime once an allegation of a sexual offence has been made. This applies to children and adults. Also, Article 22 of the Criminal Justice (Children) (NI) Order 1998 gives the courts discretion to ban the reporting of details likely to lead to the identification of a child concerned with any criminal proceedings. There is a mandatory ban on such reporting in the youth court under Article 22(2) of the 1998 Order.

Victim and witness support

1.35 Vulnerable and intimidated witnesses can receive support at all stages of the investigation. Four distinct roles or phases for witness support have been identified. They are:

- interview support – provided by someone independent of the police, who is not a party to the case being investigated. The supporter can sit in on the interview. They may be a friend or relative, but not necessarily so;
- pre-trial support – provided to the witness in the period between the interview and the start of any trial;
- court witness support – a person who may be known to the witness but who is not a party to the proceedings, has no detailed knowledge of the case or may have assisted in preparing the witness for their court appearance. A direction for evidence to be given via live link under may also provide for a supporter; and
- post-trial support – witnesses have considerable needs following a trial and it is important that practitioners are mindful of the information needs of victims and witnesses following a verdict and sentencing. The need for information is acute in discontinued cases or where lesser charges are proffered, particularly where a plea is accepted. Agencies providing support have a key role in identifying current need; linking the witness to appropriate sources of information; helping the witness to understand the outcome of proceedings; and connecting witnesses to sources of relevant ongoing support.

2 Planning and conducting interviews with children

Part 2A: Planning and preparing for interviews

What follows in this part is a recommended procedure for planning and preparing for interviews with child witnesses. Thorough planning is essential to a successful investigation and interview. Even if concerns about the child's safety necessitate an early interview, an appropriate planning session is required to identify key issues and objectives. Time spent anticipating and covering issues early in the criminal investigation will be rewarded with an improved interview later on. It is important that, as far as possible, the case is thoroughly reviewed before an interview begins to ensure that all issues are covered and key questions asked since the opportunity to do this will, in most cases, be lost once the interview has been concluded.

Part 2B covers the interview process itself. While what follows in this part and Part 2B should not be regarded as a checklist to be rigidly worked through, the sound framework that it provides should not be departed from by interviewers unless they have discussed and agreed the reasons for doing so with their senior manager or an interview adviser. Any such agreements and the rationale underpinning them should be recorded. It may subsequently be necessary to explain such departures at court.

While this chapter deals specifically with the interviewing of children, it should not be read and used in isolation from Chapters 3 and 4. This guidance has been written so that Chapters 2 - 4 form a complementary whole. For example, issues in relation to disability and intimidation will have an application across all vulnerable witnesses. Approaches that work well with children may work equally well with adults with learning disabilities and vice versa.

In preparing for interview, investigating officers must take note of the paragraph on gathering physical evidence in Chapter 1.

The importance of planning

2.1 The purpose of an investigative interview is to ascertain the child witness's account of the alleged event(s) and any other information that would assist the investigation. A well-conducted interview will only occur if appropriate planning has taken place. The importance of planning cannot be overstated. The success of an interview and, therefore, an investigation could hinge on it. Even if the circumstances necessitate an early interview, an appropriate planning session that takes account of all the information available about the witness at the time and identifies the key issues and objectives is required. Time spent anticipating and covering issues early in the criminal investigation will be rewarded with an improved interview later on. It is important that, as far as possible, the case is thoroughly reviewed before an interview begins to ensure that all issues are covered and key questions asked, since the opportunity to do this will, in most cases, be lost once the interview has been concluded.

2.2 Although the Public Prosecution Service (PPS) is not part of the investigating team and does not direct the investigation, an early meeting between the police and PPS to discuss special measures may be appropriate. The police may also seek advice from the PPS at an early stage about any other evidential issues that may affect the way in which the investigation is conducted. In some exceptional cases, the PPS may select suitably qualified counsel to advise from a very early stage.

2.3 In some cases, it may useful to obtain the assistance of an interview adviser to develop a witness interview strategy (see National Investigative Interviewing Strategy, Association of Chief Police Officers 2009).

Initial contact with child witnesses

2.4 The need to consider a video recorded interview will not always be immediately apparent either to the first police officer who has contact with the child witness or to other professionals involved prior to the police being informed. Even where it is apparent, the need to take immediate action in terms of securing medical attention and making initial decisions about the criminal investigation plan might be such that some initial questioning is necessary.

2.5 Any initial questioning should be intended to elicit a brief account of what is alleged to have taken place. A more detailed account should not be pursued at this stage but should be left until the formal interview takes place. Such a brief account should include where and when the alleged incident took place and who was involved or otherwise present. This is because this information is likely to influence decisions made in respect of the following aspects of the criminal investigation plan:

- forensic and medical examination of the victim;
- scene of crime examination;
- interviewing of other witnesses;
- arrest of alleged offender(s); and
- witness support.

2.6 In these circumstances, any early discussions with the child witness should, as far as possible, adhere to the following basic principles:

- listen to the child;
- do not stop a child who is freely recalling significant events;
- where it is necessary to ask questions, they should, as far as possible in the circumstances, be open-ended or specific-closed rather than forced-choice, leading or multiple;
- ask no more questions than are necessary in the circumstances to take immediate action;
- make a comprehensive note of the discussion, taking care to record the timing, setting and people present as well as what was said by the witness and anybody else present (particularly the actual questions asked of the witness);
- make a note of the demeanour of the witness and anything else that might be relevant to any subsequent formal interview or the wider investigation; and
- fully record any comments made by the witness or events that might be relevant to the legal process up to the time of the interview.

Competence, compellability and availability for cross-examination: the legal position

2.7 Article 31 of the Criminal Evidence (NI) 1999 Order (the 1999 Order) provides that in principle "all persons are (whatever their age) competent to give evidence". The Article qualifies this principle by saying that persons are incompetent as witnesses where the court finds that they are unable to understand questions put to them or unable to give answers to them which can be understood. However, Article 32(3) makes it clear that in considering this question a court must bear in mind the various special measures that are available under Articles 11 to 18 of the 1999 Order, as amended by the Justice Act (NI) 2011.

2.8 In the case of children, the Court of Appeal judgment in R v Barker [2010] EWCA Crim 4 makes it clear that "… although the chronological age of the child will inevitably help to inform the judicial decision about competency, in the end the decision is a decision about the individual child and his or her competence to give evidence in the particular trial.".

2.9 Where a video recorded statement is to be played in court as evidence in chief, there is no need for the witness to be sworn. Article 33(2) and (3) of the 1999 Order expressly provide that such a video recorded statement, if admitted by the court as the evidence of the witness, shall have the same legal status as that witness's direct oral testimony in court even where, if giving direct oral testimony in court, the witness would have been required to take an oath.

2.10 Where a witness is competent to give evidence, they are also compellable. This means that they can be legally required to attend trial. In general, however, the fact that a witness is compellable does not mean that they can be legally required to give any kind of preliminary statement to the police even the sort of statement that is made under this guidance.

2.11 It does not necessarily follow that because a witness is competent and compellable the PPS will insist on making them attend court to give evidence if unwilling to do so. The PPS is not legally required to call every piece of evidence available and, in some cases, may proceed without a particular witness's evidence if they believe that they can secure a conviction without it. In cases where the PPS believes that the evidence of a particular witness is essential, the PPS may not proceed if they think that to do so would be particularly damaging to the witness (in such cases the child witness and their carer must be informed of the implications of this decision). In deciding whether to include a particular witness's evidence, and whether to proceed with the case, the PPS will always take account of the wishes of the witness (although they will not necessarily defer to them). Police reports to the PPS should always include clear information about the wishes of the witness and, if appropriate, their parents or carers, about going to court. The PPS may in any event need to seek further information from the investigating team and should always be kept up-to-date throughout the case to ensure a continuous review.

2.12 A video recorded interview is usually only admissible as evidence in chief at trial where the person who made it is "available for cross-examination". However, there are exceptions to this general rule. The judge has discretion to allow the court to hear the pre-trial statements of witnesses who are unable to give evidence for various specified reasons. These include the fact that the witness is dead, "by reason of his bodily or mental condition unfit to attend as a witness" or does not give evidence at trial "through fear or because he or she is kept out of the way". It must be remembered, however, that the judge has the final word on whether or not the video recorded statement will be admitted.

Planning information

Overview

2.13 The planning phase of an interview with a child witness involves some consideration of three types of information:

- information about the witness;
- information about the alleged offence(s); and
- information important to the investigation.

2.14 At this stage, interviewers need to have differing amounts of knowledge about each type of information. In a general sense, they need to know as much as is possible in the circumstances about the child witness, and a little about the alleged offence and information important to the investigation.

Definition

2.15 Article 4 of the 1999 Order, as amended, defines child witnesses as being under the age of 18.

Preliminaries

2.16 A consideration of child protection issues, consent, medical examinations and psychiatric/psychological assessments necessarily informs the planning process as it applies to child witnesses. Each of these matters will be considered in turn prior to considering the information that should ideally be obtained before planning an interview with a child.

The context of the allegation: the intersection of the child protection and criminal justice systems

2.17 Any video recorded interview serves two primary purposes. These are:

- evidence gathering for use in criminal proceedings; and
- the evidence in chief of the child witness.

2.18 In addition, any relevant information gained during the interview can also be used in relation to any subsequent actions to safeguard and promote the child's welfare and, in some cases, the welfare of other children.

2.19 Some information may be common to both primary purposes but there will be issues specific to each to be considered at the planning phase. The video interview may additionally serve a useful purpose in informing any subsequent civil childcare proceedings or in disciplinary proceedings against adult carers (e.g. in residential institutions), and its potential value for these should not be overlooked.

2.20 At a minimum, such as instances in which the child has no previous contact with the public services, the investigating team in child protection cases should include representatives from both the police and Health and Social Care. It may also be important to involve GPs or educational professionals who know the child. For children who have had past or current involvement with Health and Social Care, useful information may already have been provided from different professionals or may be obtained from other adults who know the child (e.g. parents, carers, teachers, educational psychologists, youth workers, occupational therapists), and it may be that other individuals are offered a more active role in the planning process for the investigation (e.g. facial composite operators where the suspect is not known to the child).

2.21 Whenever suspicion has arisen that a child has suffered, or is likely to suffer, significant harm, there will be a strategy discussion or meeting involving Health and Social Care, the police and other professionals as appropriate, e.g. paediatrician, child and adolescent mental health services (Co-operating to Safeguard Children, DHSSPS). If enquiries under Article 66 of the Children's (NI) Order 1995 are pursued following the strategy discussion/meeting then the Initial Assessment undertaken using the UNOCINI (Understanding the Needs of Children in Northern Ireland) Framework (see Appendix C) will provide considerable information about the child and their carer(s). The investigative interview and criminal investigation will run alongside such Article 66 enquiries and the interviewing team may, therefore, have access to detailed information about the child which can be drawn on when planning and conducting the interview, depending on the exact timing of the video interview in relation to the Article 66 enquiries.

2.22 Where it has been agreed by the police and children's social care in a strategy discussion/meeting that it is in the best interests of the child that a full criminal investigation be carried out, the police are responsible for that investigation, including any investigative interview (video recorded or otherwise) with the victim. Having responsibility for the criminal investigation does not mean that the police should always take the lead in the investigative interview. Provided both the police officer and social worker have been adequately trained to interview child witnesses in accordance with the guidance set out in this document, there is no reason why either should not lead the interview. The decision as to who leads the interview

should depend on who is able to establish the best rapport with the child. In some cases, after joint consultation, the interview itself may be conducted by the police alone (with Health and Social Care agreement and with reference to the Protocol for Joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse - Northern Ireland). In circumstances where a social worker leads the interview, the police should retain their responsibility for the criminal investigation by ensuring that the interview is properly planned and that the police officer has an effective role in monitoring the interview. Similarly, where a police officer leads the interview, Health and Social Care should retain its duty to make enquiries under Article 66 by ensuring that the interview is properly planned and that the social worker has an effective role in monitoring the interview.

2.23 Research has shown that too often the views and opinions of children and young people are ignored or marginalized in the planning process. Wherever possible, and where practicable, older children and young people in particular should be consulted about matters appropriate to their age and understanding, and contribute to the planning and preparation for interview (e.g. when and where the interview takes place, who is present, who conducts the interview). It is, however, important to honour any commitments made to the child. The strategy agreed for interviewing a child should be noted in writing by the investigators concerned (see Form PJI4 of the Protocol for Joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – Northern Ireland).

2.24 Enquiries should be carried out in such a way as to minimise distress to the child, and to ensure that families are treated sympathetically and with respect. The decision as to whether to conduct a joint investigative interview or joint visits should be determined by what is in the best interests of the child, for example by limiting the number of occasions that the child has to relate an account of what has happened to them or reducing the frequency of agency visits to the child's home. Investigators should consult safeguarding children procedures about how enquiries relating to children suffering or likely to suffer significant harm (under Article 66) and associated criminal investigations should be conducted and the circumstances in which joint enquiries are necessary and/or appropriate.

2.25 Different circumstances experienced by the child prior to the interview will have implications both for the amount of knowledge that may already be available about the child to be shared between agencies, and subsequently for the manner in which any investigative interview is planned and proceeds:

- some children will be unknown to health and social care but known to their GP, health visitor or school;
- some children may not be known health and social care but may be known, for example, to child and adolescent mental health services or education professionals because of emotional or behavioural problems, or special educational needs; or
- some children will be known to health and social care as open cases or as previously open cases, as well as to health and education services.

2.26 Whatever the child's circumstances, the police officer, the children's social care worker and any other members of the investigating team should give a proper explanation of their roles to the child and their carer. The child's knowledge and understanding should be monitored throughout the investigation.

2.27 Children who have previously been unknown to health and social care and the police are likely to have least understanding of the interviewing process and of the nature of professional interventions. The way in which the purpose of the interview and the roles of the investigating team are explained to the child and their carer(s) will need to take account of the fact that they have had no previous contact with public services regarding child protection concerns about a child's safety or welfare.

2.28 Children who have previous experience of public services may be more knowledgeable about the roles of different personnel, though their experiences will have varied depending on their individual circumstances. However, assumptions should not be made about a particular child's level of knowledge of public service personnel, especially children's social care workers, who may have been involved with the family for a number of possible reasons (e.g. children in need services, services for disabled adults or adults with mental health problems). If there have been concerns about a child's safety and/or welfare or current concerns have resulted in the consideration of an investigative interview, an initial assessment of the child's needs and their family members will have already been undertaken by the relevant Health and Social Care Trust. The child's and/or the family's experiences and perceptions, both positive and negative, of any previous interventions may influence how receptive they are to the investigative process and may also affect the child's response in an interview.

2.29 Consideration should be given to holding a discussion between the investigating officer and the PPS to discuss what measures might be needed to assist the witness before and during the trial.

Consent

General principles

2.30 When assessing how a child's evidence should be obtained interviewers should:

- consider each child as an individual;
- assess the child's individual needs whatever the offence;
- take account of the following characteristics of the child:
    - age;
    - gender;
    - culture;
    - religion;
    - physical and/or learning disability; and
    - confidence and developmental level; and
- consider the views of the child and their carer.

2.31 When considering the needs of child witnesses interviewers should NOT:

- assume that an older child will necessarily be more confident than a younger one;
- assume that an older child will always want to give evidence live in the court room; and
- make assumptions based on the child's demeanour (for example, some children may behave with a degree of bravado even though they are actually experiencing a great deal of angst at the prospect of giving evidence).

2.32 It is important that the special measures proposed are tailored to meet the individual needs of the witness rather than being based on the nature of the offence. In no circumstances should it be assumed that all child witnesses are the same and they will want to give evidence by video recorded statement and live link.

2.33 It is not uncommon for a child witness to change their views about giving evidence using particular special measures. Therefore, special measures discussions should be ongoing and discussed at the police interview stage, before submission of a special measures application and reviewed again after a pre-court familiarisation visit.

Informed consent and the child witness opt out

2.34 The law presumes that child witnesses under 18 will normally give their evidence outside the courtroom by playing a video recorded interview as evidence in chief and cross-examination via live link unless this will not improve the quality of their evidence. However, subject to the agreement of the court, children may opt out of giving their evidence by either a video recorded interview as evidence in chief or by means of live link, or both. The process of obtaining informed consent and explaining the 'opt out' can be summarised as follows:

- explanation of video recorded evidence in chief;
- explanation to the effect that children usually give their evidence in chief by way of video recorded interview but that it is a matter of choice and that they can 'opt out' if they wish to do so; and
- if the child exercises their choice to opt out they should be told that:
    - a written record will be made of the interview in the form of notes and a statement prepared for them to sign as appropriate; and
    - the court will then presume that they will give evidence in chief first by means of live link unless they opt out with the court's permission and then from behind screens unless they opt out.

Explanation of video recorded evidence in chief

2.35 In coming to a view about video recorded evidence in chief children and/or the carers who have parental responsibility for them should be given enough information for them to come to an informed decision. Interviewers should, therefore, take steps to explain the purpose of any proposed video recorded interview to the child (and/or their carers) at a level appropriate to their age and understanding. Such an explanation should include the following:

- the benefits/disadvantages of having or not having the interview video recorded;
- who may see the video recorded interview (including the alleged offender both before the trial and at court); and
- the different purposes to which a video recorded interview may be put (e.g. if it appears the video may be useful in disciplinary proceedings against a member of staff who is suspected of abusing or neglecting a child in their care).

2.36 The child should be advised that, should the case proceed, whether a video recording is made or not, they may be required to attend court to answer further questions directly (e.g. cross-examination). A live link facility will normally be available to enable the witness to give best evidence at court. There is a

presumption that this aid will normally be required by the child. The existence of a video recorded interview does not by itself guarantee that it will be used as evidence in chief as this will be a decision for the court.

2.37 Written consent to be video recorded is not necessary from the child. However, it is unlikely to be practicable or desirable to video record an interview with a reluctant or hostile child. The interviewers are responsible for ensuring that, as far as possible, the child is freely participating in the interview and not merely complying with a request from adult authority figures.

The child witness opt out

2.38 If a child wishes to opt out of video recorded evidence in chief, they may give all their evidence by live link from outside the courtroom, if the court agrees. The child may also opt out of live link evidence, if the court agrees but the law then presumes that they will give evidence in the court room behind a screen. Should they not wish to use a screen, they may also be allowed to opt out of using it. Ultimately this is a matter for the court to decide but it must take the witness' views into account when making its decision on whether to approve an opt out request.

When interviewers do not consider a video-recorded interview to be appropriate

2.39 If, after having considered the circumstances of the child, an interviewer comes to the conclusion that a video recorded interview is not the best way of presenting the child's evidence to a court they should explain this to the child and/or their carer. It is important that the explanation is based on a consideration of the circumstances. A full written record should be made of any such explanation.

2.40 If a child and/or their carer disagrees with an interviewer's explanation for concluding that a video recorded interview is not the best way of presenting the child's evidence, a discussion between the police and the PPS should take place ideally before the interview. If the prosecutor agrees with the interviewer's view, it should be explained to the child and/or their carer and no video recorded interview should take place. If it is not practical to hold a meeting with the PPS before the interview, it should be video recorded and the child and/or their carer informed that advice will sought from the PPS at the earliest opportunity.

Informing the child's carers

2.41 It is generally presumed that the parents or carers of a child witness will be informed of any interview before it takes place. In exceptional circumstances, however, it may be necessary to interview a suspected child victim without the knowledge of the parent or carer. Such circumstances include the possibility that a child would be threatened or otherwise coerced into silence; a strong likelihood that important evidence would be destroyed; or that the child in question did not wish the parent to be involved at that stage, and is competent to take that decision. Proceeding with the interview in the absence of parental knowledge needs to be carefully managed in interventions with the family by the local children's services authority, but may be necessary for example where children are at risk of honour-based violence or forced marriage.

Medical examinations

2.42 Consideration must be given to the timing, purpose and content of any medical examination or paediatric evaluation in relation to the interview. Sometimes the medical examination will have preceded the interview, e.g. after 'acute' abuse or if the examination needs to take place before a laboratory closes (e.g. identification of sexually transmitted diseases). The Forensic Medical Officer may be aware of problems that might be making the child uncomfortable, such as soreness or vaginal discharge, and/or may suggest the significance of any symptoms reported by the child at the time of the abuse or later. When examining children, the Forensic Medical Officer should take care to avoid asking leading questions or anticipating the investigative interview. They should, however, make contemporaneous notes of any spontaneous comments by the child concerning the origins or circumstances giving rise to the evaluation or examination. On other occasions, the medical examination will be after the interview. In cases where a medical examination is a possibility, a discussion should take place with the paediatrician or Forensic Medical Officer who will undertake this to ensure that expectations of possible outcomes of the examination are realistic and appropriate. It is essential that all notes and records concerning medical examinations and decisions made in the course of investigations are preserved as they may be required for disclosure as part of any subsequent criminal or civil court proceedings.

2.43 Consideration should also be given to the identity of the examiner. The evaluation should only be carried out by suitably qualified and experienced clinicians, and should not be confined solely to examination of the child's genital and/or anal areas. A child who is concerned that abuse may have damaged them in some way can be reassured by a sensitive examination. Parents will usually require similar reassurance. Conversely, children who do not allege penetration should not receive unnecessary medical examinations.

Psychiatric/psychological assessment interviews

2.44 The role of child and adolescent mental health specialists should be considered where appropriate. Where assessment interviews by a psychiatrist or a psychologist take place, their primary purpose is to inform the childcare planning process. For this reason, they will not resemble interviews conducted in accordance with this guidance. However, such assessment interviews can also be of assistance to the criminal investigation, including the planning process for a video recorded interview. The limits and expectations of such assessments should be agreed with the psychiatrist or psychologist prior to the assessment taking place.

Information about the child witness

2.45 Consideration needs to be given to a number of factors pertaining to the child, their family and background in the planning of the investigation and interview. Some of this information may exist as a result of an Initial or Pathway Assessment having been undertaken using the UNOCINI Framework (see Appendix C) or from any pre-interview assessment. Additional information may be provided by other professionals consulted or involved in the planning process. Other information may best be provided by the child's parent(s) or carer(s). A checklist of some of the desirable information is provided in Box 2.1 and again interviewers may find the UNOCINI Guidance useful when considering the child in their family context. The Thresholds of Need Model (UNOCINI) provides detailed descriptions of the different levels of children's needs. This model is used to enable practitioners and agencies to understand and communicate better the needs of children, and any concerns relating to children. The interviewing team will need to balance the need to obtain as much of this information as possible with their desire to conduct the interview as soon as is practicable.

Box 2.1 Checklist of desirable information

Factors to be considered at the planning phase include:

- child's age;
- child's race, culture, ethnicity and first language;
- child's religion;
- child's community or (perceived) political background;
- child's gender;
- child's sexuality (where the child is old enough for this to be relevant);
- child's preferred name/form of address;
- any physical and/or learning impairments;
- any specialist health and/or mental health needs;
- any medication being taken and its potential impact on any proposed interview;
- child's cognitive abilities (e.g. memory, attention);
- child's linguistic abilities (e.g. how well do they understand spoken language, how well do they use it? An intermediary may be able to help improve the quality of evidence of any child who is unable to detect and cope with misunderstanding, particularly in the court context, i.e. if a child seems unlikely to be able to recognise a problematic question or tell the questioner that they have not understood, assessment by an intermediary should be considered);
- child's current emotional state and range of behaviours;
- likely impact on the child's behaviour of recalling traumatic events;
- child's family members/carers and nature of relationships (including foster or residential carers, or is the child a young carer?);
- child's relationship to alleged perpetrator;
- child's overall sexual education, knowledge and experiences;
- has the child been subject to sexual exploitation?;
- types of discipline used with the child (e.g. smacking, withholding privileges);
- bathing, toileting and bedtime routines;
- sleeping arrangements;
- any significant stress(es) recently experienced by the child and/or family (e.g. bereavement, sickness, domestic violence, job loss, moving house, divorce etc.);
- current or previous contact with public services (including previous contact with the police or health and social care); and
- any other relevant information or intelligence known.

2.46 Box 2.1 is not comprehensive. Investigators will develop their own agenda in the light of their experience or knowledge of the individual child, and all other relevant circumstances. Information on these issues will inform decisions about the structure, style, duration and pace of the interview. Children of the same age can differ widely in their development particularly if they have been abused or neglected. Children may also react to the investigative process itself because it is unfamiliar, and aspects such as a medical examination or personal questions may be particularly difficult and/or upsetting for the child (although a sensitively conducted medical examination or paediatric evaluation can be reassuring). The interviewer will need to pitch the language and concepts used to a level that the witness can clearly understand while the focus should be on recognising and working with the witness's capabilities rather than limitations.

2.47 Particular care and preparation needs to taken in the planning of the investigation and interview of young people who may have been subject to sexual exploitation. Few young people will ever make a disclosure or statement to this effect. Their reluctance to do so may be for various reasons including being fearful of what might happen to them should they disclose; misplaced loyalty towards those abusing or exploiting them; or failure to view this as abuse given the grooming techniques frequently employed by the perpetrators or their often traumatic early childhood experiences. It is often only after a number of months or years have elapsed before a young person can see the abusive intent behind their experiences. Many young people are reluctant to come forward and go through a period of turmoil before deciding if they should disclose the abuse. If they do, then it is crucial that this window of opportunity is taken immediately as experience has shown that when this has not happened this opportunity can often be lost because of the young person's fear of their abusers and/or mistrust of authorities. Specialist training and support should be sought for interviewers working with children who may have had these experiences. Agencies should be aware that, even where the young person makes a complaint, they may retract their statement, claiming that they have been lying. Sometimes these young people may appear compliant in the abuse and may actually defend the alleged abuser. This can be a result of both the sophisticated grooming techniques used by abusers and the level of dependency created by the abuser.

Previous interventions

2.48 In cases where the child is a suspected or known victim of previous abuse, the investigating team may find it helpful to address the issues listed in Box 2.2 below.

Box 2.2 Checklist of additional factors

Additional factors to be addressed in cases where the child is known or suspected to have been previously abused include:

- the detailed nature of the child's attachment to their parents;
- the age and developmental level of the child at onset of abuse;
- abuse frequency and duration;
- whether different forms of abuse coexist;
- the relationship of the child to the alleged abuser(s);
- the type and severity of the abusive act;
- the existence of multiple perpetrators;
- the degree of physical violence and aggression used;
- whether the child was coerced into reciprocating sexual acts;
- the existence of adult or peer supports;
- whether or not the child has been able to tell someone about the abuse;
- the parental reaction to disclosure/allegation; and
- previous interventions.

Race, gender, culture and ethnic background

2.49 The child's race, gender, culture, ethnicity, first language, religious and political beliefs must be given due consideration by the interviewing team. They have a responsibility to be informed about and take into account the needs and expectations of children from the specific minority groups in their local area. The interviewing team's knowledge of the child's religion, culture, customs and beliefs may have a bearing on their understanding of any account given by the child including the language and allusions the child may make, for example, to reward and punishment. In a Northern Ireland context, it is always important to be alert to issues which may relate to sectarianism.

2.50 The interviewing team needs to bear in mind that some families and children may have experienced discrimination and/or oppression through their contact with government agencies and local authorities. Their experiences of racism, for example, may result in them distrusting the professionals involved in an investigative interview. Asylum-seeking children and child refugees may have a fear of disclosing abuse because of what may happen to them and their family.

2.51 It is also important that the interviewing team considers the complexities of multiple discrimination, for example in the case of a child from a minority ethnic community who has a disability, and of the child's experiences of discrimination. The specific needs and experiences of dual-heritage children must also be taken into account.

2.52 Some possible relevant considerations include the following although this list is not exhaustive:

- customs or beliefs that could hinder the child from participating in an interview on certain days (e.g. holy days) or may otherwise affect the child's participation (e.g. if older children are fasting);
- the relationship to authority figures within different minority ethnic groups, for example, children from some cultures may be expected to show respect to authority figures by not referring to them by their first names, and by not correcting or contradicting them;
- the manner in which love and affection are demonstrated;
- the degree to which extended family members are involved in caring for the child;
- the degree of emphasis placed on learning skills in independence and self care; and
- issues of shame, for example carers in some cultures may inhibit the child from talking about a sexual assault for fear of shaming the family.

2.53 A child should be interviewed in the language of their choice. If the child is bilingual then this may require the use of an interpreter. The interpreter should normally be selected from the PSNI register of translators and interpreters.

Other life experiences

2.54 Where the child may have experienced abuse, neglect, domestic violence and/or discrimination based on race or disability, the interviewers must consider its potential impact on the interview. There is no single 'diagnostic' symptom of abuse or discrimination but some of the possible effects on children are set out in Boxes 2.3 to 2.6. When considering the possibility of abuse or discrimination, it must be understood that children who have experienced it will not necessarily exhibit all, or indeed any, of the behaviours set out in these boxes.

Box 2.3 Some possible effects of abuse and neglect

These include:

- fear:
- behavioural problems;
- sexualised behaviours;
- poor self-esteem;
- post-traumatic stress disorder;
- self-injury and suicidal behaviour;
- increased emotional problems, e.g. anxiety and depression;
- decreased cognitive functioning;
- negative social behaviour, e.g. increased aggression, non-compliance, anti-social behaviour and criminal activity; and
- lower intellectual functioning and academic achievement.

Box 2.4 Some possible effects of racism

These include:

- fear;
- poor self-esteem;
- fear of betrayal of community;
- mistrust of people from outside own community;
- difficulty in establishing positive (racial) identity; and
- increased vulnerability to racist abuse.

Box 2.5 Some possible effects of discrimination based on disability

These include:

- decreased autonomy, experience of being patronised by able-bodied people;
- increased dependency;
- difficulty in establishing positive self-identity;
- experience of being isolated (geographical, physical, social);
- experience of being patronised by people who do not have a disability;
- experience of being treated as a 'voiceless object';
- feelings of being perceived as 'asexual'; and
- increased vulnerability to abuse.

Box 2.6 Some possible effects of domestic violence

These include:

- fear for safety of self and others in family;
- sadness/depression, possibly reflected in self-harm or suicidal tendencies;
- anger, which may be demonstrated in aggressive behaviour;
- negative impact on health (e.g. asthma, eczema, eating disorders or developmental delays); and
- negative impact on behaviour (e.g. aggression, lack of concentration, truanting).

2.55 It is important for interviewers to consider these matters in relation to each individual child rather than work from assumptions based on stereotypes. Being sensitive to such factors should contribute towards a safe and non-judgmental interview environment for the child. It is essential that the interview process itself does not reinforce any aspects of discriminatory or abusive experiences for the child.

Assessment prior to the interview

2.56 Interviewers may often decide that the needs of the child and the needs of criminal justice are best served by an assessment of the child prior to the interview taking place particularly if the child has not had previous or current involvement with social services or other public services. Such an assessment should be considered for any child as it offers the opportunity to explore a number of general factors (see Box 2.7 below).

Box 2.7 General factors to be explored via an assessment prior to interview

These include:

- the child's preferred name/form of address;
- the child's ability and willingness to talk within a formal interview setting to a police officer, social worker or other trained interviewer;
- an explanation to the child of the reason for an interview;
- the ground rules for the interview;
- the opportunity to practise answering open questions;
- the child's cognitive, social and emotional development (e.g. does the child appear 'streetwise' yet in reality have limited understanding?);
- the child's use of language and understanding of relevant concepts such as time and age. (As a general rule of thumb, an intermediary may be able to help improve the quality of evidence of any child who is unable to detect and cope with misunderstanding, particularly in the court context, i.e. if a child seems unlikely to be able to recognise a problematic question or tell the questioner that they have not understood, assessment by an intermediary should be considered.);
- any special requirements the child may have (e.g. do they suffer from separation anxiety or have an impairment, are they known to have suffered past abuse or to have previously undergone an investigative interview?);
- any apparent clinical or psychiatric problems (e.g. panic attacks, depression) which may impact on the interview, and for which the child may require referral for a formal assessment; and
- an assessment of the child's competency to give consent to interview and medical examination.

2.57 Interviewers must be careful to balance the need to ensure that the child is ready and informed about the interview process against the possibility of allegations at trial of coaching or collusion (for further discussion of coaching see Appendix D).

2.58 The UNOCINI Framework for assessing children may be helpful. A full written record of any such assessment(s) must be kept (on form PJI3 where the assessment is conducted as part of a Joint Protocol investigation into alleged or suspected child abuse). This record should be revealed to the PPS under the requirements of the Criminal Procedure and Investigations Act 1996.

2.59 Interviewers should have clear objectives for assessment(s) prior to interview and should apply this guidance on talking with children during such assessment. For example, they should avoid discussing substantive issues (in any detail) and must not lead the child on substantive matters. Interviewers should never stop a child who is freely recalling significant events. Instead, the interviewers must make a full written record of the discussion, making a note of the timing and personnel present, as well as what was said and in what order. The interviewers should begin by explaining the objectives of the interview to the child: "We will talk about the things you are concerned about tomorrow. Today, I want to get to know you a bit better and explain what will happen if we do a video interview.".

2.60 The interviewer can also use the opportunity to answer any questions the child may have about the conduct of the interview and explain any transport arrangements. Some interviewers use this opportunity to introduce some of the ground rules to the child while others do so exclusively on the tape as part of the rapport phase of the interviews. If any of the ground rules are introduced at this stage, then they should be repeated in the formal interview to demonstrate that the necessary procedures have been completed.

2.61 The needs of the child may require that this assessment should take place over a number of sessions. No inducements should be offered for complying with the investigative process.

2.62 It is likely that for some children, assessment(s) will indicate that their needs are not best met by proceeding with a full formal interview.

Information about the alleged offence(s)

2.63 It is preferable (but not always necessary or essential) that the interviewer knows little detail of the alleged offence(s) for the purposes of the interview. However, in order to plan and prepare for the interview, the interviewer will need a little general knowledge about:

- the type of alleged offence(s);
- the approximate time and location of the alleged offence(s);
- the scene of the alleged offence(s) (note that this should only be enough general knowledge to help the interviewer understand what might be said during the interview); and
- how the alleged offence(s) came to the notice of the police.

2.64 Where the interviewer is also the investigating officer and has been involved in a multi-agency strategy discussion (Co-operating to Safeguard Children, DHSSPS, 2003 - paragraphs 5.15 -5.19; Protocol for Joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – Northern Ireland 2004 – paragraphs 2.30 – 2.38), it is accepted that circumstances and practical resource considerations might be such that they are likely to know more about the alleged offence(s) than is set out above. In this situation, the interviewer should try as far as possible to avoid contaminating the interview process with such knowledge.

2.65 It is also accepted that circumstances and resource considerations might be such that it could be necessary for an interviewer to interview more than one witness during the course of an investigation. In such a situation, care should be taken to avoid asking questions of a witness based on the responses of previous interviewees because this could contaminate the witness's account.

2.66 Nothing in this guidance is intended to limit operational decision-making in cases where the nature of the investigation, the context of the interview and the circumstances as they are known at the time make it necessary for interviewers to have a more detailed knowledge of the offence than the general information outlined in the paragraphs above.

Information important to the investigation

2.67 While obtaining an account of the alleged event is essential, other matters might need to be covered during the interview in order to progress the investigation. These matters can be regarded as 'information important to the investigation'. Obtaining a complete picture of all the relevant issues within an interview is essential because it will provide the investigating officer with the information necessary to conduct a comprehensive investigation. It could also prove beneficial in discussions with the PPS if the subject of witness assessment is raised. Information important to the investigation falls into two categories: general investigative practice and case-specific material. Where such information has not already been covered as part of the child's account, interviewers should consider introducing it either in the latter part of the questioning phase or in a subsequent interview session, depending on the complexity of the case and what is alleged to have been seen by the witness.

2.68 The amount of knowledge that the interviewer has about information important to the investigation prior to the interview depends on what they know about what is alleged to have been witnessed by the child. It is preferable that the interviewer knows little detail of the alleged offence(s) before the interview. Only a little knowledge that could form the basis of potential questions about information important to the investigation is, therefore, likely to be available to the interviewer at this point in time. However, while planning the interview, the interviewer should apply what they know of the alleged offences to determine the areas of general investigative practice that might need to be covered in the interview. More case-specific material could either be made available to the interviewer (from the investigating officer or the second interviewer) after an attempt has been made to elicit and clarify the child's account, or be included in the planning information for a later interview to avoid potential contamination of the process.

Information important to the investigation relating to general investigative practice

2.69 Information important to the investigation relating to general investigative practice includes:

- points to prove any alleged offence(s);
- information that should be considered when assessing a witness's identification evidence, as suggested in R v Turnbull and Camelo ([1976] 63 Cr App R 132) and embodied in the mnemonic ADVOKATE (Practical Guide to Investigative Interviewing (National Centre for Policing Excellence, 2004)):

  A Amount of time under observation
  D Distance from the eyewitness to the person/ incident
  V Visibility – including time of day, street lighting, etc.
  O Obstructions – anything getting in the way of the witness's view
  K Known or seen before – did the witness know, or had they seen, the alleged perpetrator before?
  A Any reason to remember – was there something specific that made the person/incident memorable?
  T Time lapse – how long since the witness last saw the alleged perpetrator?
  E Errors or material discrepancies;

- anything said by the witness to a third party after the incident (evidence of first complaint etc.); and
- any other witnesses present.

2.70 This is not intended to be an exhaustive list. The nature of the information important to the investigation pertaining to general investigative practice varies according to the circumstances of the case.

Information important to the investigation relating to case-specific material

2.71 Information important to the investigation relating to case-specific material includes:

- how and where any items used in the commission of the offence (e.g. clothing, vehicles, weapons, cash, documents, other property) were disposed of if the child might have some knowledge of this;
- access by the young person and suspect to electronic media including computers and mobile telephones;

- relevant financial transactions by the young person and suspect;
- any background information relevant to the child's account (e.g. matters that might enhance or detract from the credibility of the child's evidence such as the amount of any alcohol consumed);
- any lifestyle information relevant to the child's account;
- where the child has knowledge of an alleged victim or a suspected perpetrator, an exploration of their relationship, background history, places frequented and any events related or similar to the matter under investigation; and
- any risk assessment issues that the child might know about that concern the likely conduct of the alleged perpetrator, family or associates.

2.72 This is not intended to be an exhaustive list. The nature of any case-specific material varies according to the circumstances of the alleged offence, the nature of any relationship between the child and the alleged perpetrator, and what is alleged to have been seen, heard or otherwise experienced. Significant evidential inconsistencies and significant evidential omissions (case-relevant information) are discrete categories of case-specific material.

Significant evidential inconsistencies

2.73 During the course of an investigation it may be necessary to ask a child to explain a significant evidential inconsistency between what they have said during the interview and other material gathered during the course of the investigation. Such inconsistencies would, for example, include significant differences between the account provided by the child during the interview and:

- what the child is reported to have said on a previous occasion;
- the accounts of other witnesses; and
- injuries sustained by either the alleged victim or the alleged offender.

2.74 There are a number of reasons for significant evidential inconsistencies between what a child says during an interview and other material gathered during the course of an investigation. Many of these reasons are innocent in nature (e.g. genuine mistakes by the child or others stemming from a memory-encoding or recall failure, or subconscious contamination of their memory by external influences) but occasions may arise where the child is motivated to either fabricate or exaggerate their account of an event.

2.75 Whatever the reason for the significant evidential inconsistency, occasions may arise where it is necessary to ask the child to explain it. The following principles should be taken into account when considering whether, when and how to solicit such an explanation:

- explanations for evidential inconsistencies should only be sought:
  - where the inconsistency is a significant one;
  - after careful consideration has concluded that there is no obvious explanation for them; and
  - after the child's account has been fully explored, either at the end of the interview or in a further interview, as appropriate;
- interviewers should always be aware that the purpose of asking a child to explain an evidential inconsistency is to pursue the truth in respect of the matter under investigation; it is not to put pressure on a child to alter their account;
- explanations for evidential inconsistencies should take account of the extent to which the child may be vulnerable to suggestion, compliance or acquiescence; and
- questions intended to elicit an explanation for evidential inconsistencies should be carefully planned, phrased tactfully and presented in a non-confrontational manner.

2.76 The intermediary's advice will be helpful when considering whether, when and how to solicit an explanation for significant evidential inconsistencies.

Significant evidential ommissions

2.77 During the course of an investigation, it may be necessary to ask a child about relevant information that they have not mentioned in their account. This may arise, for example, where others say that the alleged offender was carrying an object, or the alleged offender's behaviour was unusual, or that there was something particular about the alleged offender's description or vehicle, but this is not mentioned by the child. There are a number of reasons why this type of information can be omitted from an account and situations may arise where it is important to seek an explanation from the child. In these circumstances, it may be necessary to ask a question to establish whether the child has knowledge of the information. Such a question should only be asked after the child's account has been fully explored at the end of the interview (or in a further interview if necessary).

2.78 When planning such a question, the interviewer should consider:

- whether the information omitted by the child is likely to be important enough to be worthy of explanation;
- the extent to which the child may be vulnerable to suggestion, compliance or acquiescence; and
- which type of question is most likely to elicit the information in a manner least likely to have an adverse effect on the value of any answer.

2.79 A plan for soliciting an explanation for the omission of case-relevant information from a child's account must take account of the reliability of any answer. For example, a useful starting point might be to ask the child a specific-closed question such as: 'What else can you tell me about the incident?'. If the child's answer:

- includes the case-relevant information but lacks sufficient detail, the interviewer should ask the child to provide a more detailed response by means of an open question (e.g. 'Tell me about…'). When the case-relevant information has been covered, the child should be tactfully asked to explain its omission from their account unless the reason for its omission is apparent from the child's response or the circumstances of the case; or
- does not include the case-relevant information, a further decision will need to be made as to whether it is necessary to ask a question that might be regarded as leading (e.g. 'Do you recall seeing/hearing…?'). It should be noted that if the answer to such a leading question contains the case-relevant information, it is likely to be of limited evidential value. The evidential value of such an answer may, however, be enhanced if the interviewer then asks the child to provide a more detailed response by means of an open question (e.g. 'Tell me about…') followed by questions intended tactfully to elicit an explanation for its omission from their account (unless the reason for the omission is apparent from the child's response or the circumstances of the case).

2.80 Where the child cannot recall the case-relevant information, this may be due to not attending to the information or to memory loss. Further reading on case-relevant information can be found in The Evaluation of the Investigation and Legal Process Involving Child Abuse Offences to Establish a Model of Investigation for Investigators by K.B. Marlow (unpublished MSc thesis, Portsmouth, 2002).

Using the planning information

Overview

2.81 The planning information should be used to:

- set aims and objectives for the interview;
- determine the techniques used within the phased interview; and
- decide:
  - the means by which the interview is to be recorded;
  - who should conduct the interview and if anybody else should be present (including social care support for the child);
  - if anybody should monitor the interview (investigating officer, supervising officer, specialist/interview adviser, etc.);
  - who will operate the equipment;
  - the location of the interview;
  - the timing of the interview;
  - the duration of the interview (including pace, breaks and the possibility of more than one session); and
  - what is likely to happen after the interview.

Aim and objectives

2.82 The aim of the interview should be to achieve all the objectives that are set for it while being as concise as reasonably possible.

2.83 Setting clear objectives is important because they give direction to the interview and contribute to its structure. The interview objectives should focus on:

- the alleged incident or event(s); and
- any case-specific information important to the investigation.

Techniques

2.84 The kind of techniques used within the phased structure will vary according to what is known about both the child and the offence when planning the interview as well as how the child behaves and what emerges during the interview itself. For example, it might be productive to make use of some of the cognitive procedures referred to in the relevant paragraphs within the phased interview approach with a witness who is able and willing to participate in the process. On the other hand, such techniques are unlikely to be productive with a witness who is less cooperative and hostile, and a more managed communication is necessary.

How the interview is to be recorded

2.85 The decision whether or not to video record an interview should take into account:

- the needs and circumstances of the child (e.g. age, development, impairments, degree of trauma experienced, whether the child is now in a safe environment);
- whether the measure is likely to maximise the quality of that particular child's evidence;
- the type and severity of offence;
- the circumstances of the offence (e.g. relationship of the child to the alleged abuser);
- the child's state of mind (e.g. likely distress and/or shock); and
- perceived fears about intimidation and recrimination.

2.86 Given the variety of children's backgrounds and the different circumstances leading to suspicion of abuse, there are no hard and fast rules, or unequivocal criteria that apply to the video recording of interviews. Among the considerations to be taken into account before proceeding with any video recorded interview with a child are the following:

- the individual child's circumstances, current or previous contact with public services, previous concerns around parenting, neglect or abuse, and history of the current allegation;
- the purpose and likely value of a video recorded interview on this occasion;
- competency, compellability and availability of the child for cross-examination;
- the child's ability and willingness to talk in a formal interview setting;
- the use of an intermediary and/or aids to communication (interviews involving intermediaries and/or aids to communication should be video recorded unless the child does not consent or there are exceptional circumstances for not doing so); and
- preparation of the child before interview.

2.87 Discussions at the planning phase will enable the investigating team to decide whether a video recorded interview or an interview for the purposes of taking a written statement is appropriate for any particular individual. It is likely that a video recorded interview will be considered if a child has already made a clear allegation of abuse or if someone has witnessed the child being abused. A video recorded interview may also be appropriate, subject to the deliberations of the investigating team, if the child is emotionally distressed or has a psychiatric disorder. Where the child has not made a verbal allegation of abuse then the interviewing team may decide that other specialist help or assessment of the child is more appropriate to the needs of the child than a video recorded interview.

2.88 In circumstances where the investigating team conclude that it is more appropriate to take a written statement, the interviewer(s) should consider the P.E.A.C.E. model of investigative interviewing advocated by the Association of Chief Police Officers in 'The Practical Guide to Investigative Interviewing'.

2.89 Regardless of how the interview is recorded, notes should always be taken which are sufficiently detailed to assist the investigating officer to determine any further lines of enquiry that might be necessary and to brief the custody officer and any other interviewers where a suspected perpetrator is in custody. Responsibility for the compilation of such notes should be agreed during the planning phase of the interview. Where a video recorded interview is conducted as part of a Joint Protocol investigation into alleged or suspected child abuse, this responsibility would fall to the second interviewer and captured in Form PJ16.

Interviewers and others present at the interview

2.90 The interviewer, second interviewer and equipment operator must all be trained to the relevant standards.

The interviewer

2.91 Consideration should be given to who is best qualified to lead the interview. A special blend of skills is required to take the lead in video recorded interviews. The lead interviewer should be a person who has or is likely to be able to establish rapport with the child, who understands how to communicate effectively with witnesses who might become distressed, and who has a proper grasp of the rules of evidence and criminal offences. The lead interviewer must have good knowledge of information important to the investigation, including the points needed to prove particular offences.

2.92 In addition to taking account of the prospective interviewer's skills, the following factors should be taken into consideration when considering who should conduct the interview:

- the experience of the prospective interviewer in talking to children in respect of the type of offence under investigation and any other skills that they possess that could be useful;
- any personal or domestic issues that the prospective interviewer has that might have an adverse impact on the interview; and
- whether any previous experience that the prospective interviewer has with the child is likely to either inhibit rapport building, or give rise to challenges of coaching, prompting or offering inducements.

2.93 The child's gender, race, culture and ethnicity must always be given due consideration and advice sought where necessary but stereotypic conclusions about who is to conduct the interview should be avoided.

2.94 Where the child expresses a preference for an interviewer of a particular gender or sexual orientation, or from a particular race, cultural or ethnic background, this should be accommodated as far as is practical in the circumstances.

2.95 The interviewer should consider the appropriate mode of dress for the particular witness. For example, research shows that a person's perceived authority can have an adverse effect on the witness especially with respect to suggestibility.

2.96 Exceptionally, it may be in the interests of the child to be interviewed by an adult in whom they have already put confidence but who is not a member of the investigating team. Provided that such a person has appropriate professional qualifications, is independent and impartial, is not a party to the proceedings, is prepared to co-operate with appropriately trained interviewers and can accept adequate briefing (including permitted questioning techniques), this possibility should not be precluded.

The second interviewer

2.97 Regardless of who takes the lead, the interviewing team should have a clear and shared remit for the role of the second interviewer. Too often this role is subjugated to the need for someone to operate the video equipment, when, in reality, the second interviewer has a vital role in observing the lead interviewer's questioning and the child's demeanour. The second interviewer should be alert to identifying gaps in the child's account, interviewer errors, and apparent confusions in the communication between lead interviewer and child. The second interviewer can reflect back to the planning discussions and communicate with the lead interviewer as necessary. Such observation and monitoring can be essential to the overall clarity and completeness of the video recorded account, which will be especially important at court. Research with child witnesses has further reported that often children do not understand why the second interviewer was present in the interview if that interviewer had no recognisable role to play.

Equipment operators

2.98 The lead interviewer, or designated member of the interviewing team, should take responsibility for checking the availability and working order of the video equipment ahead of the interview. In particular, if interviewers intend to communicate with each other, or with the equipment operator via an earpiece, then this equipment should be tested in situ to ensure its effectiveness. Problems with earpieces are highly distracting to the interviewer and child, and can be very destructive to the interview itself. Where an intermittent fault is suspected in the equipment, it may be better to stop and reschedule the interview rather than stop and restart the interview which places additional stress on the child. Interviewers should also consider the possibility that earpieces can be viewed as 'intrusive' by children. It can seem that the interviewer is receiving 'secret' instructions which, in fact, can often be heard by the child.

2.99 The equipment should always have an operator for the duration of the interview. This will allow the view recorded by the camera to be adjusted if the child moves. It should also provide an opportunity for the interviewer to be alerted at the earliest possible moment in the event of an equipment failure rather than such a failure not being discovered until the end of the interview (see also Appendix E).

Interpreters

2.100 A child should always be interviewed in the language of their choice unless exceptional circumstances prevail (e.g. with regard to the availability of interpreters). This will normally be the child's first language unless specific circumstances result in the child's second language being more appropriate. Interviewers should be aware that some children will be perfectly fluent in English but will use their family language for intimate parts of the body, for example. Preparation needs to take account of this. If the child is bilingual, then this may require the use of an interpreter. Some children might have very strong views on the preferred gender or ethnicity of interpreters, and these should be accommodated wherever possible.

2.101 Interpreters should be appropriately accredited and trained so that they understand the need to avoid altering the meaning of questions and replies. They should normally be selected from the PSNI register of translators and interpreters. If it is not possible to select an interpreter from these registers then the interpreter may be chosen from some other list provided that the interpreter meets standards at least equal to those required for entry onto the registers in terms of academic qualifications and proven experience of interpreting within the criminal justice system. While the familiarity of the interpreter to the child is not a bar to use and

may indeed facilitate communication, all interpreters need to be independent, impartial and unbiased. Family members or other close relatives should not be used either during the interview or when preparing the witness for it.

2.102 Interpreters should be involved in the planning process. They should have a clear understanding of the objectives of the interview, its structure and the function served by any specific techniques used (e.g. those of the cognitive interview). It should be remembered that some words in English might not have an exact equivalent in other languages and communication systems. This possibility should, therefore, be discussed while planning the interview with a view to developing strategies to address what might otherwise be a problem.

2.103 If interviewers are working with an interpreter, it is important to have clarified at the outset who will lead the interview in terms of maintaining direct communication with the child. If the child is communicating via an interpreter, the lead interviewer should identify themselves as such while maintaining appropriate eye contact with the child so that the child understands that they should address the interviewer not the interpreter. If, however, a signer is being used to communicate with a child who has a hearing impairment, it may be more important for the signer to maintain the direct communication with the child.

2.104 Where an interpreter is present, they must be clearly identified at the beginning of the interview. Whenever possible, they should also be visible in one of the shots recorded.

2.105 Where a sign language interpreter is being used to communicate with a child with a hearing impairment, a camera should be used to record the signer's hand movements as well as those of the child. In some interview suites, it might be necessary to make use of a portable camera, in addition to the static equipment already set up in the suite, for this purpose. Interviewers should also emphasise to the signer that it is important to avoid inadvertently leading the witness by presenting only one particular option when some of the more generic signs are used, e.g. the signs for 'weapon' and 'touch' depend on the context so it may be important to present the witness with a number of alternatives.

2.106 Where a signer is to be used, it is important to remember that the energy involved in signing is such that the hands of the signer and the witness are likely to get tired. The interview plan should therefore take account of the need for breaks to give the signer and the witness an opportunity to rest their hands.

Intermediaries (note: this special measure is not yet available)

2.107 The information provided here is intended to summarise the role of the intermediary and general principles that need to be considered in criminal investigations. Detailed procedural guidance will be produced when this special measure is commenced. While the services of an intermediary are likely to be particularly helpful where the child is very young, is traumatised or uses a specialised system of communication, it is important to note that an intermediary may be able to help improve the quality of evidence of a child of any age who is unable to detect and cope with misunderstanding, or to clearly express their answers to questions especially in the context of an interview or while giving evidence in court.

2.108 Article 17 of the 1999 Order makes it clear that intermediaries can assist a witness to communicate by explaining questions put to and answers given by a vulnerable witness. Intermediaries can also assist during the planning phase of an interview by providing advice on how questions should be asked and then to intervene during the interview where miscommunication is likely by assisting the interviewer to rephrase the question or by repeating the witness's answers where they might otherwise be inaudible or unclear on the recording. The extent to which the intermediary is actively involved in the communication of questions and answers will vary from witness to witness depending on the witness's particular needs and communication style. It will also depend on the degree of compliance with the intermediary's recommendations by the interviewer. It is very important to remember that the intermediary is there only to assist communication and understanding – they do not take on the function of investigator.

2.109 Following commencement of this special measure, registration and accreditation arrangements will be put in place.

2.110 Before an intermediary can assist with communication, they need to conduct one or more assessment meetings with the witness. The criminal case is not discussed during assessment meetings. These meetings enable the intermediary to consider the witness's communication needs, and devise strategies and recommendations on how to maximise understanding. The meetings also enable the intermediary to build the necessary rapport with the witness and to determine whether they (the intermediary) are the right person to act as an intermediary for that witness. Intermediaries should never be alone with a witness; a responsible third party must be present. This should usually be a police officer at the investigation phase.

2.111 Registered Intermediaries should be used. The use of an unregistered person as an intermediary can only be considered once the options for using a Registered Intermediary have been exhausted. When this is the case, an unregistered intermediary has the same responsibility to the court. They must be independent of the case being investigated (i.e. not witnesses or suspects). There is a preference on unregistered intermediaries to be professional people rather than family members, friends or associates. In the event that the particular circumstances of the case are such that it appears that only a non-professional person can perform the function of an intermediary, it is important that the witness is assessed by a Registered Intermediary before proceeding, in order to confirm that the role can only be performed by the non-professional.

2.112 Discussions with the intermediary at the planning phase should include the arrangements for leading the interview, legal and confidentiality requirements, and the exact role that the intermediary will take. The potentially explicit nature of the topics to be covered should be addressed. The intermediary should be provided with information that is relevant to their role and will help them to maximise communication/understanding (e.g. the specific vocabulary used by the witness and relevant relationships).

Interview supporters

2.113 Deliberations at the planning phase may lead to a decision to include a supporter in the interview (termed an 'interview supporter'). Although it is important to guard against undue influence of the child by another adult, it may be helpful to the child (and to the process of securing an account) if someone is present to offer support, especially if the child is very young or upset. It is possible that such a person could withdraw once rapport has been established and the child has settled. Parent/carer(s) should not be automatically excluded from this role but their appropriateness will very much depend on the circumstances and nature of the case together with any issues arising out of the allegations made by the child. Also there are good reasons why their presence may not be in the best interests of the child (see paragraphs below). Having a parent or carer close by in another room may be sufficient. Other possibilities might include a teacher, nursery helper or other family member.

2.114 The supporter must be clearly instructed not to participate in the interview itself, whether by instructing or correcting the child, answering the interviewer's questions, head nodding or facial expressions. It may be helpful for the interview supporter to refer to the guidance in the Young Witness Pack (NSPCC (NI) 2011). Interview supporters should never offer the child inducements, such as a toy or trip, in

return for general co-operation or answering particular questions. Persons involved as a witness in the case in any capacity (i.e. not just someone who has seen the incident in question) cannot take on the role of interview supporter. This would include a parent to whom the child first disclosed abuse, or a parent whose partner or former partner is the subject of the allegation of abuse. It is important to ensure that the interview supporter has not been involved in the alleged offence nor will be perceived by the child as being involved (this may be particularly relevant to parent(s) acting as supporters). Carers can, however, wait in an adjacent room if it is thought that physical proximity might be helpful to the child.

2.115 Research suggests that the presence of a carer or parent at the time of the interview can actually be an additional source of stress if the child is concerned about them hearing unpleasant details. Also, the child may feel uncomfortable about someone they see on a daily basis, or in a particular relationship (e.g. their teacher), knowing intimate details of their personal life. For this reason, interviewers are strongly advised wherever possible to seek the views of the child on interview support as part of the planning for the interview. The interviewer needs to make it very clear that the child has a real choice and that whatever they choose is acceptable – some children may agree for their parent or carer to be present just to please the interviewer or parent.

2.116 Any interview supporter(s) must be clearly identified at the beginning of the taped interview. Whenever possible, they should also be visible in one of the shots recorded on the tape. Good practice would be for the supporter to make sure they are outside of the child's line of vision by sitting behind the child, for example.

2.117 The interview supporter should consider carefully how they may best comfort the particular child should they become distressed. The child should be reassured but it may not be appropriate to physically touch the child as this may be perceived as an invasion of personal space or even as abusive by some children.

Location of the interview

2.118 Active consideration should be given to the location of the interview and the layout of the room in which it is to take place. The location should be quiet enough to avoid a situation in which background noise is likely to interfere with the quality of the sound on any visual or audio record, and should be free from interruptions, distractions, and fear and intimidation so that the interviewer and the child can concentrate fully on the task in hand: the interview. The interviewer should ensure that sufficient pens and paper are available for use where a child's recall could be assisted by drawing a sketch plan.

2.119 Where the interview is conducted in a purpose-built interview suite (preferred option), the room decor should be welcoming and friendly (e.g. pictures on the wall which will appeal to children and young people of all ages, races and cultures, and indicate that other children visit the interview suite). Appendix E provides guidance on the selection and placement of furniture in the interview room. Food and drinks provided for comfort breaks should be appropriate for children from different ethnic groups.

2.120 Toys and other play materials should be located out of immediate view of the child so that any not introduced by the interviewer do not act as a distraction to the child during the interview. A limited range of gender- and age-appropriate playthings should be available. Suitable items are likely to include pens/crayons and paper. Dolls, puppets, puzzles and toys could also be considered where they appear likely to make the child's experience more positive (e.g. in establishing rapport) and/or help the child to give their account more effectively. Whilst toys can be used both to reduce stress and anxiety, and as a method to improve communication, interviewers should be alert to the possibility that toys could distract a restless or young child, or possibly patronise an older child.

2.121 In the event of it being necessary to interview a child at their home address, care should be taken to avoid saying anything or video recording any background material that might lead to the location being identified (the use of background screens should be considered if necessary).

Timing of the interview

2.122 The investigating team should pay particular attention to when the interview takes place as research has shown this to be one of the main concerns of child witnesses. Although the interview will normally take place as soon after an allegation or referral emerges as is practicable, rushing to conduct an interview without properly considering the child's needs and consulting them as far as possible, and without proper planning can undo any of the benefits of obtaining an early account from the child. The child's normal daytime routine and general needs should be considered as well as those of the adult(s) who care for the child. Interviewers should avoid starting an interview just before a mealtime or bedtime (or at any other time when the child is likely to be suffering from the effects of fatigue).

2.123 The decision about when to conduct an interview should also take account of the potential effects of trauma and/or stress. Trauma and stress can interfere with the process of recall but this should be determined by asking the child rather than by the imposition of an arbitrary period of time. Some child witnesses will want to be interviewed relatively quickly while others might wish to be interviewed at a later date. It should always be borne in mind that the potential for memory contamination taking place increases with the delay.

2.124 Children are very sensitive to being taken out of school classes, and on the rare occasions when it is unavoidable, the interviewer should liaise with the child's teachers to ensure it is affected as discreetly as possible.

2.125 In the event of circumstances being such that it is absolutely essential for a witness to be interviewed at a time when they are likely to be suffering the effects of fatigue (for example, where an alleged offender is in police custody for a serious offence and an interview is necessary to secure potentially vital evidence), consideration may be given to conducting a brief interview in the first instance which sets out the witness's account and addresses any issues on which immediate action needs to be taken. A more substantial interview can then be arranged at an appropriate time.

Duration of the interview (including pace, breaks and the possibility of more than one session)

2.126 The interviewing team should anticipate the likely number and length of the video recorded interview(s) as part of the planning process. It will help both the interviewer and the child to have an idea of approximately how long each interview is likely to last.

2.127 The pace of the interview should be dictated by the age and circumstances of the individual child. Interviews should proceed at the pace of the child not at that of the interviewer. Professionals whose experience of interviewing has been mostly with adults may be tempted to adopt too fast a pace for the child while those with only childcare experience may adopt an overcautious approach and spend too long in the rapport phase when the child is ready to proceed with their account. Whenever possible, the interviewer should seek advice from people who know the child about the likely length of time that they can be interviewed, and whether a pause or break is desirable.

2.128 The interviewer should allow comfort breaks during the interview for refreshment, use of the toilet or to have a break from the task if this is requested or felt necessary. The reason for any breaks should always be explained by the interviewer on the video recording. Where comfort breaks are necessary to enable the child to go to the toilet, the child should always be accompanied by one of the interviewers and discouraged from talking to others. If interactions with others do occur, they should be fully documented. When a break is less than 15 minutes, the recording should be allowed to run; if a break exceeds 15 minutes, then a new analogue tape or digital disk should be used. At no time should breaks or refreshments appear to be offered as a reward for co-operation or withheld from the child in the absence of co-operation with the interviewer or making a disclosure.

2.129 The absolute length of the interview will depend on a range of factors, including:

- the developmental age of the child;
- any disability the child may have;
- the number of alleged incidents to be described;
- how forthcoming the child is; and
- how much time is required to establish rapport.

2.130 It is not possible or desirable to put forward an ideal duration for an interview. However, shorter times may be necessary for developmentally younger children with limited attention spans while older children may be comfortable with an interview that lasts longer. If a child is becoming distressed or if their attention is beginning to wander then a break may be advisable. If the distress continues then the interview should be curtailed at that point and resumed, if possible, on a later occasion. Interviewers should not persist in interviewing a reluctant child: not only is this damaging to the child but such interviews are unlikely to be accepted by the courts.

2.131 In some circumstances, it might be necessary to conduct the interview over more than one session (e.g. in complicated cases where allegations of multiple offences are involved or where the child has a short attention span). The interviewer must plan appropriately for each interview/session in a focused way that is differentiated from the strategic planning of the overall investigation. It is not appropriate to neglect such planning or to leave preparation for the interview itself to the last minute. These sessions might be separated by a matter of hours or, if necessary, could take place over a number of days. When this occurs, care must be taken to avoid repetition of the same focused questions over time because these could lead to unreliable or inconsistent responses from some children, and interviews therefore being ruled inadmissible by the courts.

Planning for immediately after the interview

2.132 Although the interviewer cannot predict the course of an interview, planning discussions should cover the possible outcomes and consider the implications for the child and family taking account of knowledge about the child's circumstances, and previous or current involvement with social care or other public services. This should include the possibility of a medical examination (where this has not taken place before the interview), the possible need for alternative accommodation and any other steps necessary to protect the witness or reduce the possibility of harassment. Research has shown that children and their carers are often left unsupported subsequent to an interview (especially if the alleged abuser is outside the immediate family) which can be a source of great stress. The interviewing team itself is unlikely to be responsible for the child and family's continuing support

needs but they could be advised of the range of support services that are available. In addition, early consideration by the wider professional team may alleviate some of the child's and carers' anxieties. For instance, various outcomes of the video interview can be anticipated:

- interviewers are satisfied that something untoward has happened to the child, for example a clear disclosure is obtained or other forensic evidence is available;
- interviewers are satisfied that nothing untoward has happened to the child; and
- interviewers remain uncertain as to whether anything has happened to the child or not.

2.133 Planning should anticipate these various eventualities. Where a child is a witness but not the victim of an alleged crime, different sets of outcomes exist and these too should be considered at the planning phase.

2.134 For each possible outcome, the interviewer should prepare explanations of what may happen next for the child and their carer(s). Answers can be prepared to commonly asked questions such as 'What is the likelihood of a prosecution?' and 'Will [perpetrator] go to prison?'. A contact person should be identified to whom the child and carer(s) can direct any subsequent queries or further information.

2.135 It must be remembered that non-disclosure of abuse is an acceptable outcome of an interview either because the child has not experienced or witnessed any maltreatment, or because the child was not ready, able or willing to tell at the time of the interview. Differences in how and when children disclose abuse are described in Box 2.8.

Box 2.8 How and when children talk about abuse

- statements may be 'accidental' or deliberate, verbal or non-verbal;
- suspicion may arise from one or more sources: medical query, witness reports, confession, photographic evidence, children's behaviour or verbal statements;
- children may not report all the details of their abuse at once – they may minimise or withhold information;
- disclosure may be immediate but is very often delayed for long periods;
- children may deny or retract such statements, even if other evidence exists, and this may be symptomatic of the abuse itself;
- the presence of an earlier informal statement does not guarantee an allegation will be repeated in a formal interview; and
- age, culture and many other factors may affect children's willingness and ability to make such statements.

Child witnesses who might become suspects

2.136 So far as is practicable, consideration should be given in the planning phase as to how the interviewer will deal with any confessions to criminal offences made by the child in the course of the interview. Any decision on an appropriate course of action will involve taking into account the seriousness of the crime admitted and weighing it against the seriousness of the crime under investigation.

2.137 It is preferable to anticipate and plan for such an eventuality while recognising that any decisions on a particular course of action are likely to depend on what has been disclosed by the child during the course of the interview (see paragraphs in Part 2B for guidance in respect of incriminating statements made by child witnesses during interviews).

Recording the planning process

2.138 A full written record should be kept of the decisions made during the planning process, and of the information and rationale underpinning them. This record should be referred to in the statement of evidence subsequently made by the interviewer in relation to the planning, preparation and conduct of the interview, and should be revealed to the PPS under the requirements of the Criminal Procedure and Investigations Act 1996. In addition, if the investigation is conducted under the Protocol for Joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – Northern Ireland, Form PJI4 should be completed.

Preparing the child for an interview

2.139 Children should always be prepared for an interview. In some cases, this might be fairly brief and take place immediately prior to the interview. In other instances, it might be necessary to take more time (e.g. where the child can also be considered to be an intimidated witness) and/or for it to take place several hours or days before the interview.

2.140 The preparation of the child should include an explanation of the purpose of the interview and the reason for video recording it (including who might subsequently view it), the role of the interviewer(s) and anybody else to be present, the location of the interview and roughly how long it is likely to take. The interviewer(s) should also outline the general structure of the interview and provide some explanation of the ground rules that apply to it (including the child not making any assumptions about the interviewer's knowledge of the event). Substantive issues relating to the evidence should not be discussed while preparing a child for an interview.

2.141 The child's carer(s) should also be provided with suitable information at this stage unless one or both are suspected of involvement in the offences under investigation. For example, they should be discouraged from discussing the details of the alleged offence(s) with their child or any other individual who may be involved in the investigation but must be able to reassure the child who wishes to talk or express anxieties. They should be asked to document carefully any discussions they have with their child or other persons regarding the allegation or investigation (e.g. who was present, date/time and setting, what exactly was said). The child should never be offered inducements for complying with the investigative process. Carer(s) should also be encouraged to provide emotional support to the child such as physical comfort and reassurance. They should be given information about what further role, if any, they may have in planning the interview or in being present while it is conducted (or given reasons why the interviewer(s) would prefer them not to be present). Where possible, any support needs of the carer(s) that are identified should be brought to the attention of the relevant authorities/agencies. In cases where the child may have been abused within the family, concerns may arise as to the non-abusing carer's ability to support the child or to take seriously what the child has said.

2.142 Any issues or concerns raised by the child or their carer(s) should be addressed while preparing them for the interview (e.g. welfare issues or concerns about the possibility of a later court appearance).

2.143 Most child witnesses will be anxious prior to an investigative interview, and few will be familiar with the formal aspects of this procedure. It is, therefore, important that the interviewer uses the time spent preparing a child for an interview to build up a rapport with them. The nature and the extent of rapport building required very much depends on what has been established about the child during the planning phase of the interview.

2.144 Some children who have been traumatised might need to spend more time getting to know the interviewer(s) before they are ready and/or willing to take part in an investigative interview. The interviewer(s) should consider whether one or more meetings with a child should be planned to take place prior to the interview because this familiarisation process may take some time.

2.145 Some children may feel that their initial, lawful co-operation with a person who subsequently commits an offence may make them blameworthy and they may assume that they must have done something wrong simply because they are being interviewed. The interviewer might need to try to reassure the child on these points but promises or predictions should not be made about the likely outcome of the interview. So far as possible, the interview should be conducted in a 'neutral' atmosphere with the interviewer taking care not to assume, or appear to assume, the guilt of an individual whose alleged conduct may be the subject of the interview.

2.146 Some children may be unhappy, or feel shame or resentment about being questioned especially on personal matters. In the rapport phase, and throughout the interview, the interviewer should convey to the child that they have respect and sympathy for how they feel. A child may be apprehensive about what may happen after the interview if they do provide an account of what happened. Such worries should be addressed.

2.147 Initial discussions with the child could focus on events and interests not thematically related to the investigation: sport, television programmes, favourite games, school curriculum, and so on. Sometimes, where the child and the interviewer have had some previous contact this can be quite brief. At other times, especially when the child is nervous or has been subject to threats from the alleged abuser, a much longer period of rapport-building when the child is prepared for the interview may be warranted.

2.148 Rapport-building while the child is prepared for the interview can also serve to set the tone for the style of questions to be used by the interviewer during the interview. It is, therefore, important that the child is encouraged to talk freely through the extensive use of open-ended questions because this can help to encourage them to give detailed accounts; a style of communication consistent with the guidance set out in this document.

2.149 In some instances, it might be helpful to conduct a practice interview while preparing the child for the interview. In these circumstances, the child could be asked to recall a personal event unrelated to the issue of concern (e.g. a birthday or a holiday). This serves to provide the child with an example of the kind of detail that will be required in relation to the issue of concern and to practise extended verbal responses. Such practice interviews might be particularly useful with younger witnesses who might not appreciate the demands of a witness interview for detailed and context information.

2.150 Rapport-building while the child is prepared for the interview also gives the interviewer the opportunity to build on their knowledge of the witness's communication skills and degree of understanding of vocabulary. The interviewer can then adjust their language use and the complexity of their questions in the light of the child's responses.

2.151 It may prove problematic to attempt to proceed with an interview until rapport has been established. Should establishing rapport when the child is prepared for the interview proves difficult, it may be preferable to postpone the interview rather than proceeding with an interview that may well turn out to be of no benefit.

2.152 Assistance should be sought if necessary from interview supervisors and interview advisers concerning the issues that might arise during the preparation of a child witness for an interview.

2.153 Full written notes must be kept of the preparation of a child for an interview and must be given to the PPS on request. The information obtained to plan the interview should be reviewed and revised if necessary in the light of any additional information that arises from preparing the child witness for the interview.

Part 2B: Interviewing child witnesses

General principles

2.154 The basic goal of an interview with a witness of any age is to obtain an accurate and truthful account in a way which is fair, is in the witness's interests and is acceptable to the court. What follows is a recommended procedure for interviewing a child which is based on a phased approach. Much professional experience and published research now exist on the conduct of the phased interview with children and have found that it produces a good balance between quality and quantity of information elicited from a witness. The phased interview normally consists of the following four phases:

- establishing rapport;
- asking for free narrative recall;
- asking questions; and
- closure.

2.155 Each phase will be described in greater detail below. These phases are compatible with and underpin the PEACE (Planning and Preparation; Engage and Explain; Account, Clarification and Challenge; Closure; Evaluation) interview framework advocated by the Association of Chief Police Officers (ACPO).

2.156 The phased approach acknowledges that all interviews contain a social, as well as a cognitive, element. As regards the social element, witnesses, especially the young, will only divulge information to persons with whom they feel at ease and whom they trust. Therefore, the first phase of any interview involves establishing rapport with the witness, and the final or closure phase requires the interviewer to try to ensure that the witness leaves the interview feeling that they have been given the fullest opportunity to be heard. As regards the cognitive element, the phased interview attempts to elicit evidence from the witness in a way which is compatible with what is known about the way human memory operates and the way it develops through childhood. A variety of interviewing techniques are deployed, proceeding from free narrative to open and then specific-closed questions where a hierarchy of reliability of the information is obtained. The technique is designed to ensure that, as far as possible, witnesses of all ages provide their own account rather than the interviewer putting suggestions to them with which they are invited to agree. The techniques of the phased interview are not those of casual conversation: they must be learned and then practised to ensure that they are applied consistently and correctly.

2.157 The emphasis on the phased approach should not be taken to imply that all other interview techniques are necessarily unacceptable or preclude their development. Nor should what follows be thought of as a checklist that must be rigidly adhered to: every interview is a unique event which requires the interviewer to adapt procedures to the developmental age and temperament of the child, and the nature of the alleged offence(s). Flexibility is the key to skilful interviewing. A good interviewer is someone who can adapt their interviewing style in accordance with the witness sitting in front of them. However, the sound framework provided by the principles of the phased interview should not readily be departed from by the interviewer unless they have fully discussed and agreed the reasons with their senior manager or an interview adviser (tier 5 of ACPO's National Investigative Interviewing Strategy (ACPO, 2009)). It may subsequently be necessary to explain such deviations at court.

Preliminaries

2.158 The investigating team will first have to decide whether a video interview is appropriate or whether, in the circumstances of the investigation, the option of a written statement is preferable. The police may wish to hold an early meeting with the PPS at this point if such a meeting has not already taken place. The decision will be based on the nature and circumstances of the alleged offence, and the age and preference of the child. The child, or their parent or carer, should to be consulted and informed that they may opt out of a video recorded interview. Any decision to do so must take into account:

- age and maturity of the witness;
- ability of the witness to understand the consequences of giving evidence otherwise than by video recording;
- any relationship between the witness and the accused;
- witness's social, cultural and ethnic background or origin; and
- nature and circumstances of the alleged offence.

If a video recorded interview is the preferred option then normally one person, the lead interviewer, will be responsible for interviewing the child. A second interviewer may be present, in the room or outside. In addition, it may also be appropriate for the child to have an interview supporter.

2.159 The interviewing team will have decided at the planning meeting who will be the lead interviewer, taking into account any strong gender or ethnic preferences expressed by the child. It is essential that the interviewing team allows sufficient time prior to the interview to check that all equipment is working satisfactorily. To have to stop and restart the interview places additional stress on the child. Decisions should also be taken about where the child and interviewer will be placed so as to ensure that they are within clear view of the cameras. For the benefit of the court, the interviewer should begin an interview by:

- introducing all those present to the child, using the name by which the child prefers to be known;
- explaining in terminology appropriate to the developmental age of the child the role and function of police officers and/or social workers involved in the investigation;
- announcing where the interview is taking place, and the time and date of the interview; and
- pointing out the presence and location of cameras in the room, and their function as a permanent record of the interview.

2.160 Research confirms that many children believe that being interviewed by the police is an indication of their wrongdoing and any misperceptions need to be corrected at this early stage. The type of explanation offered for the purpose of the interview will vary with the developmental age of the child. Younger children may be told that other people need to view what they have to say in order for them to decide how best to help them if they have any problems. Older children can be reassured that making a recording of the interview will result in fewer requests to repeat their account to others.

Phase one: establishing rapport (including engaging and explaining)

Explaining the formalities

2.161 Firstly, it is necessary when video recording the interview to check that the equipment is turned on; all of the people in the room can be clearly seen on the monitor through the camera with the wide-angle lens where two cameras are in use; and the witness is appropriately framed in the main camera image (see Appendix E). Next, the interviewer should say out loud the day, date, time and place (not the detailed address) of the interview, and give the relevant details of all those present.

Building rapport

2.162 All interviews should have a rapport phase where relationships are established between the child and the interviewing team, and, towards the end of this phase, the aim and conventions of the interview are explained. Some interviewers prefer to deal with elements of rapport in the interview preparation phase (ground rules, reassurance). If so, such procedures need to be properly documented and reiterated during rapport. More formally, the rapport phase should normally encompass the following:

- initially discussing neutral topics and, where appropriate, playing with toys and reassuring the child that they have done nothing wrong;
- explaining the ground rules;
- exploring the child's understanding of truth and lies, and establishing the purpose of the interview; and
- supplementing the interviewer's knowledge of the child's social, emotional and cognitive development.

2.163 Within the main body of the interview and, if an interview is being video recorded, it is important that any discussion of neutral topics in the rapport phase is completed within a relatively short space of time. Interviewers should remember that a lengthy rapport phase may result in some child witnesses getting:

- tired before they are asked to provide an account. This could have an adverse impact on the quality of their evidence; and
- confused about the purpose of the interview. This could increase their anxiety.

2.164 If the interview plan suggests that discussing neutral topics for a lengthy period of time may be beneficial (e.g. with very young witnesses, those with a learning disability, traumatised children) it should take place as part of witness preparation before the interview commences.

2.165 Interviewers should be aware that it is neither desirable nor essential to discuss neutral topics in every interview. Where a child witness is anxious to begin their account of the alleged incident(s) as soon as possible, a discussion of neutral topics could be counterproductive by needlessly prolonging the rapport phase thus increasing their anxiety levels. In any event, rapport should not be regarded as something that is confined to the first phase of an interview: it begins when the interviewer first meets the child witness and continues throughout the interview.

2.166 Most children will be anxious prior to an investigative interview and few will be familiar with the formal aspects of this procedure. It is, therefore, important that the interviewer uses the rapport period to build up trust and mutual understanding with the child and to help them to relax as far as possible in the novel environment. Remember, children are often taught not to talk to strangers. In addition, research has shown that anxiety hinders the reporting of detailed information. Initial discussions should focus on events and interests not thematically related to the investigation: sport, television programmes, favourite games, school curriculum, and so on. Sometimes, where the child and the interviewer have had some previous contact, this aspect of the rapport phase can be quite brief. At other times, especially when the child is nervous or has been subject to threats from the alleged abuser, a much longer period of the rapport phase may be warranted.

2.167 Rapport also gives the interviewer the opportunity to build on their knowledge of the child which they will have gathered from the planning meeting. In particular, they will learn more about the child's communication skills and degree of understanding of vocabulary. The interviewer can then adjust their language use and the complexity of their questions in the light of the child's responses. Research has shown that recall is hindered if adult appropriate (as opposed to age appropriate) language is used.

2.168 Rapport also serves to set the tone for the style of questions to be used by the interviewer for the main part of the interview. It is important that the child is encouraged in the rapport phase to talk freely through the extensive use of open-ended questions. A stream of questions that the child can answer 'yes' or 'no' to, or make an equally brief response, should be avoided. This not only helps the interviewer to assess the child's level of language, as the child should be talking at length relative to answering more specific-closed questions, but also teaches the child to talk (i.e. give detailed accounts). An interview is a learning experience even from the outset of the interview.

2.169 In some instances, it might be helpful to conduct a practice interview during the rapport phase of the interview during which the child is asked to recall a personal event unrelated to the issue of concern (e.g. a birthday celebration or a holiday treat). This serves to provide the child with an example of the kind of detail that will be required in relation to the issue of concern and to practise extended verbal responses. Such practice interviews might be particularly useful with younger witnesses who do not appreciate the demands of a witness interview for detailed and context information.

Ground rules

2.170 Children, especially young children, will perceive interviewers as figures of authority. Research suggests that when such authority figures ask questions, however misinformed, some children will endeavour to provide answers. Likewise, when authority figures offer interpretations of events or actions, however misleading, some children will agree with them and even elaborate on them in an effort to please the interviewer. It is necessary for the interviewer not to overemphasise their authority in relation to the child. They should also use the rapport phase actively to combat any tendency towards answers from the child which reflect an eagerness to please. This can be done by stating explicitly at the outset that:

- the interviewer was not present when the events under investigation allegedly took place and that, therefore, they are relying on the child's account;
- if the interviewer asks a question that the child does not understand, the child should feel free to say so;
- if the interviewer asks a question to which the child does not know the answer, the child should say, 'I don't know'; and
- if the interviewer misunderstands what the child has said or summarises incorrectly what has been said, the child should point this out.

3.171 These points are best put across in the context of concrete examples. It is recommended that the interviewer gives the child the chance to practise saying 'I don't know' or 'I don't understand' (see Box 2.9 for sample material).

Box 2.9 Establishing the ground rules for the interview

'Today, I am going to be asking you to tell me about things that have happened to you. Now, I wasn't there when these things happened so I need you to help me understand everything. Have I explained that properly?'

[Pause]

'One of the rules for me today is that I listen hard and try to understand everything you tell me. So, I might have to ask you some questions later. But, it's not like school – you know if the teacher asks you a question and you say you don't know – what does your teacher say to you?'

[Child's response, e.g. 'Miss Jackson tells you off but Miss Smith is okay', 'I have to try and answer' or 'I have to guess the answer.']

'Well, today, it's really okay for you to say you don't know. Because I'm a grown up, I might also ask you a question that you don't understand. I'll try hard not to, but if I do, I want you to tell me, so that I can try and put it another way.'

[Pause]

'And the last rule on me is if I get something wrong, I need you to tell me to make sure I get it right.'

After Robinson Howes (2000).

Truth and lies

2.172 Toward the end of the rapport phase, when ground rules have been explained to the child, the interviewer should advise the witness to give a truthful and accurate account of any incident they describe. There is no legal requirement to do this, but since the video may be used as evidence in court, it is helpful to the court to know that the child was made aware of the importance of telling the truth. This should be done in the rapport phase and not later in the interview because this might run the risk of the child concluding that the interviewer had not believed what they had said up to that point.

2.173 It is inadvisable to ask children to provide general definitions of what is the truth or a lie (a task that would tax an adult). Rather they should be asked to judge from examples. The interviewer should use examples suitable to the child's age, experience and understanding. Secondary school-age children can be asked to give examples of truthful statements and lies while younger children can be offered examples and be asked to say which are true and which are lies. It is important that the examples chosen really are lies not merely incorrect statements: lies must include an intent to deceive another person. An example of one approach is shown in Box 2.10. Different examples are suggested for different ages of children. If a child shows a proper appreciation of the difference between truth and lies, it is important to conclude by emphasising the importance of being truthful and as accurate as possible in everything they say in the interview. How this is put across will again vary with the age of the child.

2.174 If a child shows no appreciation of the distinction between truth and lies during this phase of the interview, consideration should be given to commissioning an expert assessment by a clinician of the child's abilities following consultation with the PPS if necessary. A lack of understanding of truth and lies by the child during the interview and any subsequent clinical assessment may seriously jeopardise the evidential value of the interview. (Understanding the difference between truth and lies should also form part of the preparation process by the young witness supporter and should follow the guidance set out above.)

Box 2.10 Exploring the difference between truth and lies

'Now [name], it is very important that you tell me the truth about things that have happened to you. So before we begin, I want to make sure you understand the difference between the truth and a lie.'

Example for younger children

'Let me tell you a story about John. John was playing with his ball in the kitchen and he hit the ball against the window. The window broke and John ran upstairs into his bedroom. John's mummy saw the broken window and asked John if he had broken the window. John said, 'No mummy.'

'Did John tell a lie or the truth, or don't you know?'

[Pause]

[Child responds]

'What should he have said?'

[Pause]

[Child responds]

Example for older children

'So, for example, Tony was having a smoke in his bedroom after his mum had told him not to. He heard his mum coming and hid the cigarette. His mum said 'Have you been smoking?' Tony said, 'No mum.'

'Did Tony tell a lie or the truth, or don't you know?'

[Pause]

[Child responds]

'What should he have said?'

[Pause]

[Child responds]

'Why do you think he said 'no mum'?'

[Pause]

[Child responds]

Adapted from A. Williams and S. Ridgeway (2000).

Explaining the outline of the interview

2.175 The interviewer should provide an explanation of the outline of the interview appropriate to the child's age and abilities. Typically the outline will take the form of the interviewer asking the child to give a free narrative account of what they remember and follow this with a few questions in order to clarify what has been said. It should also be explained that the interviewer might take a few brief notes.

Establishing the purpose of the interview

2.176 The reason for the interview needs to be explained in a way that makes the focus of the interview clear but does not specify the nature of the offence: to do so would be regarded as unnecessarily leading. Where a child has made an explicit complaint against a named individual, and especially when this has been repeated in a pre-interview assessment, it should be possible to raise the issue by referring to previous conversations. The law permits the interviewer to raise an earlier complaint by the child to a third party though the substance of the complaint should not be raised by the interviewer. It is also important to stress that what the interviewer wants to discuss with the child is their memory of the incident(s) which gave rise to the complaint not the complaint itself (i.e. what the child remembers about the incident not what they remember telling someone else). The situation is less straightforward where the child has made no previous complaint but where there are legitimate reasons for the interview (e.g. the results of medical examinations, allegations by a sibling or confessions by an alleged abuser).

2.177 The child should be given every opportunity to raise the issue spontaneously with the minimum of prompting (see Box 2.11 for examples of acceptable prompts). Where such prompts fail, the interviewer can initiate discussion of the particular groups from which they are drawn (home, school, etc.). If this too is unsuccessful then the interviewer can consider asking which persons among a given group the child likes or dislikes and their reasons. Again, on no account must the explicit allegation be raised directly with the child because this might jeopardise any legal proceedings and could lead to a false allegation.

Box 2.11 Raising issues of concern

'Tell me why you are here today.'

[If no response]

'If there is something troubling you, it is important for me to understand.'

[If no response]

'I heard you said something to your teacher/friend/mummy last week. Tell me what you talked about.'

[If no previous allegation]

'I heard that something may have been bothering you. Tell me everything you can about that.'

[If no response]

'As I told you, my job is to talk to children about things which may be troubling them. It is very important I understand what may be troubling you. Tell me why you think [carer] has brought you here today.'

[If no response]

'I heard that someone may have done something that wasn't right. Tell me everything you know about that. Everything you can remember.'

(Adapted from the NICHD Protocol for Investigative Interviews of Alleged Sex-abuse Victims by M.E. Lamb, K.J. Sternberg, P.W. Esplin, I. Hershkowitz and Y. Orbach (unpublished manuscript, NICHD, Maryland, 1999).

Phase two: initiating and supporting a free narrative account

2.178 If it is deemed appropriate, having established rapport, to continue with the interview, the child should be asked to provide in their own words an account of the relevant event(s). The free narrative phase is the core of the interview and the most reliable source of accurate information. During this phase, the interviewer's role is that of a facilitator not an interrogator. Every effort should be made to get information from the child that is spontaneous and free from the interviewer's influence.

2.179 The aim of the free narrative phase is to secure a full and comprehensive account from the child of the alleged incident in the child's own words. The child should not at this stage be interrupted to ask for additional details or to clarify ambiguities: this can be done in the questioning phase. The free narrative phase should never be curtailed by jumping into questions too soon. Instead, the interviewer should adopt a posture of 'active listening': letting the child know that what they are saying has been heard by the interviewer. The interviewer can offer prompts and

encouragement if the child's account falters. The use of affirmative responses 'ah huh' and 'OK', and head nods helps to maintain the child's account. Interviewers should be careful to ensure that affirmative responses are provided throughout the interview and do not relate solely to those sections of the interview dealing with allegations. Reflecting back what the child has just said also assists in eliciting more information (e.g. Child: 'so we went round to his house…' [pause] Interviewer: 'I see, so you went round to his house…'). Such prompts should relate only to the child's account and should not include relevant information not so far provided by the child. Children vary in their speed of delivery and the child, not the interviewer, should dictate the pace of the interview.

2.180 In many interviews, particularly those relating to allegations of child sexual abuse, children may be reluctant to talk openly and freely about incidents. Sometimes this can be overcome simply by the interviewer offering reassurance, for example: 'I know this must be difficult for you. Is there anything I can do to make it easier?'. It is quite in order for the interviewer to refer to a child by their first or preferred name but the use of terms of endearment ('dear', 'sweetheart'), verbal reinforcement (telling the child they are 'doing really well') and physical contact between the interviewer and the child (hugging, holding a hand) are inappropriate. However, this should not preclude physical reassurance being offered by an interview supporter to a distressed child. Another cause of reticence could be that the child has been taught that the use of certain terms is 'rude' or otherwise improper. If the interviewer believes this to be a problem, they can tell the child: 'Perhaps you have been taught that you shouldn't say certain words. Don't worry, in this room you can use what words you like. We have heard all of these words before. It's all right to use them here.' The interviewer should not assume that, when the child uses a sexual term, they attach the same meaning to it as the interviewer. Any ambiguities can be clarified in the questioning phase.

2.181 Some children provide greater amounts of information more spontaneously than others. In general, developmentally younger children provide less free narrative than older children. This should not prevent the interviewer doing as much as possible to elicit a clear and full account from such children: bear in mind that research has consistently demonstrated that young children's accounts are the most likely to be tainted through inappropriate questioning. Pauses and silences may be tolerated by the interviewer but need careful handling where a child has been traumatised. Too long a silence can be oppressive and conversational pace can be lost. Tolerance should also be extended to what might appear irrelevant or repetitious information. Prompting is quite in order provided it is neutral ('and then what happened?') and does not imply positive evaluation ('right', 'good'). The interviewer needs also to be aware of the danger of intentionally or unintentionally communicating approval or disapproval through inflexions of the voice or facial expressions.

2.182 Sometimes reticence can reflect the fact that an abuser has told the child that what has occurred is a secret between them, or has made physical threats against the child or their loved ones. Where this is suspected, an appeal to the child's wish to stop the abuse is often effective. The child can be asked directly whether they have been asked to keep a secret. If the child gives a positive indication, it is in order to say: 'So, you've been told to keep a secret. Tell me what would happen if you told me this secret.' The interviewer can then address or debunk the threat, stressing that: 'We need to know what the secret is so that we can try to help you.' Sometimes children will be happier communicating secret information through indirect means such as using a toy telephone or writing down information on a piece of paper. If such methods are used, it is important that the interviewer refers to such devices on the recording, and that any written material is properly preserved and documented.

2.183 If the child has said nothing at all relevant to the alleged offences, the interviewer should consider, in the light of the plans made for the interview and in consultation with the second interviewer, if present, whether to proceed with the next phase of the interview. Nothing untoward may have happened to the child, or the child may be unwilling or reluctant to speak about these events at this time. The needs of the child and of justice should both be considered. It may be necessary and proper to proceed to the closure phase if nothing of significance has emerged from free narrative or if a satisfactory, verifiable explanation has emerged for the original cause for concern.

Phase three: questioning

Prior to the questioning phase of the interview

2.184 Prior to entering the questioning phase of the interview, it may be beneficial to reiterate some of the ground rules noted at the start of the interview. This is especially the case if the child has given a long free narrative account and/or there has been a break in the interview. In particular, consideration should be given to stating explicitly that:

- the interviewer was not present when the events under investigation allegedly took place and that, therefore, they are relying on the child's account;
- if the interviewer asks a question that the child does not understand, the child should feel free to say so;
- if the interviewer asks a question that to which the child does not know the answer, the child should say, 'I don't know'; and
- if the interviewer misunderstands what the child has said or summarises incorrectly what has been said, the child should point this out.

Style of questions

2.185 Children vary in how much relevant information they provide in free narrative. However, in nearly all cases it will be necessary to expand on the child's initial account through questions. It is important that the interviewer asks only one question at a time and allows the child sufficient time to complete their answer before asking a further question. Patience is always required when asking questions particularly with developmentally younger children who will need time to respond. Do not be tempted to fill pauses by asking additional questions or making irrelevant comments. Sometimes silence is the best cue for eliciting further information. However, it can also be oppressive and care needs to be taken in the use of this technique. It is important also that the interviewer does not interrupt the child when they are still speaking. Interrupting the child may disempower them and also suggests that only short answers are required.

2.186 There are different types of question which vary in the amount of information they are likely to provide and their susceptibility to produce inaccurate responses from children. The most important types are:

- open-ended;
- specific-closed;
- forced-choice; and
- leading questions.

Content of questions

2.187 Questions should be kept as short and simple in construction as possible. Each question should contain only one point (see Chapter 4 for more information about multiple questions). The younger the child, the shorter and more simply phrased the question should be. Interviewers should avoid complex questions with witnesses of all ages such as those involving double negatives ('Did John not say later that he had not meant to hurt you?') and double questions ('Did you go next door and was Jim waiting for you?'). It is also important that questions do not involve vocabulary with which the child is unfamiliar. Very young children, for instance, have particular problems with words denoting location ('behind', 'in front of', 'beneath' and 'above') and, in the event of ambiguity, it may be necessary to ask the child to demonstrate what they mean. Merely asking a child whether they understand a given word is insufficient as they may be familiar with a word but still not understand its real meaning (for instance, they may think of 'the defendant' as someone who defends themselves against assault).

2.188 Vocabulary can be particularly important in dealing with allegations of sexual abuse where children may use terms that are personal to themselves or their families. Also, they may use terms like 'front bottom' which are vague and non-specific. It is always advisable for the interviewer to ensure that they understand what the child means. The use of a doll or diagrams is always preferable to children referring to their own bodies when reference needs to be made to the location of sexual acts. Where a young child uses the appropriate adult terminology, it may still be necessary to check their understanding.

2.189 The information requested in questions should always take account of the child's stage of development. Many concepts that are taken for granted in adult conversation are only acquired gradually as children develop. Therefore, questions that rely on the grasp of such concepts may produce misleading and unreliable responses from children which can damage the overall credibility of their statements in the interview. Concepts with which children have difficulty include:

- dates and times;
- length and frequency of events; and
- weight, height and age estimates.

2.190 Such concepts are only gradually mastered. For the concept of time, for instance, telling the time is learned by the average child at around seven years of age but an awareness of the days of the week and the seasons does not occur until at least a year later. Age norms are only a guide and it should be anticipated in the planning phase whether a particular child is likely to perform above or below such norms. There are a number of techniques for overcoming difficulties of measurement. Height, weight and age can be specified relative to another person known to the child (e.g. the interviewer or a member of the child's family). Time and date estimates can also be made by reference to markers in the child's life (e.g. festive seasons, holidays, birthday celebrations or their class at school). Time of day and the duration of events can sometimes be assisted by questions that refer to television programmes watched by the child, or to home or school routine.

2.191 When posing questions, the interviewer should try to make use of information that the child has already provided and words/concepts that the child is familiar with (e.g. for time, location, persons). Some children have difficulty understanding pronouns (e.g. he, she, they). In these circumstances, it is better for the interviewer to use people's names wherever possible.

Open-ended questions

2.192 An open-ended question is one that is worded in such a way as to enable the child to provide more information about an event in a way that is not leading, suggestive or putting them under pressure. Open-ended questions allow the witness to control the flow of information and minimise the risk that the interviewer will impose their view of what happened. The temptation for the interviewer of a child who has disclosed relevant information in the free narrative phase is for the interviewer to immediately ask a series of very focused or even leading questions to 'get to the heart of the matter'. This should be resisted: such a procedure may upset the child and risk producing misleading information, and may cause difficulties if the recording is played at court. Research and practice show that the most reliable and detailed answers from children of all ages are secured from open-ended questions. It is important, therefore, that the questioning phase should begin with open-ended questions and that this type of question should be widely employed throughout the interview.

2.193 Questions beginning with the phrases 'Tell me', or the words 'describe' or 'explain' are useful examples of this type of question. Examples of open-ended questions are: 'You said you were... Tell me everything that you remember.'

2.194 Open-ended questions can provide the child with the opportunity to expand on relevant issues raised in their free narrative account. Therefore, if the child has said that her stepfather had hit her once with a cricket bat, the interviewer might say: 'You said that he hit you with a bat. Can you tell me anything more about that?'. This type of question can be used to try to expand on any other salient or relevant parts of the child's narrative. There will be children who have said very little in the free narrative phase. Here, an open-ended question can still be asked to prompt any further information. If such open-ended questions cause the child to become distressed, it may be necessary for the interviewer to move away from the topic on to a neutral theme of the kind explored in the rapport phase and then to return to the topic again when the child has regained their composure.

2.195 It is rarely possible to use only open-ended questions with children. For instance, research suggests that children who have been threatened or sworn to secrecy about abuse may only respond to more specific questions. Even when children are prepared to provide information in response to open-ended prompts, further specific-closed questions may be necessary to obtain enough evidence to proffer detailed charges. Young children too may be unable to access material in memory through open-ended questions alone. Where it is necessary to ask more specific questions, it is advisable to follow them with an open-ended question to return the initiative to the child.

Specific-closed questions

2.196 A specific-closed question is a question that closes down a witness's response and, therefore, allows only a relatively narrow range of responses to be obtained where the response usually consists of one word or a short phrase. Closed questions can, therefore, be appropriate or inappropriate in nature depending on the quality of the information likely to be obtained from the witness. Specific-closed questions are appropriate and serve to ask in a non-suggestive way for extension or clarification of information previously supplied by the witness. Specific-closed questions vary in their degree of explicitness and it is always best to begin with the least explicit version of the question. For example, a child in a sexual abuse investigation may have responded to an open-ended prompt by mentioning that a named man had climbed into her bed. A specific-closed but non-leading follow-up question might be: 'What was he wearing at the time?'. If this yielded no clear answer, a further, more explicit question might be: 'Was he wearing any clothes?'.

2.197 Examples of specific-closed questions are the questions that begin Who, What, Where, When, Why. 'Why' questions should be used with special care in abuse investigations as they may be interpreted by children as implying blame or guilt to them (e.g. 'Why didn't you tell anyone?'). Such 'why' questions can often usefully be replaced with 'what' questions ('What stopped you telling anyone?'). Specific-closed questions should not be repeated in the same form when the first answer is deemed unsatisfactory or incomplete. Children may interpret this as a criticism of their earlier response and sometimes change their response as a consequence perhaps to one that they believe is closer to the answer the interviewer wants to hear.

2.198 For some young witnesses, open-ended questions may not assist them in accessing their memories because their abilities to search their memory systematically are insufficiently developed. However, they may well respond accurately to specific-closed questions that target information they know. Therefore, a young child may provide little information to an open-ended prompt such as: 'Can you describe what he was wearing?' but respond readily to a specific-closed question such as: 'What did his clothes look like?'. Care must be taken in framing such questions in that the more focused and narrow the specific-closed question becomes, the more likely it is to provoke suggestive responding and may then be labelled leading.

2.199 If the child has alleged in their free narrative that they have been the victim of repeated abuse but have not described specific incidents in any or sufficient detail, specific-closed questions can be employed to try to clarify the point. In considering how best to assist the child to be more specific, the interviewer should bear in mind the difficulties children have in isolating events in time, especially when

the individual events follow a similar pattern. A good strategy in isolating such specific events is to enquire about whether there were any which were particularly memorable or exceptional. The questioner can then use this event as a label in asking questions about other incidents ('You told me that you had bruises on your leg after he hit you in Coleraine. Did you have any bruises after he hit you the second time?'). Alternatively, they can enquire about the first or last time an event occurred, or about events that occurred at atypical times or locations, because such incidents are likely to more accessible in memory. When questioning a child about repeated events, it is always better to ask all questions about one event before moving on to the next.

2.200 Another use of specific-closed questions is to explore whether the child is giving an account of an incident for the first time or whether they have told others beforehand. A classic pattern in abuse disclosures is for incidents to come to the attention of investigating agencies after the child has first confided in a trusted person typically a close friend, teacher or relative. This information is valuable in establishing the consistency of any statements made by the child and tracing the development of the allegation. Where a significant delay has occurred between an alleged incident and the child reporting it, the interviewer should take care in probing the reasons for this as such enquiries can be construed as blaming.

2.201 A closed-specific question may be seen to be inappropriate if it is asked too early in the interview (e.g. in the free narrative account phase) or it is asked when an open-ended question could have been asked instead.

Forced-choice questions

2.202 If a specific-closed question proves unproductive, it may be necessary as a last resort to ask a forced-choice or selection question. This type of question is one that poses fixed alternatives and the child is invited to choose between them (e.g. 'Were you in the bedroom or in the living room when this happened?'). The dangers of using such questions is that children respond with one or other choice without enlarging on their answer and that in the absence of a genuine memory, or if the correct alternative is missing, children tend to guess and pick an option given, rather than saying 'I don't know' or giving the correct (but missing) alternative. The latter may be countered by prefacing the question with a reminder to the child that 'don't know' is an acceptable response and that the interviewer does not know what happened. Alternatively, 'don't know' can be included as an option in the question ('Were you in the bedroom, the living room, or can't you remember?'). Forced-choice questions should never be used for probing central events in the child's account that are likely to be disputed at court as information obtained by such questions may be seen to have limited evidential value.

Leading questions

2.203 Put simply, a leading question is one which implies the answer or assumes facts that are likely to be in dispute. Whether a question is construed as leading will depend not only on the nature of the question but also on what the witness has already said in the interview. When a leading question is put improperly to a witness giving evidence at court, opposing counsel can make an objection before the witness replies. This, of course, is not possible during recorded interviews but it is likely that should the interview be submitted as evidence in court proceedings, portions might be edited out or, in the worst case, the whole recording may be ruled inadmissible (see Appendix F).

2.204 In addition to legal objections, research indicates that witnesses' responses to leading questions tend to be determined more by the manner of questioning than by valid remembering. Leading questions can serve not merely to influence the child's answer but may also significantly distort the child's memory in the direction implied by the leading question. For these reasons, leading questions should only be used as a last resort where all other questioning strategies have failed to elicit any kind of response. On occasions, a leading question can produce relevant information that has not been led by the question. If this does occur, the interviewer should take care not to follow up this question with further leading questions. Rather, they should revert to open-ended questions in the first instance or specific-closed questions.

2.205 A leading question that prompts a child into spontaneously providing information going beyond that implied by the question will normally be acceptable to the courts. However, unless there is absolutely no alternative, the interviewer should never be the first to suggest to the witness that a particular offence has been committed or that a particular person was responsible. Once such a step has been taken, it will extremely difficult to counter the argument that the interviewer 'put the idea into the witness's head' and that the account is, therefore, tainted.

2.206 Of course, there may be circumstances in the interview where the use of leading questions is unlikely to result in any legal challenge; for instance, during the rapport phase when a witness is being taken through their name and address, or is being asked for agreed factual information such as members of the family and their names. However, good interviewing practice should discourage leading questions with all but the youngest and most reticent witnesses. The use of leading questions in the rapport phase may inhibit the child from responding in their own words later in the interview and it is not always possible at the time to anticipate what facts might subsequently be in dispute. Moreover, the use of inappropriate leading questions may produce nonsensical or inconsistent replies which may damage the child's credibility as a witness.

Topic selection

2.207 Within the questioning phase of the interview, the interviewer should subdivide the witness's account into manageable topics or episodes, and seek elaboration on each area using open-ended and then specific-closed questions as outlined above. Each topic/episode should be systematically dealt with until the child is unable to provide any more information. Interviewers should try to avoid topic-hopping (i.e. rapidly moving from one topic to another and back again) as this is not helpful for the child's remembering processes and may confuse them.

2.208 Good questioning should also avoid the asking of a series of predetermined questions. Instead the sequence of questions should be adjusted according to the child's own retrieval processes. This is what 'witness-compatible questioning' means. Each individual will memorise information concerning the event in a unique way. Therefore, for maximum retrieval/information gain, the order of the questioning should resemble the structure of the child's knowledge of the event, and should not be based on the interviewer's notion or a set protocol. It is the interviewer's task to deduce how the relevant information is stored by the child (via the free narrative account) and to organise the order of questions accordingly.

Misleading statements

2.209 Children can on occasion provide misleading accounts of events but these are often the result of misunderstandings or misremembering rather than deliberate fabrication. The most common cause of such misunderstandings is the interviewer failing to ask appropriate types of question or reaching a premature conclusion that the interviewer then presses the child to confirm. Like adult witnesses, children can on occasion be misleading in their statements either by fabricating allegations or by omitting evidentially important information from their answers. Where inconsistencies in the child's account give rise to suspicion, the interviewer should explore these inconsistencies with the child after they have completed their basic account. Children should only be challenged directly over an inconsistency in exceptional circumstances and even then only when it is essential to do so. Rather, such inconsistencies should be presented in the context of puzzlement by the interviewer and the need to be quite clear what the child has said. On no account should the interviewer voice their suspicions to the child or call them a liar: there may be a perfectly innocuous explanation for any inconsistency.

2.210 In evaluating accounts, the interviewer should not rely on cues from the child's behaviour as guides to the reliability or otherwise of children's statements. Where a child uses language or knowledge, particularly of sexual matters, that is believed to be inappropriate for a child of that age, specific questions can be asked to try to locate the source of that knowledge. Likewise, if it is suspected that children alleging sexual abuse may have been exposed to sexually explicit films, videos, internet sites or magazines, specific questions can be employed to explore whether parts of the child's account could conceivably be derived from such sources. It is important that all such questions should be reserved for the end of the formal questioning so as not to disrupt the child's narrative.

Phase four: closing the interview

2.211 Every interview should have a closure phase. Closure should occur irrespective of whether an interview has been completed or been terminated prematurely. Closure can be brief but should normally involve the following features:

- check with the second interviewer, if present;
- summarise the evidentially important statements made by the child, as much as possible in the child's own words, having told the child to intervene if any of the summarising is incorrect;
- answer any questions from the child;
- thank the child for their time and effort;
- provide advice on seeking help and a contact number;
- return to rapport or neutral topics; and
- report the end-time of the interview.

2.212 The lead interviewer should first consult with the second interviewer, if present, as to whether there are any additional questions that need to be raised, or ambiguities or apparent contradictions that could usefully be resolved. Where the child has provided significant evidence, the lead interviewer should check with the child that they have correctly understood the important parts of the child's account. This should be done as much as possible using the child's own language and terms not as a summary provided by the interviewer in adult language. There is a danger that any summary may include statements or assumptions at variance with the child's account so it is useful if the child is reminded that they should correct any errors made by the interviewer. The opportunity should also be taken to check that the child has nothing further they wish to add. The interviewer should not "over summarise". Where summaries have been conducted appropriately throughout the interview, there is no need to provide a complete summary at the closing phase.

2.213 Where nothing of evidential value has emerged from the interview, it is important that the child should not be made to feel that they have failed or have somehow disappointed the interviewer.

2.214 In addition to any summary, the child should be thanked for taking part in the interview, and for the time and effort involved. They should also be asked if they have any questions which the interviewer can answer. Children frequently ask what will happen next. Answers and explanations should be appropriate to the age of the child. It is important that promises, which cannot be kept, should not be made. It is also good practice to offer a child (or, if more appropriate, the accompanying adult) a contact name and telephone number should the child subsequently wish to discuss any matters of concern with the interviewer.

2.215 Sometimes in the planning phase, plans have been made for the protection and safety of the child if, in the interview, the child expressed a view that they felt unsafe with a given person or in a particular place. Closure provides the opportunity to outline plans for the child's immediate safety especially if the child is concerned about going home and/or meeting a particular person.

2.216 The aim of closure should be that, as far as possible, the child should leave the interview in a positive frame of mind. In addition to the formal elements, it will be useful to revert to neutral topics discussed in the rapport phase to assist this. It is normal to complete a video recorded interview by stating the end-time.

Evaluation

2.217 Evaluation should take two primary forms:

- evaluation of the information obtained; and
- evaluation of the interviewer's performance.

Evaluation of the information obtained

2.218 After the interview has concluded, the interviewing team will need to make an objective assessment as to the information obtained and evaluate this in light of the whole case. Are there any further actions and/or enquires required? What direction should the case take?

Evaluation of interviewer's performance

2.219 The interviewer's skills should be evaluated. This can take the form of self-evaluation with the interviewer examining the interview for areas of good performance and poor performance. This should result in a development plan. The interview could also be assessed by a supervisor and/or someone who is qualified to examine the interview and give good constructive feedback to the interviewer highlighting areas for improvement. This should form part of a staff appraisal system (see tier 4 of ACPO's National Investigative Interviewing Strategy (ACPO, 2009)).

Post-interview documentation and storage of recordings

2.220 The interviewer should complete the relevant paperwork as soon as possible after the interview is completed including the Index to Video Recorded Interview referred to in Appendix G. A statement dealing with the preparation and conduct of the interview should be made while the events are still fresh in the interviewer's mind.

2.221 Recordings should be stored as recommended in Appendix H.

Further interviews

2.222 One of the key aims of video recording early investigative interviews is to reduce the number of times children need to provide their account. Good pre-interview planning will often ensure that all the salient points are covered within a single interview. However, even with an experienced interviewer and good planning, an additional interview may be necessary in some circumstances. These include where:

- children indicate to a third party that they have significant new information that was not disclosed at the initial interview but which they now wish to share with the interviewing team;
- the initial interview opens up new lines of enquiry or wider allegations that cannot be satisfactorily explored within the time available for the interview;
- in the preparation of their defence, the defendant raises matters not covered in the initial interview; or
- significant new information emerges from other witnesses or sources.

2.223 In such circumstances, a supplementary interview may be necessary and this too should be video recorded. Consideration should always be given as to whether holding such an interview would be in the child's interests. Supplementary interviews should not be conducted in an attempt to retrieve a situation in which the child's evidence is likely to have been compromised by the use of inappropriate techniques or questioning styles by the interviewer during a previous evidential interview. Supplementary interviews for evidential purposes should only be conducted by members of joint investigation teams when they are fully satisfied, if necessary after consultation with the PPS, that such an interview is necessary. The reasons for the decision should be fully recorded in writing.

Identification procedures

2.224 Where a video recorded interview has been conducted by virtue of this chapter, the production of facial composites using E-FIT (electronic facial identification) or other systems, or the production of an artist's impression should also be video recorded. This will enable the court to hear the evidence from the child in the same medium as the main evidence in chief and show how any new evidence has come about, giving confidence to the evidence gathering process and reducing the need for the child to give additional evidence in chief in the witness box or by live link. Staff carrying out these procedures should be suitably trained to interview and record the evidence in line with this guidance (see Appendix J).

Therapeutic help for the child

2.225 A child witness may be judged by the investigating team, and/or by those professionals responsible for the welfare of the child, to require therapeutic help prior to giving evidence in criminal proceedings. It is vital that professionals undertaking therapy with prospective child witnesses prior to a criminal trial follow the guidance in Chapter 7.

2.226 The PPS and those involved in the prosecution of an alleged offender do not have authority to prevent a child from receiving therapy and whether a child should receive therapy before the criminal trial is not a decision for the police or the PPS. However, the police and the PPS must be made aware that therapy is proposed, is being undertaken, or has been undertaken, so that consideration can be given to whether or not the provision of such therapy is likely to impact on the criminal case. At all times the importance of not coaching the child or rehearsing the child in matters of direct evidential value must be borne in mind by the professional undertaking therapeutic work with the child. (For further discussion of coaching see Appendix D.)

General guidance on using drawings, pictures, photographs, symbols, dolls, figures and props with children

2.227 Drawings, pictures, photographs, symbols, dolls, figures and props may be used for different reasons:

- to assess a child's language or understanding;
- to keep a child calm and settled, and in one place;
- to support a child's recall of events; and
- to enable a child to give an account of events.

2.228 It is these last two categories that the most controversy tends to arise. Young children and children with communication difficulties may be able to provide clearer accounts when drawings, pictures, photographs, symbols, dolls, figures and props are used compared with purely verbal approaches. For example, drawings or dolls may allow a child to clarify body parts or demonstrate an abusive act while props may help the child to describe the environment in which an incident took place.

2.229 Drawings or props can also enable children to demonstrate an understanding of truth and lies at a younger age than previously thought possible.

2.230 Drawings, pictures, photographs, symbols, dolls, figures and props can, therefore, function as very useful communication aids. However, when considering whether their use is appropriate in any given circumstances, interviewers need to be aware of the risks and pitfalls, as well as the advantages, associated with their use.

2.231 The risks and pitfalls of using drawings, pictures, photographs, symbols, dolls, figures and props include:

- potential challenge in the legal arena followed by admonitions not to use or cautionary statements;
- some props, e.g. anatomical dolls, can result in distortions or inaccuracies;
- some props, e.g. teddies, animals, dolls houses, may engender play or fantasy;
- children or carers may be upset by the use of explicit dolls or drawings; and
- children aged three and under are usually not able to use dolls, models or anatomical drawings as representational objects.

(Adapted from Hewitt 1999, Everson & Boat 2002, Faller 2007 and Lamb 2008.)

2.232 The advantages of using drawings, pictures, photographs, symbols, dolls, figures and props include:

- children may be more competent to demonstrate what happened rather than explain in words;
- allows two modes of communication so children can both show and tell;
- may mean detailed information can be collected with fewer questions;
- can provide retrieval cues or memory triggers;
- can overcome reluctance or fear, e.g. children who take 'don't tell' literally;
- may be less stressful for children to show than tell;
- may resolve concerns about false allegations; and
- may provide an organisational framework for children to give a fuller account.

2.233 Drawings, pictures, photographs, symbols, dolls, figures and props should be used with caution and never combined with leading questions.

2.234 Interviewers should try to ensure that the child's facial expressions, gestures and body language, as well as any drawings, pictures, photographs, symbols, dolls, figures and props, are visible to the interviewer and to the camera. This will require at least two cameras and an operator. The interviewer should pause if the child moves outside an agreed area to allow the camera operator time to re-focus on them.

2.235 Where necessary, verbal attention should be drawn to the child's unspoken communication. One way to do this is to comment to the child without offering an interpretation, e.g. 'you're pointing'.

2.236 Interviewers should make sure that drawings, pictures, photographs, symbols, dolls, figures and props do not prevent children gesturing[1]. It may be help to have a table at the appropriate height for the child to work at and place them on.

2.237 Any drawings, pictures, photographs, symbols, dolls, figures and props used should be preserved for production at court if required.

Using drawings

2.238 Interviewers may use the child's own drawings. Such drawings may be either produced live during the interview or prepared by the child prior to it.

2.239 Drawings can be used in different ways to help with communication and drawing has significant benefits[2]. Also, the symbolic nature of pictures and drawings is more easily understood by young children than dolls and models.

2.240 It may be useful to check whether the child can represent themselves symbolically[3] (e.g. by saying 'draw a picture of you' or 'draw [child's name]').

2.241 If possible, the child should label the drawings themselves. If they cannot, the interviewer should let them dictate the names of any people drawn to them and also write down any other features identified by the child.

2.242 It is important to think about the visibility of the drawings to both child and camera, for example colour, size and medium. It does not matter if a drawing is unrecognisable to the interviewer; the key issue is that the child recognises the drawing, and, if it is to be used to aid recall or communication, that the child assigns a stable identity to the drawing. Interviewers can check this by asking 'who's this?' and by making at least one deliberate identity error 'so this is x?'. Research suggests that asking children to draw what happened after an initial interview can help them to focus, retrieve more information and reduce their anxiety, and that 96% of children who draw in these circumstances recall more information in a second interview[4].

2.243 Human figure drawings can help children of all ages to provide clearer information about body parts but not necessarily about touch-related actions[5].

Using pictures, photographs and symbols

2.244 Pre-prepared pictures, photographs and/or symbols may be used if appropriate[6].

2.245 If the child has an existing communication system of pictures or symbols, it is important to explore any potential gaps in their vocabulary during a pre-interview assessment. Introducing new vocabulary prior to interview must be carefully done and can create difficulties but may be unavoidable[7].

Using dolls, figures and props

2.246 The use of items similar to those involved in the to-be-remembered event may assist recollection. However, they may also cause the child distress. Furthermore, it may not be certain which items were actually involved, and the introduction of incorrect items may mislead and/or confuse the child. Similarly, models or toy items may be misleading and confusing if the objects they represent were not, in fact, part of the event. Some children may not realise the link between a toy or model and the real-life object it is supposed to represent; this is particularly so for very young children and learning disabled children.

2.247 Where anatomically accurate dolls are to be used, it is particularly important that the interviewer is trained in their use and understands how they might be misused: a combination of these dolls and leading questions can elicit misleading statements from children. Children's interactions with such dolls alone are unlikely to produce evidence that could be used in criminal proceedings. In the main, anatomically accurate dolls should only be used as an adjunct to the interview to allow the child to demonstrate the meaning of terms used by them or to clarify verbal statements. Anatomically accurate dolls can be used very effectively to clarify body parts, position of bodies and so on as can conventional dolls. However, they should only be used following verbal disclosure of a criminal offence by the child or where there is a very high suspicion that an offence has been committed which the child is unable to put into words.

1 Gesture allows children to articulate information they cannot yet put into words. Gesture helps us plan what we are going to say and find the words to say it. Even adults pause more if not allowed to gesture – fluency is affected. Doherty-Sneddon 2003.

2 No speech required, immediate, easy to apply and check, tells you more than speech because unanticipated and unpractised. Unlike speech, drawing forces people to take a position (Vrij 2009).

3 Representation of self emerges between the age of 3:2 and 3:6 in white middle class children (DeLoache et al 1995).

4 'Draw me what happened' looked at the effects of event drawing on children's accounts of sexual abuse. 125 children aged 4-14 in real NICHD protocol interviews. Looked at the impact of using drawing to prompt a second retrieval. Blind trial: interviewers opened the envelope with the condition (drawing or no drawing) only after first interview completed. Children instructed to draw 'what happened' for seven minutes, children in the control group had a seven minute break. Both sets of children then re-interviewed using open ended questions, interviewers were instructed to ignore the drawing and focus only on the child's verbal account. (Katz and Hershkowitz 2009).

5 The usefulness of human figure diagrams in clarifying accounts of touch. 88 children aged 4-13 interviewed within NICHD protocol then asked a series of questions using unclothed gender neutral outline diagrams of human body (Yang et all 2009).

6 Symbols for abusive acts, feelings and private body parts are available without charge at www.howitis.org.uk. Some of these are now incorporated into generic symbol sets, e.g. see www.widgit.com

7 The Intermediary Procedural Manual (Office for Criminal Justice Reform 2011) gives guidance on how to teach new vocabulary and who should be involved (Section 5, page 35).

Special interviewing techniques

The cognitive interview (CI)

2.248 This interviewing procedure was developed by cognitive psychologists and it contains, as well as procedures based on good communication skills (many of which have been described above), a number of procedures specifically designed to assist witnesses access their memories. These procedures are usually referred to as:

- mental reinstatement of context;
- report everything;
- change the temporal order of recall; and
- change perspective.

2.249 A number of professionals who have worked with children recommend use of the cognitive interview (CI) though it is not advised for children below a developmental age of seven. In addition, research has found that unless the training of interviewers who attempt to use the CI has been appropriate, they will fail to use this technique effectively and could confuse the witness. Some witnesses may not be able to benefit from all of the CI procedures (e.g. young child witnesses and witnesses with autism may well not be able to 'change perspective' and, therefore, this component is not recommended). See Investigative Interviewing: Psychology and Practice by R. Milne and R. Bull (Wiley, 1999) for more detailed information.

2.250 Interviewers, and their senior managers, need to be aware that techniques that assist witnesses to produce more recall will result in interviews that last longer. Surveys of those who use the CI have found that they often report it to be effective. However, their workloads and their supervisors put them under pressure not to conduct interviews that are time consuming. Such pressures should be resisted for interviews with children.

2.251 Further information on the techniques that make up the CI can be found in Chapter 4 Part B of this guidance.

Other interviewing techniques

2.252 There are a number of specialised interview techniques that have been developed for interviewing children and these may be acceptable to the courts as an alternative to the method recommended in this guidance, if evidential considerations are borne in mind and the child's well-being is safeguarded. Provided the interviewer avoids suggestive questions and succeeds in eliciting a spontaneous account of the substance of the allegation, there is no reason why such evidence should not be acceptable to the courts. The investigative team should discuss with senior managers or an interview adviser (tier 5 of ACPO's National Investigative Interviewing Strategy (ACPO, 2009)) and, if necessary, consult with the PPS before undertaking these alternative procedures. It is essential that the interviewers involved are specially trained in techniques concerned. Each procedure is described only briefly and further information can be obtained by consulting the relevant sources (see Appendix T).

2.253 Among these specialised interviewing techniques are those for children who are particularly reticent or who may be under duress not to divulge information relevant to the investigation and who, therefore, may not respond to conventional questioning. In the facilitative interview, children are asked about pleasant and unpleasant experiences, 'okay' and 'not okay' actions, what the child would like to change in their life, and there may be an open-ended discussion about secrets. In the systematic approach to gathering evidence (SAGE) interview, the child is encouraged over a number of separate sessions to talk about significant persons and places in the child's life, and their attitude toward them. Systematic comparison of the child's responses enables the trained interviewer to identify areas of particular concern which can then be explored more thoroughly using open-ended questions (see A Guide to Interviewing Children: Essential Skills for Counsellors, Police, Lawyers and Social Workers by C. Wilson and M. Powell (Routledge, 2001), for more detailed information).

2.254 The structured investigative protocol is a variant on the phased approach to the interview recommended in this guidance. This has been developed by the National Institute of Child Health and Human Development (NICHD) as a result of concern over insufficient use of open-ended questions by practitioners. Interviewers use a learned series of open-ended prompts rather than following their own pattern of questioning to elaborate on the child's initial free narrative account (see The NICHD Protocol for Investigative Interviews of Alleged Sex-abuse Victims by M.E. Lamb et al (unpublished manuscript, 1999) and Using a Scripted Protocol in Investigative Interviews: A Pilot Study by J.K. Sternberg and M.E. Lamb in Applied Developmental Science (1999) for more detailed information).

2.255 Statement validity assessment (SVA) is a technique widely used in Germany, Canada and the USA to interview and assess the statements of children in sexual abuse investigations. It shares with this guidance an emphasis on obtaining a free narrative linked to open-ended questioning. A key feature of SVA is criteria-based content analysis (CBCA) where a child's statement is examined for the presence of certain features which are believed to characterise truthful accounts. The technique relies on an extended narrative being available for analysis and so it is inappropriate for witnesses who provide only limited narratives, such as the very young, children with communication difficulties or depressed children. A number of issues concerning the reliability and validity of CBCA and its use in criminal proceedings in England and Wales are as yet unresolved (see Detecting Lies and Deceit: The Psychology of Lying and its Implications for Professional Practice by A. Vrij (Wiley, 2000) for more detailed information).

Interviewing children with disabilities

Planning and preparation

2.256 The phrase 'children with disabilities' encompasses a wide range of abilities and disabilities. Interviewers need to be aware of the extensive differences between potential witnesses in their social, emotional and cognitive development, and in their communication skills, the degree of their understanding and in their particular needs. It will nearly always be necessary to seek specialist advice on what special procedures are appropriate and to consider if the services of an intermediary are required.

2.257 There is rarely any reason in principle why children with disabilities should not take part in a video recorded interview, provided the interview is tailored to the particular needs and circumstances of the child. This will require additional planning and preparation by the interviewing team, and a degree of flexibility in scheduling the interview. Particular attention will need to be taken to ensure that a safe and accessible environment is created for the child, and that the interview suite is adapted to the child's particular needs. Children with disabilities are likely to have already come to the attention of professionals, as a result of which, information is likely to be available from existing assessments and from workers who know the child well. Such information should enable the interviewing team to make an assessment of the likely impact, if any, of a disability on communication. Where children have specific communication difficulties, aids such as drawings or photographs may need to be prepared to facilitate questioning. All such aids should be preserved for possible production at court.

2.258 It is important to find out what impact the child's disability is likely to have on the communication process and to adopt a positive approach that focuses on the child's abilities when trying to find out how they can be helped to communicate.

2.259 The impact of any medication being taken by the child on the interview, including the most appropriate timing for it, should be taken into account.

2.260 For some children, a number of shorter sessions may be preferable to a single interview. For example, children with learning disabilities may have shorter attention spans giving rise to a need for regular and frequent breaks. In addition to this, some children with physical or learning disabilities might find communicating to be quite demanding, and this may also heighten the need for breaks and a slow pace, therefore lengthening the duration of the interview(s).

2.261 Children with learning disabilities may adapt more slowly to unusual situations than their peers. It may, therefore, be likely that more time may be needed to prepare the child for the interview and extra time might be needed for the rapport phase.

2.262 Children with learning disabilities may be easily distracted. Interview rooms should, therefore, be organised so as to minimise the opportunity for distraction.

2.263 The possibility that children with learning disabilities may have difficulty with time concepts should be taken into account while planning the interview.

2.264 The procedures that make up the cognitive interview can be used in respect of children with mild learning disabilities over the age of seven although the change perspective technique is not recommended.

The interview

Phase one: rapport

2.265 It is important that adequate time is allowed for this phase. Establishing rapport between the interviewer and the child will in itself require more time and attention especially if an intermediary is needed to assist communication. There are also additional functions of the rapport phase for children with disabilities. These are to:

- relax the interviewer;
- educate the viewer of the video about the child and their disabilities;
- dispel common myths and prejudices (e.g. physical impairments affect a child's intelligence); and
- allow the child to demonstrate communication and understanding.

2.266 It is important for the child to sense the importance of communicating clearly, and for the interviewer to develop as much skill as possible in talking with and understanding the child. Any difficulty that the interviewer or the interview monitor has in understanding the child's account at the time is likely to be magnified for any person subsequently viewing the video recording. The interviewer needs to be comfortable about referring to this and asking the child to repeat, rephrase or clarify as necessary, and the interview monitor needs to ensure that the recording can demonstrate the child's communication method.

2.267 The child needs to be given an opportunity to explain their world especially where this might be unusual and relevant for the interview (e.g. if the child stays away from their family, if there are different adults involved with their care at home or elsewhere, or if the child needs intimate care or other 'unusual' help in day-to-day life). It is important to establish the context at this stage to give meaning to what may follow as it is often harder to do so later. If, for example, a child with disabilities has a number of adults involved in their care, it will be important to demonstrate their ability to distinguish reliably between these different people. Alternatively, if a child needs very invasive care procedures (e.g. intermittent catheterisation), it will be helpful to establish the child's comprehension of this as a process before any discussion of possible sexual abuse ensues.

2.268 The experience of some children with disabilities might make them more compliant and eager to please, or to see themselves as devalued. Some children with learning disabilities could have problems understanding the concept of truth and interpreted communication may lead to additional confusion. Some children may need explicit permission to refute adult suggestions. Even with this permission, some children may find this impossible to do. It can help if everyone in the room makes a commitment to tell the truth (including the interviewer and any additional adults). It is important to convey that the child and the interviewer, and any additional adults (including the intermediary), should say 'I don't know', 'I don't know how to say that' (where the child's understanding has sufficiently developed), or 'I don't understand', and not to guess if they are unsure.

2.269 Children with disabilities might need very explicit permission to request breaks, and a clear, simple sign, gesture or word with which to do so. Given the concentration required by all parties, it is important to establish that the adults can request breaks as well as the child.

Phase two: free narrative account

2.270 Communication impairments do not necessarily prevent a child from giving a spontaneous account. Exceptions to this include when a child is:

- relying heavily on yes/no signalling;
- using a communication board with a vocabulary that makes it difficult to discuss certain topics; or
- where a child has not reached the developmental stage of being able to tell a story.

2.271 In these circumstances, the services of an intermediary should be secured to assist communication.

2.272 Children with learning disabilities are capable of providing accurate free narrative accounts although such accounts are likely to be less complete than those provided by their peers. While some omissions are likely to be the result of the child remembering less, some will probably be due to an assumption by the child that the interviewer already knows about the alleged event. It might, therefore, be advisable to repeat that the interviewer was not present and to reiterate the need for the child to report as much as they can remember at a number of points in the interview including the free narrative phase.

2.273 Children with learning disabilities may often require a greater degree of facilitation before it is clear whether an offence has occurred and, if so, what form it took. Open-ended prompts should be used as far as possible. Reflecting back to the child in an open, non-directive manner what they have told the interviewer helps to ensure accuracy as well as facilitating the production of further details.

Phase three: questioning

2.274 A clear and informed plan for questioning is essential to ensure that a child with disabilities is not expected to respond to questions they cannot answer or questions that are inherently confusing. This is important not just in terms of the child's emotional welfare but also in order to avoid undermining the child's credibility. For example:

- children with disabilities might be dependent on others for intimate care (interviewers will need to be able to distinguish between necessary caring or medical procedures and abusive or criminal actions);
- children may be receiving orthopaedic treatment or using postural management equipment that might cause pain or discomfort but should never cause injury;

- a child's condition may restrict the positions they can get into or be placed into and some positions might in themselves be dangerous;
- certain physical or neurological conditions are likely to affect the sensations a child can feel; or
- a child with a sensory impairment may be restricted in some of the information they can provide about the identity of the alleged suspect or details of the alleged offence(s).

2.275 Questions should be simple and concrete. The use of abstract concepts, double negatives and other inappropriate questions should be avoided.

2.276 With some methods of communication, such as communication boards, questions can only be asked in a closed form which demands a yes or no response. Techniques that can increase the evidential validity of closed questions include:

- avoiding a series of 'yes' responses by suggesting less likely alternatives first;
- completing any series of related questions rather than halting at the first 'yes'; and
- reverting to open questions wherever possible.

2.277 When offering the child a range of alternatives, consistent wording is needed for each, particularly if the child has a learning disability or poor short-term memory.

Phase four: closing the interview

2.278 Given the relative lack of knowledge of investigative interviewing of children with disabilities, it would helpful for developing practice to obtain feedback from the child on their experience of the interview, and perhaps also to acknowledge again additional barriers to communication that discussion of sensitive issues such as abuse can provide. As long as there is no discussion of the evidence itself, such debriefing need not take place on camera though a note should be kept of the points raised.

2.279 For children who have been sexually exploited, it is particularly important to maintain contact post-interview as they will often find themselves still at risk of further exploitation. For this group of children, it is vital that police officers and social workers honour any commitments that are made as these children find it very difficult to trust professionals and a 'window of opportunity' can be easily lost. Delay can have a very negative impact on these cases and it is vital that there is good ongoing communication with the victim.

Interviewing very young or psychologically disturbed children

2.280 When a child is very young or known to be psychologically disturbed, the planning phase for the interview needs to be undertaken with great care. Consideration should be given to the use of an intermediary in the planning process and during such interviews.

2.281 Thought should be given to the venue for the interview. Young children may find the unfamiliar surroundings of an interview suite intimidating. Adequate time should be allowed for rapport, and age-appropriate toys and colouring materials should be provided to settle the child. Consideration should be given to seeking specialist advice or bringing in an interviewer with particular skills and experience in the area. It may not be possible to conduct a conventional interview: such children may say very little in the free narrative phase and not respond well to open-ended questions. However, the use of purely focused questions carries with it the risk that the child will say what they believe the interviewer wants to hear. Such risks are further increased through the use of leading questions. Children of this age often lack social experience and do not feel at ease with strangers. This may require interviewers to seek support from an independent adult known to the child.

2.282 One response to these difficulties may be to make a decision to distribute the interview over a number of short sessions, conducted by the same interviewer, and spread over a number of days. When this occurs, care must be taken to avoid repetition of the same focused questions over time, which could lead to unreliable or inconsistent responding in some children and interviews being ruled inadmissible by the court. Rapport and closure should be included in each session.

The child who becomes a suspect

2.283 It may happen that a child who is being interviewed comes under suspicion of involvement in a criminal offence perhaps by uttering a self-incriminating statement. Although this is not a frequent occurrence, interviewers should bear in mind that victims and witnesses could also on occasion be perpetrators.

2.284 If it is concluded that the evidence of the child as a suspect is also highly relevant to a particular case, the interview should be terminated and the child told that it is possible that they may be interviewed concerning these matters at a later time. Care should be taken not to close the interview abruptly in these circumstances. Instead, the child should be allowed to complete any statement they wish to make. Any admission by a child in the course of an investigative interview may not be admissible as evidence in criminal procedures. Normally, a further interview would

need to be carried out in accordance with the relevant provisions of the Code for the Detention, Treatment and Questioning of Persons by Police Officers (Police and Criminal Evidence (NI) Order 1989, Code C)). The Code provides, among other matters, for the cautioning of a suspect and for the presence of an appropriate adult during questioning.

2.285 A child who confesses to a criminal offence during the course of an interview may ask the interviewer for some guarantee of immunity. On no account should any such guarantee be given to a child over the age of criminal responsibility (10 years), however remote the prospect of criminal proceedings against the child might seem. Nor should the interviewer give any kind of undertaking regarding the child's future care arrangements. If the child is to be interviewed in accordance with Code C, they will be cautioned and the purpose of the interview made clear.

2.286 Where the priority is to obtain evidence from the child as a victim or a witness, the interview can proceed and should follow this guidance. So far as is practicable, consideration should be given in the planning phase as to how interviewers will deal with any confessions of criminal offences made by the child in the course of the interview. Any decision on an appropriate course of action will involve taking into account the seriousness of the crime admitted and weighing it against the seriousness of the crime perpetrated against the witness. It is preferable to anticipate and plan for such an eventuality while recognising that any decisions on a particular course of action are likely to depend on what has been disclosed by the witness during the course of the interview.

3 Planning and conducting interviews with vulnerable adult witnesses

Part 3A: Planning and preparing for interviews

What follows is a recommended procedure for planning and preparing for interviews with the witnesses referred to in this chapter. Part 3B covers the interview itself and treats the interview as a process in which a variety of interviewing techniques are deployed in the framework of a phased approach. While what follows in this chapter should not be regarded as a checklist to be rigidly worked through, the sound framework that it provides should not be departed from by interviewers unless they have discussed and agreed the reasons for doing so with their senior manager or an interview advisor (tier 5 of the Association of Chief Police Officers' National Investigative Interviewing Strategy, ACPO 2009). Any such agreements and the rationale underpinning them should be recorded. It may subsequently be necessary to explain such departures at court.

While this chapter deals specifically with the interviewing of vulnerable adult witnesses, it should not be read and used in isolation from Chapters 2 and 4. This guidance has been written so that Chapters 2 - 4 form a complementary whole. For example, issues in relation to disability and intimidation will have an application across all vulnerable witnesses. Approaches that work well with children may work equally well with adults with learning disabilities and vice versa.

In preparing for interview, investigating officers must take note of the paragraph on gathering physical evidence in Chapter 1.

The importance of planning

3.1 The purpose of an investigative interview is to ascertain the witness's account of the alleged event(s) and any other information that would assist the investigation. A well-conducted interview will only occur if appropriate planning has taken place. The importance of planning cannot be overstated. The success of an interview and, therefore, an investigation could hinge on it. Even if the circumstances necessitate an early interview, an appropriate planning session that takes account of all the information available about the witness at the time, and identifies the key issues and objectives is required. Time spent anticipating and covering issues early in the criminal investigation will be rewarded with an improved interview later on. It is important that, as far as possible, the case is thoroughly reviewed before an interview is embarked upon to ensure that all issues are covered and key questions asked since the opportunity to do this will in most cases be lost once the interview(s) have been concluded.

3.2 Although the Public Prosecution Service (PPS) is not part of the investigating team and does not direct the investigation, an early meeting between the police and PPS to discuss special measures may be appropriate. The police may also seek advice from the PPS at an early stage about any other evidential issues that may affect the way in which the investigation is conducted. In some exceptional cases, the PPS may select suitably qualified counsel to advise from a very early stage.

3.3 In some cases, it may useful to obtain the assistance of an interview adviser to develop a witness interview strategy (see National Investigative Interviewing Strategy, Association of Chief Police Officers 2009).

Initial contact with vulnerable victims and witnesses

3.4 The need to consider a video-recorded interview will not always be immediately apparent either to the first police officer who has contact with the witness or to other professionals involved prior to the police being informed. Even where it is apparent, the need to take immediate action in terms of securing medical attention and making initial decisions about the criminal investigation plan might be such that some initial questioning is necessary.

3.5 Any initial questioning should be intended to elicit a brief account of what is alleged to have taken place. A more detailed account should not be pursued at this stage but should be left until the formal interview takes place. Such a brief account should include where and when the alleged incident took place, and who was involved or otherwise present. This is because this information is likely to influence decisions made in respect of the following aspects of the criminal investigation plan:

- forensic and medical examination of the victim;
- scene of crime examination;
- interviewing of other witnesses;
- arrest of alleged offender(s); and
- witness support.

3.6 In these circumstances, any early discussions with the witness should, as far as possible, adhere to the following basic principles:

- listen to the witness;
- do not stop a witness who is freely recalling significant events;
- where it is necessary to ask questions, they should, as far as possible in the circumstances, be open-ended or specific-closed rather than forced-choice, leading or multiple;
- ask no more questions than are necessary in the circumstances to take immediate action;
- make a comprehensive note of the discussion, taking care to record the timing, setting and people present as well as what was said by the witness and anybody else present (particularly the actual questions asked of the witness);
- make a note of the demeanour of the witness, and anything else that might be relevant to any subsequent formal interview or the wider investigation; and
- fully record any comments made by the witness or events that might be relevant to the legal process up to the time of the interview.

Competence, compellability and availability for cross-examination: the legal position

3.7 Competency may be an issue with some vulnerable witnesses. Article 31 of the Criminal Evidence (NI) 1999 Order (the 1999 Order) provides that in principle 'all persons are (whatever their age) competent to give evidence'. The Article qualifies this principle by saying that persons are incompetent as witnesses where the court finds that they are unable to understand questions put to them or unable to give answers to them which can be understood. However, Article 32(3) makes it clear that in considering this question a court must bear in mind the various special measures that are available under Articles 11 to 18 of the 1999 Order, as amended by the Justice Act (NI) 2011.

3.8 The defence, as well as the prosecution, may have an interest in having the witness declared competent. The party calling the witness is required to satisfy the court that, on a balance of probabilities, the witness is competent to give evidence in the proceedings. It is, therefore, important that the prosecution (or the defence) ensure that applications have been made for any special measures that will maximise the competence of the vulnerable witness.

3.9 In cases where competence requires definition, the court, following existing procedures, will also decide whether the witness is competent to take the oath. There may be occasions when the court will decide that a person may not be permitted to give evidence on oath in the proceedings. This will not, however, debar the witness from giving evidence. Where a conviction results from unsworn evidence, it is not in itself grounds for appeal. However, if the witness is deemed unable to take the oath, a test of competence to tell the truth should be considered.

3.10 Where a video recorded statement is to be played in court as evidence in chief, there is no need for the witness to be sworn. Article 33(2) and (3) of the 1999 Order expressly provide that such a video recorded statement, if admitted by the court as the evidence of the witness, shall have the same legal status as that witness's direct oral testimony in court even where, if giving direct oral testimony in court, the witness would have been required to take an oath.

3.11 Where a witness is competent to give evidence, they are usually also compellable. This means that they can be legally required to attend trial. In general, however, the fact that a witness is compellable does not mean that they can be legally required to give any kind of preliminary statement to the police even the sort of statement that is made under this guidance.

3.12 It does not necessarily follow that because a witness is competent and compellable the PPS will insist on making them attend court to give evidence if unwilling to do so. The PPS is not legally required to call every piece of evidence available and, in some cases, may proceed without a particular witness's evidence if they believe that they can secure a conviction without it. In cases where the PPS believes that the evidence of a particular witness is essential, the PPS may not proceed if they think that to do so would be particularly damaging to the witness. In deciding whether to include a particular witness's evidence, and whether to proceed with the case, the PPS will always take account of the wishes of the witness (although they will not necessarily defer to them). Police reports to the PPS should always include clear information about the wishes of the witness and, if appropriate their carers, about going to court. The PPS may in any event need to seek further information from the investigating team and should always be kept up-to-date throughout the case to ensure a continuous review.

3.13 A video recorded interview is usually only admissible as evidence in chief at trial where the person who made it is "available for cross-examination". However, there are exceptions to this general rule. The judge has discretion to allow the court to hear the pre-trial statements of witnesses who are unable to give evidence for various specified reasons. These include the fact that the witness is dead, "by reason of his bodily or mental condition unfit to attend as a witness" or does not give evidence at trial "through fear or because he or she is kept out of the way". It must be remembered, however, that the judge has the final word on whether or not the video recorded statement will be admitted.

Planning information

Overview

3.14 The planning phase of an interview with a witness involves some consideration of three types of information:

- information about the witness;
- information about the alleged offence(s); and
- information important to the investigation.

3.15 At this stage, interviewers need to have differing amounts of knowledge about each type of information. In a general sense, they need to know as much as is possible in the circumstances about the witness and a little about the alleged offence and information important to the investigation.

Definition

3.16 The statutory definition of a vulnerable adult witness is set out in Article 4 of the 1999 Order. Briefly, vulnerable adult witnesses are those who have a mental disorder, learning disability or physical disorder/disability that is likely to have an impact on the quality of their evidence.

3.17 It must be remembered that a physical disorder may include individuals with communication difficulties, which may not be attributable to a mental disorder, or learning or physical disability. Difficulties with speech, language and communication can also be hidden like problems with vision and hearing.

3.18 In addition to considering the provisions of the 1999 Order, as amended, it should be noted that the Disability Discrimination (NI) Order 2006 may apply to these vulnerable groups where discrimination occurs in respect of the services provided to them. Interviewers should also be aware of Articles 12 (Equal recognition before the law and legal capacity) and 13 (Access to justice) of the United Nations Convention on the Rights of Persons with Disabilities.

Preliminaries

Recognising vulnerable adult witnesses

3.19 Recognition of vulnerability may be particularly difficult when interviewing takes place at a police station shortly after an alleged offence due to the stress and immediacy of the action. The guidance provided here is in accord with the separate guidance to the police contained in Vulnerable and Intimidated Witnesses: A Police Service Guide (Ministry of Justice 2011), which can be consulted for additional information.

3.20 If a witness exhibits confusion, some initial clarification may be necessary to establish whether it could be due to:

- intoxication through intake of alcohol and/or drugs;
- withdrawal from drugs;
- mental disorder;
- impairment of intelligence and social functioning (learning disability);
- a physical disability or disorder (including a speech or communication disorder);
- incapacity through age;
- trauma; and/or
- fear or distress.

3.21 All of these factors may affect cognition and the ability to give a clear statement. Witnesses may be affected by more than one vulnerable condition, for example, a witness with a mental disorder may also be subjected to fear and distress. When in doubt, and where practicable, the police officer must consider an early assessment by an expert, such as a clinical psychologist, a speech and language therapist or a psychiatrist, to avoid compromising any evidence obtained during the interview.

Mental disorder

3.22 Mental disorder is legally defined in Article 3(1) of the Mental Health (NI) Order 1986 as mental illness, mental handicap, severe mental handicap, severe mental impairment, or any other disorder or disability of mind.

3.23 This may be the most difficult category to identify for support through special measures because of the fluctuating nature of many mental disorders. A person with such a disorder may need special assistance only at times of crisis.

3.24 A brief interview may not reveal mental disorder but if clear evidence and/or a clear diagnosis becomes available which suggests the need for special measures, then these should take account of any emotional difficulties so as to enable the witness to give evidence with the least possible distress.

3.25 Currently there is no accepted and consistent approach to the assessment of witness competence. It is likely that varying criteria may be used by experts called to make assessments.

3.26 In addition, mental instability might be aggravated by alcohol, drugs and withdrawal from drugs. The effect may be temporary and the time elapsed before a witness is able to give clear evidence will vary according to the type and severity of the intoxication from a few hours to a few days.

Significant impairment of intelligence and social functioning (learning disability)

3.27 Learning disability is not a description of one disability but a collection of many different factors that might affect a person's ability in relation to learning and social functioning to greatly varying degrees. While some 200 causes of learning disability have been identified, most diagnoses are still 'unspecified learning disabilities'. People with high support needs may be easily identified but those with mild or moderate learning disabilities may be more difficult to identify.

3.28 It is impossible to give a single description of competence in relation to any particular disability because there is such a wide range of abilities within each in terms of degree of intellectual and social impairment. However, there are some indicators that may help identify a witness with a learning disability.

3.29 A police officer or social care worker in the community may know the witness so an initial request should be made for any local information. If the witness is not known to the services, some early discussion/questioning by a specially trained member of the investigating team might be helpful in identifying possible disabilities. Relevant questions include:

- Where did the witness go to school?
  Was the school designated as a 'special school'?
- If the school was not designated as a 'special school' but was mainstream', did the witness have a designated support teacher?
  Does the witness have any reading or writing difficulties?
- What does the witness do during the day?
  Does the witness attend a college that makes particular provision for students with learning disabilities?
- Where does the witness spend their leisure time?
  At a day centre or Gateway Club?
- Where does the witness live?
  Is this a group home or sheltered housing?
- Does the witness have an adult social care social worker or care assistant?
  Would the witness like this person to be contacted for interview or pre-trial support? (This question is not appropriate where the social care worker or care assistant is suspected of having abused the person.)
- Does the witness receive any benefits relating to disability?

Behavioural indications of learning disability

3.30 These are indications only and by themselves do not necessarily indicate that the witness has a learning disability:

- a slow and/or confused response to questions;
- difficulty in understanding simple questions;
- speech difficulties;
- difficulty/inability with reading and writing;
- limited understanding of a wide range of concepts, for example:
  - time and place;
  - sequences (before, after, first, last, etc.);
  - spatial position (in, on, under, above, etc.);
  - relationships; and
- difficulty in remembering personal details or events.

3.31 Though generalisations cannot be made, some characteristics may exist in relation to some syndromes. For example, witnesses with autistic spectrum disorder, which includes Kanner's syndrome and Asperger's syndrome, have a range of abilities/disabilities but:

- they often have difficulty in making sense of the world and in understanding relationships;
- they are likely to have little understanding of the emotional pain or problems of others; and
- they may display great knowledge of certain topics and have an excellent vocabulary but could be pedantic and literal, and may have obsessional interests.

3.32 Some people with learning disabilities are reluctant to reveal that they have a disability and may be quite articulate. It is, therefore, not always immediately obvious that they do not understand the proceedings in whole or in part.

Physical disability

3.33 Recognition of this type of disability is less likely to be a problem although some disabilities may be hidden (for example, hearing, vision and communication disabilities) but it is important to be aware of whether or how a physical disability may affect the person's ability to give a clear statement. Most witnesses will be able to give evidence with support.

3.34 Some physical disabilities may require support. Hearing or speech difficulties may require the attendance of a skilled interpreter and/or speech and language therapist.

Speech, language and communication difficulties and disabilities

3.35 Speech, language and communication difficulties or disabilities will, like many physical disabilities, be fairly obvious at a first encounter with the witness. However, it is important to emphasise the degree to which speech, language and communication difficulties or disabilities can be hidden. As is often the case with impairment of vision and hearing, aspects of presentation may be missed, misinterpreted or mistaken for something else. People who struggle with communication may present the type of compliance or acquiescence highlighted further on in this chapter. Signs that a person may have communication needs might include:

- a loss of attention, getting restless, becoming agitated;
- seeming to agree often (nodding head);
- asking for clarification;
- seems to lack an understanding of word meanings;
- forgetting instructions;
- confused by non-literal language ('show me the ropes'), sarcasm or jokes;
- difficulty thinking of words;
- talks in short, choppy sentences;
- a limited vocabulary (lots of 'yes' and 'no', and no basic words);
- difficulty explaining or providing details;
- giving up easily when trying to explain something;
- talking a lot but saying very little (no substance to content);
- difficulty asking questions; and
- difficulty staying on topic.

3.36 This highlights why advice from, and assessment by, speech and language therapists can be so vital in the preparation for, and conduct of, an interview with a vulnerable witness.

Support for vulnerable adult witnesses prior to interview

Witnesses with a mental disorder

3.37 A mental disorder does not preclude the giving of reliable evidence. However, for many disorders there is a need to protect the witness from additional stress and provide support to enable them to give reliable evidence. The recall of traumatic events can cause significant distress, and recognition of the mental state of the witness and its effect on their behaviour is crucial. There is also the need to ensure that the type of behaviour is identified, as far as possible.

3.38 Witnesses with a mental disorder, such as schizophrenia or other delusional disorders, may give unreliable evidence through delusional memories or by reporting hallucinatory experiences, which are accurate as far as the witness is concerned but bear no relationship to reality (e.g. they might describe a nonexistent crime). Challenges to these abnormal ideas may cause extreme reactions and/or distress. Interviewers should probe these accounts carefully, sensitively and in a non-judgemental way with a view to identifying which elements of the account may be delusional and which elements might have a firmer foundation in reality.

3.39 Witnesses may suffer from various forms of anxiety through fear of authority, exposure or retribution. Extreme fear may result in phobias, panic attacks or unjustified fears of persecution. Anxious witnesses may wish to please, they may tell the interviewer what they believe they wish to hear or fabricate imaginary experiences to compensate for loss of memory. The evidence given by depressed witnesses may be influenced by feelings of guilt, helplessness or hopelessness. Witnesses with anti-social or borderline traits may present with a range of behaviours, such as deliberately giving false evidence. These disorders cause the most difficulties and contention in diagnosis, and require very careful assessment.

3.40 Witnesses, particularly some older witnesses, may also have dementia, which can cause cognitive impairment. A psycho geriatrician, psychiatrist, or clinical psychologist with experience of working with older people should be asked to assess their ability to give reliable evidence and the effect such a procedure might have on their health and mental welfare. For witnesses with dementia, it will be important to gather evidence as quickly as possible given the degenerative nature of the condition. Consideration should be given at an early stage to the use of video recorded evidence and all agencies should be alert to the negative impact of delay in such cases. Investigators and interviewers should also be aware that, although less prevalent, there are forms of dementia that can affect people under the age of 65 years. Particular care and preparation needs to be taken in relation to interviewing persons who have dementia. Specialist training and support, such as the advocates employed by the Alzheimer's Society, should be sought for interviewers working with persons with dementia.

3.41 Witnesses with a mental disorder may show some of the behaviour seen in witnesses with a learning disability, such as confusion, memory loss and impaired reasoning. For this reason, many of the interview practices that are likely to help witnesses with a learning disability may also benefit witnesses with a mental disorder. Properly preparing the witness for the interview may help to identify and reduce confusion, emotional distress and anxiety. Cognition may not be an immediate difficulty but attention to the way a statement is given and how questions are posed must always be considered.

3.42 The witness may wish to please the person in authority. They may be suspicious of the person, aggressive or wish to impress the interviewer. Interviewing teams should be aware of such possibilities. Consultation with people who know the witness well should give some indication of their likely behaviour and some suggestions as to how interviewers can best interact with the witness.

3.43 Confusion may be exacerbated by the use of drugs or alcohol, or withdrawal from drugs. An assessment should include information as to how this is likely to affect the interview and how long this effect is likely to last.

3.44 Preparation of the witness for the interview and a rapport phase prior to formal questioning during the interview is essential. This will allow the witness to have some familiarity with the personnel who will be involved in the interview, including the interviewer, interview monitor and intermediary (where used).

Witnesses with a significant impairment of intelligence and social functioning (learning disability)

3.45 Some witnesses with a learning disability may wish to please people in authority. Some may be suspicious of people, aggressive or may wish to impress the interviewer. Interviewing teams should be aware of such possibilities. Consultation with people who know the witness well should give some indication of their likely behaviour and some suggestions as to how interviewers can best interact with the witness.

3.46 Some witnesses with a learning disability may show confusion, memory loss and impaired reasoning. Properly preparing the witness for the interview may help to identify and reduce confusion, emotional distress and anxiety.

3.47 In some instances of mild and moderate learning disability, a difficulty with cognition may not be immediately apparent. The experience that many people with learning disabilities have of discrimination towards them in society is likely to act as an incentive to conceal or minimise their disability whenever possible. Where there are concerns that a witness has a learning disability, even if the extent of the disability is considered to be relatively mild, it is essential that a great deal of care is taken in framing questions and evaluating the witness's response to them.

3.48 Some witnesses with a learning disability communicate using a mixture of words and gestures (e.g. Makaton signs/symbols when used as an augmentative communication system). While an intermediary should be considered in every case where a witness has a learning disability, the services of an intermediary are essential in circumstances where a witness communicates using a mixture of words and gestures.

3.49 Some witnesses with a learning disability do not use speech but communicate using alternative methods. Such alternative methods of communication include sign and symbol systems. Examples of sign systems include Makaton signing and

Sign-a-long (these systems may be used either as an augmentative system with speech or as an alternative system without it). Examples of symbol systems include Rebus, Bliss and Makaton. The symbols may be printed on boards or cards, or contained in booklets. They vary from being iconic and concrete to being more abstract in their composition. They may be personalised and can be composed of words, pictures and symbols. While an intermediary should be considered in every case where a witness has a learning disability, the services of an intermediary are essential in circumstances where a witness uses an alternative method of communication instead of speech.

3.50 Many witnesses with a learning disability will be unable to give their evidence in one long interview. In many instances, several short interviews, preferably held on the same day (though not necessarily), would be more likely to lead to a satisfactory outcome.

3.51 Preparation of the witness for the interview and a rapport phase prior to formal questioning during the interview is essential. This will allow the witness to have some familiarity with the personnel who will be involved in the interview, including the interviewer, second interviewer and intermediary (where used).

Witnesses with a physical disability

3.52 For witnesses with hearing and communication difficulties, every effort should be made to ensure that their usual means of communication is supported at interview by means of an interpreter (and/or an intermediary, if appropriate).

3.53 If the witness does not communicate by speech, alternative communication systems are available, such as British Sign Language (BSL), Irish Sign Language (ISL) and Sign Supported English (SSE). In these instances, an interpreter capable of signing will be required.

3.54 Other sign and symbol systems may be required for witnesses with additional disabilities. Examples of sign systems include Makaton signing and Sign-a-long. Symbol systems include alphabet boards and boards/books/cards containing pictorial symbols (these symbols vary from being iconic and concrete to being more abstract in their composition). Examples of pictorial symbol systems include Makaton, Rebus and Bliss. Communication boards may also be personalised and composed of words, pictures and symbols. In these circumstances, an intermediary capable of using the communication system in question will be required.

3.55 Some witnesses may also communicate using a mixture of words and gestures. If a witness has an idiosyncratic speech or communication pattern, a vocabulary should be worked out which will need to be explained to all the personnel present at the interview. Initially at least, signs for 'yes', 'no', 'don't know' and 'don't understand' should be identified. In one case, a young woman who used single words along with expressive gestures, which were clearly understood by those close to her, gave a good account of events. Those interviewing her were made aware of her mode of communication prior to the interview.

3.56 Witnesses who have limited movement may require computer or other electronic communication equipment that can be accessed via fingers by pointing to letters or symbols on a board, or by indicating letters or symbols by blinking or by some other means. It is important that witnesses move or point to the letters or symbols themselves; the involvement of a third party is likely to lead to the evidence being ruled as inadmissible.

3.57 The witness may have some associated health or mobility difficulties, and would benefit from short interviews spaced out with periods of rest and refreshment.

3.58 Preparation of the witness for the interview and a rapport phase prior to formal questioning during the interview is essential. This will allow the witness to have some familiarity with the personnel who will be involved in the interview, including the interviewer, second interviewer and intermediary (where used).

Consent

3.59 It is a general principle that all witnesses should freely consent to be interviewed and to have the interview recorded on video. For this reason, interviewers should explain the purpose of a video recorded interview to the witness in a way that is appropriate to their understanding. Such an explanation should include:

- the benefits/disadvantages of having or not having the interview video recorded;
- who may see the video recorded interview (including the alleged offender, both before the trial and at court); and
- the different purposes to which a video recorded interview may be put (e.g. if it appears the video may be useful in disciplinary proceedings against a member of staff who is suspected of abusing a vulnerable adult in their care).

3.60 While interviewers should make a record of the action taken to obtain consent for a video recorded interview, it is not necessary for the witness to give their consent in writing.

3.61 Obtaining consent for a video recorded interview may raise difficulties with regard to some groups of vulnerable witnesses, such as those with a learning disability or a mental disorder. In these circumstances, it is important to take account of the following principles:

- every adult has the right to make their own decisions and must be assumed to have capacity to make them unless it is proved otherwise;
- a person must be given all practicable help before anyone treats them as not being able to make their own decisions;
- just because an individual makes what might be seen as an unwise decision, they should not be treated as lacking capacity to make that decision;
- anything done or any decision made on behalf of a person who lacks capacity must be done in their best interests; and
- anything done for or on behalf of a person who lacks capacity should be the least restrictive of their basic rights and freedoms.

3.62 A communication issue should not be confused with a capacity issue and every effort should be made to communicate with people using whatever methods are necessary. An intermediary may be of use in these circumstances.

3.63 If, following an assessment (the extent of which depends on the circumstances), it is concluded that lack of capacity is an issue, actions should be taken in the 'best interests' of the witness. As far as is reasonably ascertainable, when considering the person's best interests particular account should be taken of the matters set out in Box 3.1.

Box 3.1 Matters to be taken into account when considering best interests

The matters to be taken into account include:

- the person's past and present wishes and feelings;
- the beliefs and values that would be likely to influence the person's decision if they had capacity; and
- the other factors that the person would be likely to consider if they were able to do so.

3.64 In seeking to determine the matters set out in Box 3.1, particular account should be taken of the views of those referred to in Box 3.2.

Box 3.2 Views to be taken into account when considering best interests

The following should be considered:

- such views as the witness is able to express (with such assistance as is necessary); and
- where it is practicable and appropriate to consult them, the views of:
  - anyone named by the person as someone to be consulted on the matter in question or on matters of that kind; and
  - anyone engaged in caring for the person or interested in their welfare.

3.65 Where somebody who is involved in the care of a person believed to lack capacity is also suspected of abusing them, this should be taken into account when considering their views of the person's best interests.

3.66 The scope of the consultation with others involved in the care, welfare and treatment of the person lacking capacity very much depends on the nature of the decision and the time available in the circumstances. This means taking account of the urgency of the case and the time at which it arises.

3.67 When considering best interests, account should also be taken of any possibility that the witness will regain capacity and, if so, when this is likely to be. This is important in circumstances where, for example, the effect of a witness's medication on their capacity to make a decision changes over time; when a witness is likely to recover from an injury or an illness to the extent that they are likely to be able to participate more fully in the process of making a decision; or, in the case of persons with dementia, capacity can fluctuate considerably and factors such as location and time of day can be significant.

3.68 Records should be kept of all decisions taken in a person's best interests, the rationale for that decision and the scope of the consultation that took place in reaching that decision.

Sharing information with carers

3.69 Adult witnesses have the right to privacy including the right to choose to provide information that they do not wish to share with their carer. Therefore, account needs to be taken of their understanding when considering whether their carer also needs to be consulted. The same considerations apply in relation to seeking further information from the carer after a vulnerable adult has made their own statement.

Planning and preparing for the interview

3.70 Having identified the type of vulnerability and the effect this will have on the evidence that the witness can give in terms of reliability, careful attention must be paid to planning the interview. Time spent at the planning phase will enhance the delivery of best evidence, and minimise errors and inconsistencies at a later stage.

3.71 Planning should take account of the abilities and needs of vulnerable witnesses. Additional time is likely to be required to ensure that witnesses are able to understand and respond to the difficulties and pressures placed on them by the need to make a statement which will be acceptable to the court. Attention should be paid at all times to issues of age, disability, gender, race, culture, religion and language.

3.72 Where vulnerability is likely to be an issue, early individual assessment by an expert of the abilities and disabilities of the witness may be desirable to identify any particular difficulties that the witness may experience in producing a satisfactory statement at interview. Interviewers could also consider the use of advocates for vulnerable groups, for example, people with learning disabilities or those with dementia. An advocate could assist in the preparation for an interview and could provide support for the vulnerable witness through the criminal justice process.

3.73 At the court's discretion, a responsible person who knows the witness well or is an expert with generic knowledge of the witness's condition might subsequently be called to provide advice on whether the witness would benefit from special measures. An early request for special measures can be made by either the prosecution or the defence.

Information about vulnerable adult witnesses

3.74 While circumstances will sometimes limit what can be found out about the witness prior to the interview taking place (e.g. as a result of time constraints where the alleged perpetrator is in custody), as much of the following information should be obtained about the witness as is possible:

- age;
- gender;
- sexuality (where the alleged offence might contain a homophobic element);
- community or (perceived) political background (where the alleged offence might have been motivated by this);
- preferred name/form of address;
- the nature of the witness's disability or mental disorder, and the implications of this for the interview process;
- any medication being taken and its potential impact on the interview (including its timing);

- domestic circumstances (including whether the witness is currently in a 'safe' environment, and if the witness has any dependants or caring responsibilities);
- the relationship of the witness to the alleged perpetrator;
- current emotional state (including trauma, distress, shock, depression, fears of intimidation/recrimination and recent significant stressful events experienced);
- the likely impact of recalling traumatic events on the behaviour of the witness;
- current or previous contact with public services (including previous contact with the police, the local authority adult services or health professionals); and
- any relevant information or intelligence known.

3.75 Interviewing teams should also be alert to issues relating to literacy as this will affect a witness's ability to understand documents and, in some cases, may impact on their ability to give informed consent based on information that is provided in a written format. In other cases, difficulties with reading and writing may have a link to a range of disabilities, for example learning disability, dementia, sensory impairment, stroke or head trauma. Interviewers should remember that many people with literacy deficits will often be adept at hiding the problem to avoid social stigma and through learning to cope in everyday life without these skills.

Race, gender, culture and ethnic background

3.76 The witness's race, gender, culture, ethnicity, first language, religious and political beliefs must be given due consideration by the interviewing team. They have a responsibility to be informed about and take into account the needs and expectations of witnesses from the specific minority groups in their local area. The interviewing team's knowledge of the witness's religion, culture, customs and beliefs may have a bearing on their understanding of any account given by the witness, including the language and allusions the witness may make, for example, to reward and punishment. In a Northern Ireland context, it is always important to be alert to issues which may relate to sectarianism.

3.77 The interviewing team needs to bear in mind that some families may have experienced discrimination and/or oppression through their contact with government agencies and local authorities. Their experiences of racism, for example, may result in them distrusting the professionals involved in an investigative interview (see also Box 3.4). Asylum-seeking witnesses and refugees may have a fear of disclosing abuse because of what may happen to them and their family.

3.78 It is also important that the interviewing team considers the complexities of multiple discrimination, for example in the case of a witness from a minority ethnic community who has a disability, and of individuals' experiences of discrimination. The specific needs and experiences of dual-heritage witnesses must also be taken into account.

3.79 Some possible relevant considerations include the following although this list is not exhaustive:

- customs or beliefs that could hinder the witness from participating in an interview on certain days (e.g. holy days) or may otherwise affect the witness's participation (e.g. when fasting);
- the relationship to authority figures within different minority ethnic groups, for example, witnesses from some cultures may be expected to show respect to authority figures by not referring to them by their first names, and by not correcting or contradicting them;
- the manner in which love and affection are demonstrated;
- the degree to which extended family members are involved in caring for the witness;
- the degree of emphasis placed on learning skills in independence and self-care; and
- issues of shame, for example, carers in some cultures may inhibit the witness from talking about a sexual assault for fear of shaming the family.

3.80 A witness should be interviewed in the language of their choice. If a witness is bilingual then this may require the use of an interpreter. The interpreter should normally be selected from the PSNI register of translators and interpreters.

Other life experiences

3.81 Where the witness may have experienced abuse, neglect, domestic violence and/or discrimination based on race or disability, the interviewers must consider its potential impact on the interview. There is no single 'diagnostic' symptom of abuse or discrimination but some of the possible effects on vulnerable adult witnesses are set out in Boxes 3.3 to 3.6. When considering the possibility of abuse or discrimination, it must be understood that vulnerable adult witnesses who have experienced it will not necessarily exhibit all, or indeed any, of the behaviours set out in these boxes.

Box 3.3 Some possible effects of abuse and neglect

These include:

- poor self-esteem;
- post-traumatic stress disorder;
- self-injury and suicidal behaviour;
- increased emotional problems, e.g. anxiety and depression;
- decreased cognitive functioning;
- sexualised behaviour; and
- negative social behaviour, e.g. increased aggression, non-compliance and criminal activity.

Box 3.4 Some possible effects of racism

These include:

- fear;
- poor self-esteem;
- fear of betrayal of community;
- mistrust of people from outside own community;
- difficulty in establishing positive (racial) identity; and
- increased vulnerability to racist abuse.

Box 3.5 Some possible effects of discrimination based on disability

These include:

- decreased autonomy;
- increased dependency;
- difficulty in establishing positive self-identity;
- experience of being isolated (geographical, physical, social);
- experience of being patronised by people who do not have a disability;
- experience of being treated as a 'voiceless object';
- feelings of being perceived as 'asexual'; and
- increased vulnerability to abuse.

Box 3.6 Some possible effects of domestic violence

These include:

- fear for safety of self and others in family;
- sadness/depression, possibly reflected in self-harm or suicidal tendencies;
- anger, which may be demonstrated in aggressive behaviour;
- negative impact on health (e.g. asthma, eczema or eating disorders); and
- negative impact on behaviour (e.g. aggression).

3.82 It is important for interviewers to consider these matters in relation to each individual witness rather than work from assumptions based on stereotypes. Being sensitive to such factors should contribute towards a safe and non-judgmental interview environment for the witness. It is essential that the interview process itself does not reinforce any aspects of discriminatory or abusive experiences for the witness.

Witnesses with a mental disorder

3.83 Where there is a major concern about the mental health of a witness or information that suggests mental disorder, consent for an early psychiatric assessment might be sought to establish whether the witness is able to give a reliable account of events. Under the Criminal Procedure and Investigations Act 1996, any report might have to be disclosed to the defence prior to the trial as unused prosecution material.

3.84 It might be helpful to ask the witness if they are in contact with a professional such as a doctor, adult social care social worker, community psychiatric nurse or legal representative who might be able to assist them. In some cases, it may be clear either from the location of the witness (e.g. hospital), from other information volunteered by the witness or by one of the professionals known to the witness that they have a mental disorder.

3.85 Witnesses with a mental disorder are eligible for an intermediary where their use would maximise the quality of their evidence.

Witnesses with a significant impairment of intelligence and social functioning (learning disability)

3.86 Some people with learning disabilities can be isolated and distanced from other communities, congregated together, dependent on others (learned helplessness) and waiting for 'permission' to do anything. Interviewers should try to establish what impact this kind of situation may have had on the witness and take it into account when planning the interview, preparing the witness for the interview and conducting the interview. It is essential that every possible effort is made to encourage the witness's active participation in the interview process and to ensure that they know that their contribution is valued, whatever the outcome.

3.87 It is not possible to provide advice in this guidance covering every form of learning disability because there are over 200 of them. Autistic spectrum disorder (autism) and Down's syndrome are simply highlighted in these paragraphs as examples. When planning and conducting interviews, it should be remembered that there will be significant variation in the abilities of individuals with autism or Down's syndrome, or with learning disabilities more generally: each witness is an individual and should be treated as such.

3.88 When interviewing witnesses with autism, being aware of the following may be helpful:

- the interviewer should try to be calm, controlled and non-expressive;
- the witness may be frightened of emotion or shouting;
- the witness may be fearful of unfamiliar stimuli, including noise, colour and unknown people;
- the witness may not like people to come too close to them;
- the witness may not like to make direct eye contact; and
- the witness may prefer a consistent and stable environment. For example, if there is more than one interview, they should be carried out in the same place with the same people in the same positions within the room. This would also apply to the courtroom situation if they have to appear on more than one day.

3.89 Witnesses with Down's syndrome and many other people with learning disabilities might be:

- disturbed and become anxious if there is shouting or aggression, especially if they are questioned by unknown people, particularly authority figures; and
- affected by noise. If they have a significant hearing loss they may, for example, confuse similar sounding words (this has particular relevance in responses to questions regarding when, where, what, why and who).

3.90 All witnesses with learning disabilities are eligible for an intermediary where their use would maximise the quality of their evidence. Communication is naturally ambiguous and often depends on tone, gesture and body language as well as words. This is also the case for witnesses with learning disabilities, who may use a combination of single words, signs and gestures. It will be important to ascertain any differences in their use of language and to identify a person who knows how the witness communicates (such as a parent, carer, adult social care social worker, or speech and language therapist) to facilitate the identification of an intermediary with the appropriate skills prior to the interview.

3.91 There is also the possibility of additional physical disabilities, which might contribute to intellectual impairment and add to the difficulty of giving evidence.

3.92 Elderly witnesses may also have cognitive impairments (e.g. as a result of dementia). They may require the support of special measures in order to be able to give full and reliable testimony.

Witnesses with a physical disability

3.93 A physical disability may cause additional health problems. Witnesses who have associated health or mobility difficulties may benefit if their interviews are spaced out with periods for rest and refreshment. Planning should allow for the extra time necessary. Physically disabled witnesses may need a carer on hand to give assistance with toileting, medication and drinks. Access requirements may also need additional planning. Where the witness has speech and/or hearing losses, this may require the use of an intermediary. Interviewers should always remember that physical disability includes sensory impairment or loss, and these can often be hidden. For reasons of combating social stigma, many people with visual or hearing disabilities will have compensated to a degree that their disability may not be immediately apparent.

Information about the alleged offence(s)

3.94 It is preferable (but not always necessary or essential) that interviewers know little detail of the alleged offence(s) for the purposes of the interview. However, in order to plan and prepare for the interview, interviewers will need a little general knowledge about:

- the type of alleged offence(s);
- the approximate time and location of the alleged offence(s);
- the scene of the alleged offence(s) (note: this should only be enough general knowledge to help the interviewer understand what might be said during the interview); and
- how the alleged offences came to the notice of the police.

3.95 Where the interviewer is also the investigating officer and has been involved in a multi-agency strategy meeting/discussion (see Protocol for Joint Investigation of Alleged and Suspected Cases Abuse of Vulnerable Adults (Health and Social Care Board, July 2009)) or has been interviewing other witnesses during the course of an investigation, it is accepted that circumstances and practical resource considerations might be such that they are likely to know more about the alleged offence(s) than is set out above. In this situation, the interviewer should try as far as possible to avoid contaminating the interview process with such knowledge.

3.96 It is also accepted that circumstances and resource considerations might be such that it could be necessary for an interviewer to interview more than one witness during the course of an investigation. In such a situation, care should be taken to avoid asking questions of a witness based on the responses of previous interviewees, because this could contaminate the witness's account.

3.97 Nothing in this guidance is intended to limit operational decision-making in cases where the nature of the investigation, the context of the interview and the circumstances as they are known at the time make it necessary for interviewers to have a more detailed knowledge of the offence than the general information outlined in the paragraphs above.

Information important to the investigation

3.98 While obtaining an account of the alleged event is essential, other matters might need to be covered during the interview in order to progress the investigation. These matters can be regarded as 'information important to the investigation'. Obtaining a complete picture of all the relevant issues within an interview is essential because it will provide the investigating officer with the information necessary to conduct a comprehensive investigation. It could also prove beneficial in discussions with the PPS if the subject of witness assessment is raised. Information important to the investigation falls into two categories: general investigative practice and case-specific material. Where such information important to the investigation has not already been covered as part of the witness's account, interviewers should consider introducing it either in the latter part of the questioning phase or in a subsequent interview session depending on the complexity of the case and what is alleged to have been witnessed by the interviewee.

3.99 The amount of knowledge that interviewers have about information important to the investigation prior to the interview depends on what they know about what is alleged to have been witnessed by the interviewee. It is preferable that interviewers know little detail of the alleged offence(s) before the interview. Therefore, only a little knowledge that could form the basis of potential questions about information important to the investigation is likely to be available to the interviewer at this point in time. However, while planning the interview, interviewers should apply what they know of the alleged offences to determine the areas of general investigative practice that might need to be covered in the interview. More case-specific material could be either made available to the interviewer (from the investigating officer, interview monitor or recording equipment operator) after an attempt has been made to elicit and clarify the witness's account, or included in the planning information for a later interview to avoid potential contamination of the process.

Information important to the investigation relating to general investigative practice

3.100 Information important to the investigation relating to general investigative practice includes:

- points to prove any alleged offence(s); and
- information that should be considered when assessing a witness's identification evidence, as suggested in R v Turnbull and Camelo ([1976] 63 Cr App R 132) and embodied in the mnemonic ADVOKATE (Practical Guide to Investigative Interviewing (National Centre for Policing Excellence, 2004)):
  - **A** Amount of time under observation
  - **D** Distance from the eyewitness to the person/ incident
  - **V** Visibility – including time of day, street lighting, etc.
  - **O** Obstructions – anything getting in the way of the witness's view
  - **K** Known or seen before – did the witness know, or had they seen, the alleged perpetrator before?
  - **A** Any reason to remember – was there something specific that made the person/incident memorable?
  - **T** Time lapse – how long since the witness last saw the alleged perpetrator?
  - **E** Errors or material discrepancies;
- anything said by the witness to a third party after the incident (evidence of first complaint etc.); and
- any other witnesses present.

3.101 This is not intended to be an exhaustive list. The nature of the information important to the investigation pertaining to general investigative practice varies according to the circumstances of the case.

Information important to the investigation relating to case-specific material

3.102 Information important to the investigation relating to case-specific material includes:

- how and where any items used in the commission of the offence (e.g. clothing, vehicles, weapons, cash, documents or other property) were disposed of, if the vulnerable adult witness might have some knowledge of this;
- access by the witness and suspect to electronic media including computers and mobile telephones;
- relevant financial transactions by the witness and suspect;
- any background information relevant to the witness's account (e.g. matters that might enhance or detract from the credibility of the witness's evidence, such as the amount of any alcohol consumed);
- any lifestyle information relevant to the witness's account;
- where the witness has knowledge of an alleged victim or a suspected perpetrator, an exploration of their relationship, background history, places frequented, and any events related or similar to the matter under investigation; and
- any risk assessment issues that the witness might know about that concern the likely conduct of the alleged perpetrator, their family or associates (this should be dealt with after the witness's account has been covered to avoid confusion).

3.103 Again, this is not intended to be an exhaustive list. The nature of any case-specific material varies according to the circumstances of the alleged offence, the nature of any relationship between the witness and the alleged perpetrator, and what is alleged to have been seen, heard or otherwise experienced.

3.104 Significant evidential inconsistencies and significant evidential omissions (case-relevant information) are discrete categories of case-specific material.

Significant evidential inconsistencies

3.105 During the course of an investigation it may be necessary to ask a vulnerable adult witness to explain a significant evidential inconsistency between what they have said during the interview and other material gathered during the course of the investigation. Such inconsistencies would, for example, include significant differences between the account provided by the witness during the interview and:

- what the witness is reported to have said on a previous occasion;
- the accounts of other witnesses; and
- injuries sustained by either the alleged victim or the alleged offender.

3.106 There are a number of reasons for significant evidential inconsistencies between what a witness says during an interview and other material gathered during the course of an investigation. Many of these reasons are perfectly innocent in their nature (e.g. genuine mistakes by the witness, those stemming from a memory-encoding or recall failure, or subconscious contamination of their memory by external influences) but occasions may arise where the witness is motivated to either fabricate or exaggerate their account of an event.

3.107 Whatever the reason for the significant evidential inconsistency, occasions may arise where it is necessary to ask the witness to explain it. The following principles should be taken into account when considering whether, when and how to solicit such an explanation:

- explanations for evidential inconsistencies should only be sought:
  - where the inconsistency is a significant one;
  - after careful consideration has concluded that there is no obvious explanation for them; and
  - after the witness's account has been fully explored, either at the end of the interview or in a further interview, as appropriate;
- interviewers should always be aware that the purpose of asking a witness to explain an evidential inconsistency is to pursue the truth in respect of the matter under investigation, it is not to put pressure on a witness to alter their account;
- explanations for evidential inconsistencies should take account of the extent to which the witness may be vulnerable to suggestion, compliance or acquiescence; and
- questions intended to elicit an explanation for evidential inconsistencies should be carefully planned, phrased tactfully and presented in a non-confrontational manner.

Significant evidential omissions

3.108 During the course of an investigation it may be necessary to ask a vulnerable adult witness about relevant information that they have not mentioned in their account. This may arise, for example, where others say that the alleged offender was carrying an object, the alleged offender's behaviour was unusual, or there was something particular about the alleged offender's description or vehicle but this is not mentioned by the witness. There are a number of reasons why this type of information can be omitted from an account and situations may arise where it is important to seek an explanation from the witness. In these circumstances, it may be necessary to ask a question to establish whether the witness has knowledge of the information. Such a question should only be asked after the witness's account has been fully explored at the end of the interview (or in a further interview if necessary).

3.109 When planning such a question, the interviewer should consider:

- whether the information omitted by the witness is likely to be important enough to be worthy of explanation;
- the extent to which the witness may be vulnerable to suggestion, compliance or acquiescence; and
- which type of question is most likely to elicit the information in a manner that will not have an adverse effect on the value of any answer.

3.110 A plan for soliciting an explanation for the omission of case-relevant information from a witness's account must consider the reliability of any answer. For example, a useful starting point might be to ask the witness a specific-closed question, such as: 'What else can you tell me about the incident?'. If the witness's answer:

- includes the case-relevant information but lacks sufficient detail, the interviewer should ask the witness to provide a more detailed response by means of an open question (e.g. 'Tell me about…'). When the case-relevant information has been covered, the witness should be tactfully asked to explain its omission from their account unless the reason for its omission is apparent from the witness's response or the circumstances of the case; or
- does not include the case-relevant information, a further decision will need to be made as to whether it is necessary to ask a question that might be regarded as leading (e.g. 'Do you recall seeing/hearing…?'). It should be noted that if the answer to such a leading question contains the case-relevant information, it is likely to be of limited evidential value. The evidential value of such an answer may, however, be enhanced if the interviewer then asks the witness to provide a more detailed response by means of an open question (e.g. 'Tell me about…') followed by questions intended tactfully to elicit an explanation for its omission from their account (unless the reason for the omission is apparent from the witness's response or the circumstances of the case).

3.111 Where the witness cannot recall the case-relevant information, this may be due to not attending to the information or to memory loss.

Using the planning information

Overview

3.112 The planning information should then be used to:

- set aim and objectives for the interview;
- determine the techniques used within the phased interview; and
- decide:
  - the means by which the interview is to be recorded;
  - who should conduct the interview and if anybody else should be present (including support for the witness);
  - if anybody should monitor the interview (e.g. investigating officer, supervising officer, specialist/interview adviser, etc.);
  - who will operate the equipment;
  - the location of the interview;
  - the timing of the interview;
  - the duration of the interview (including pace, breaks and the possibility of more than one session); and
  - what is likely to happen after the interview.

Aim and objectives

3.113 The aim of the interview should be to achieve all the objectives that are set for it while being as concise as reasonably possible.

3.114 Setting clear objectives is important because they give direction to the interview and contribute to its structure. The interview objectives should focus on:

- the alleged incident or event(s);
- any case-specific information important to the investigation.

Techniques

3.115 The kind of techniques used within the phased structure set out in Part 3B will vary according to what is known about the witness and the offence when planning the interview as well as how the witness behaves and what emerges during the interview itself. For example, it might be productive to make use of some of the cognitive mnemonics within the phased interview approach with a direct witness who is able and willing to participate in the process whereas such techniques are unlikely to be productive while a witness remains hostile and less co-operative, and where a more managed communication is necessary.

How the interview is to be recorded

3.116 Any decision as to the form of the witness's statement, whether as a video recorded interview or a written statement, will need to be taken on an individual basis taking into account information and any expert opinion that is available. One important factor would be the presence of any memory disabilities. If the witness has unusual difficulties in retrieving past events readily then an early video recorded interview may be advisable. Likewise, if a witness is likely to suffer undue stress in giving evidence in chief live in the courtroom, a video recorded statement may again be preferable.

3.117 All decisions need to take account of the witness's own expressed preferences as to the form of their statement.

3.118 Regardless of how the interview is recorded, notes should always be taken that are sufficiently detailed to assist the investigating officer to determine any further lines of enquiry that might be necessary, and to brief the custody officer and any other interviewers where a suspected perpetrator is in custody. Responsibility for the compilation of such notes should be agreed during the planning phase of the interview. This responsibility should fall to the second interviewer. While the lead interviewer may consider taking brief notes to assist them during the free narrative phase of the interview, where this is appropriate, they should not be responsible for taking notes for the purposes of briefing others because it is likely to distract the witness, obstruct the flow of recall and slow the interview process down therefore hindering the maximum retrieval of information.

Interviewers and others present at the interview

The interviewer

3.119 Consideration should be given to who is best qualified to lead the interview. A special blend of skills is required to take the lead in video recorded interviews. The lead interviewer should be a person who has or is likely to be able to establish rapport with the vulnerable adult, who understands how to communicate effectively with witnesses who might become distressed, and who has a proper grasp of the rules of evidence and criminal offences. The lead interviewer must have good knowledge of information important to the investigation, including the points needed to prove particular offences.

2.120 In addition to taking account of the prospective interviewer's skills, the following factors should be taken into consideration when considering who should conduct the interview:

- the experience of the prospective interviewer in talking to vulnerable adults in respect of the type of offence under investigation and any other skills that they possess that could be useful;
- any personal or domestic issues that the prospective interviewer has that might have an adverse impact on the interview; and
- whether any previous experience that the prospective interviewer has with the witness is likely to either inhibit rapport building, or give rise to challenges of coaching, prompting or offering inducements.

3.121 The witness's gender, race, culture and ethnicity must always be given due consideration and advice sought where necessary. However, stereotypic conclusions about who is to conduct the interview should be avoided.

3.122 Where the witness expresses a particular preference for an interviewer of either gender or sexual orientation, or from a particular race, cultural or ethnic background, this should be accommodated as far as is practical in the circumstances.

3.123 The interviewer should consider the appropriate mode of dress for the particular witness. For example, research shows that a person's perceived authority can have an adverse effect on the witness especially with respect to suggestibility.

3.124 Exceptionally, it may be in the interests of the witness to be interviewed by somebody with whom they are already confident but who is not a member of the investigating team. Provided that such a person has appropriate professional qualifications, is independent and impartial, is not a party to the proceedings, is prepared to co-operate with appropriately trained interviewers and can accept adequate briefing (including permitted questioning techniques), this possibility should not be precluded.

The second interviewer

3.125 The presence of a second interviewer is desirable because they can help to ensure that the interview is conducted in a professional manner, can assist in identifying any gaps that emerge in the witness's account and can ensure that the witness's needs are kept paramount. Careful consideration needs to be made with regard to whether the second interviewer is present in the interviewing room itself or in the adjoining room with the monitoring equipment. The possibility that the witness might feel intimidated by the presence of too many people in the interview room should be taken into account in determining where a second interviewer is situated particularly where an interview supporter, intermediary and interpreter are also to be present in the interview room.

3.126 Regardless of who takes the lead, the interviewing team should have a clear and shared remit for the role of the second interviewer. Too often this role is subjugated to the need for someone to operate the video equipment when, in reality, the second interviewer has a vital role in observing the lead interviewer's questioning and the witness's demeanour. The second interviewer should be alert to interviewer errors and to apparent confusions in the communication between the lead interviewer and the witness. The second interviewer can reflect back to the planning discussions and communicate with the lead interviewer as necessary. Such observation and monitoring can be essential to the overall clarity and completeness of the video recorded account which will be especially important at court.

Equipment operators

3.127 The equipment should always have an operator for the duration of the interview. This will allow the view recorded by the camera to be adjusted if the witness moves. It should also provide an opportunity for the interviewer to be alerted at the earliest possible moment in the event of an equipment failure rather than such a failure only being discovered at the end of the interview (see also Appendix C).

Interpreters

3.128 Witnesses should always be interviewed in the language of their choice unless exceptional circumstances prevail (for example, in respect of the availability of interpreters). This will normally be the witness's first language unless specific circumstances result in their second language being more appropriate. Interviewers should be aware that some witnesses could be perfectly fluent in English but might use their first language to express intimate or more complex concepts. As a result, the possibility of using an interpreter should be considered while planning the interview even where a witness is bilingual.

3.129 Interpreters should be appropriately accredited and trained so that they understand the need to avoid altering the meaning of questions and replies. They should normally be selected from the PSNI register of translators and interpreters. If it is not possible to select an interpreter from these registers then the interpreter may be chosen from some other list provided that the interpreter meets standards at least equal to those required for entry onto the registers, in terms of academic qualifications and proven experience of interpreting within the criminal justice system. While the familiarity of the interpreter to the witness is not a bar to employment and may indeed facilitate communication, all interpreters need to be independent, impartial and unbiased. Family members or other close relatives should not be used either during the interview or when preparing the witness for it.

3.130 Interpreters should be involved in the planning process. They should have a clear understanding of the objectives of the interview, its structure and the function served by any specific techniques used (e.g. those of the cognitive interview). It should be remembered that some words in English might not have an exact equivalent in other languages and communication systems. This possibility should, therefore, be discussed while planning the interview with a view to developing strategies to address what might otherwise be a problem.

3.131 If interviewers are working with an interpreter, it is important to have clarified at the outset who will lead the interview in terms of maintaining direct communication with the witness. If the witness is communicating via an interpreter, the lead interviewer should identify themselves as such while maintaining appropriate eye contact with the witness so that the witness understands that they should address the interviewer not the interpreter. However, if a signer is being used to communicate with a witness who has a hearing impairment, it may be more important for the signer to maintain the direct communication with the witness.

3.132 Where an interpreter is present, they must be clearly identified at the beginning of the interview. Whenever possible, they should also be visible in one of the shots recorded.

3.133 Where a sign language interpreter is being used to interpret for a witness with a hearing impairment, a camera should be used to record the signer's hand movements as well as those of the witness. In some interview suites, it might be necessary to make use of a portable camera, in addition to the static equipment already set up in the suite, for this purpose. Interviewers should also emphasise to the signer that it is important to avoid inadvertently leading the witness by presenting only one particular option when some of the more generic signs are used, e.g. the signs for 'weapon' and 'touch' depend on the context so it may be important to present the witness with a number of alternatives.

3.134 Where a signer is to be used, it is important to remember that the energy involved in signing is such that the hands of the signer and the witness are likely to get tired. The interview plan should therefore take account of the need for breaks to give the signer and the witness an opportunity to rest their hands.

Intermediaries (note: this special measure is not yet available)

3.135 An intermediary may be able to help improve the quality of evidence of any vulnerable adult witness who is unable to detect and cope with misunderstanding, or to clearly express their answers to questions especially in the context of an interview or while giving evidence in court. The information provided here is intended to summarise the role of the intermediary and provide general principles that need to be considered in criminal investigations. Detailed procedural guidance will be produced when this special measure is commenced.

3.136 Article 17 of the 1999 Order makes it clear that an intermediary can assist a witness to communicate by explaining questions put to and answers given by a vulnerable witness. In addition, intermediaries can assist during the planning phase of an interview by providing advice on how questions should be asked and then to intervene during the interview where miscommunication is likely, by assisting the interviewer to rephrase the question or by repeating the witness's answers where they might otherwise be inaudible or unclear on the recording. The extent to which the intermediary is actively involved in the communication of questions and answers will vary from witness to witness depending on the witness's particular needs and communication style. It will also depend on the degree of compliance with the intermediary's recommendations by the interviewer. It is very important to remember that the intermediary is there only to assist communication and understanding – they do not take on the function of investigator.

3.137 Following commencement of this special measure, registration and accreditation arrangements will be put in place.

3.138 Before an intermediary can assist with communication, they need to conduct one or more assessment meetings with the witness. The criminal case is not discussed during assessment meetings. These meetings enable the intermediary to consider the witness's communication needs, and devise strategies and recommendations for how to maximise understanding. The meetings also enable the intermediary to build the necessary rapport with the witness and to determine whether they (the intermediary) are the right person to act as an intermediary for that witness. Intermediaries should never be alone with a witness; a responsible third party must be present. This should usually be a police officer at the investigation phase.

3.139 Registered Intermediaries should be used. The use of an unregistered person as intermediary can only be considered once the options for using a Registered Intermediary have been exhausted. When this is the case, an unregistered intermediary has the same responsibility to the court. They must be independent of the case being investigated (i.e. not witnesses or suspects). There is a preference for unregistered intermediaries to be professional people rather than family members,

friends or associates. In the event that the particular circumstances of the case are such that it appears that only a non-professional person can perform the function of an intermediary, the rationale for this decision should be clearly recorded.

3.140 Discussions with the intermediary at the planning phase should include the arrangements for leading the interview, legal and confidentiality requirements, and the exact role that the intermediary will play. The potentially explicit nature of the topics to be covered should be addressed. The intermediary should be provided with information that is relevant to their role and will help them to maximise communication/understanding (e.g. the specific vocabulary used by the witness and relevant relationships).

Interview supporters

3.141 It may often be helpful for a person who is known to the witness to be present during the interview to provide emotional support (the 'interview supporter'). They may also be able to offer extra information regarding the particular communication needs of the witness. However, in some circumstances it has been found that the use of a person who is well-known to the witness as an interview supporter can prove counterproductive by inhibiting the disclosure of information (e.g. as a result of embarrassment arising from sensitive information being disclosed in the presence of a person seen by the witness on a day-to-day basis). For this reason, discussions as to the identity of any potential interview supporter should take account of the nature of their relationship with the witness and its potential impact on the interview process. Wherever possible, the views of the witness should be established prior to the interview as to whether they wish another person to be present and, if so, who this should be.

3.142 Other witnesses in the case, including those giving evidence of an early complaint, cannot act as interview supporters.

3.143 If an interpreter or intermediary is included then they will need to be distinct from the interview supporter and these different functions should not be vested in one person.

3.144 Interview supporters must be clearly told that their role is limited to providing emotional support and that they must not prompt or speak for the witness especially on any matters relevant to the investigation.

3.145 Where an interview supporter is present, they must be clearly identified at the beginning of the interview. Whenever possible, they should also be visible in one of the angles recorded. Good practice would be for the interview supporter to make sure they are outside of the witness's line of vision, for example by sitting on the opposite side of the witness to the interviewer.

Location of the interview

3.146 Active consideration should be given to the location of the interview and to the layout of the room in which it is to take place. In the planning phase, the interviewer should attempt to determine where the witness would prefer to be interviewed. Some witnesses may be happy to be interviewed in an interview suite while others might prefer to be interviewed in a setting familiar and comfortable to them. Whatever the decision, the location should be quiet enough to avoid a situation in which background noise is likely to interfere with the quality of the sound on any visual or audio record, and free from interruptions, distractions, and fear and intimidation so the interviewer and witness can concentrate fully on the task in hand: the interview. All decisions need to take account of the witness's own expressed preferences as to the location of the interview.

3.147 Interviewers should ensure that sufficient pens and paper are available for use where a witness's recall could be assisted by drawing sketches/plans (NB: it is important to remember that any sketches/plans, etc. drawn in the interview will need to be retained so that they can either be adduced as evidence or disclosed as unused material under the terms of the Criminal Procedure and Investigations Act 1996).

3.148 In the event of a witness being interviewed at their home address, care should be taken to avoid saying anything or video recording any background material that might lead to the location being identified (the use of background screens should be considered if necessary).

Timing of the interview

3.149 The decision when to conduct an interview needs to take account of the demands of the investigation (e.g. a suspected perpetrator being in custody) as well as the potential effects of trauma and/or stress. Trauma and stress can interfere with the process of remembering but this should be determined by asking the witness rather than by the application of an arbitrary period of time. Some witnesses will want to be interviewed relatively quickly while others might wish to be interviewed at a later date. It should always be borne in mind that the potential for memory contamination taking place increases with the delay.

3.150 Interviews should not take place at a time when the witness is likely to be suffering from the effects of fatigue (other than in the exceptional circumstances mentioned). The effect of the witness's routine and the potential impact of any medication, as well as their views, must be taken into account in determining the best time to conduct the interview.

3.151 In the event of circumstances being such that it is absolutely essential for a witness to be interviewed at a time when they are likely to be suffering the effects of fatigue (for example, where an alleged offender is in police custody for a serious offence and an interview is necessary to secure potentially vital evidence), consideration may be given to conducting a brief interview in the first instance which sets out the witness's account and addresses any issues on which immediate action needs to be taken. Where it is necessary to conduct a brief interview, the principles set out in the paragraphs about initial contact with vulnerable adult witnesses should be adhered to. A more substantial interview can then be arranged at an appropriate time.

Duration of the interview (including pace, breaks and the possibility of more than one session)

3.152 Whenever possible, the interviewer should, in the preparation and planning phase, seek advice from people who know the witness about the likely length of time that the witness can be interviewed before a pause or break is offered, and breaks should be offered or taken during the interview in accordance with this information. If there is an accompanying interviewer, this person can share responsibility with the lead interviewer concerning the active use of pauses and breaks. For some vulnerable witnesses, there will be a need to plan for several pauses/breaks and for the interview to be spread over more than one day. When this occurs, care must be taken to avoid repetition of the same focused questions over time which could lead to unreliable or inconsistent responding in some witnesses and interviews being ruled inadmissible by the court.

3.153 As well as being less able to concentrate for as long as other witnesses, some vulnerable witnesses may find that the experience of being interviewed is 'too much' for them especially if emotional matters are being dealt with. Ways of assisting such witnesses may include planning for breaks in the interview and/or pauses in which the interviewer moves the conversation on to more neutral topics (e.g. those mentioned in the rapport phase before returning to the matter under investigation).

Planning for immediately after the interview

3.154 Although interviewers cannot predict the course of an interview, planning discussions should cover the different possible outcomes and consider the implications for the witness. This should include the possibility of a medical examination (where this has not taken place before the interview), the possible need for alternative accommodation, and any other steps necessary to protect the witness or reduce the possibility of harassment.

Witnesses who might become suspects

3.155 So far as is practicable, consideration should be given in the planning phase as to how interviewers will deal with any confessions to criminal offences made by the witness in the course of the interview. Any decision on an appropriate course of action will involve taking into account the seriousness of the crime admitted and weighing it against the seriousness of the crime under investigation.

3.156 It is preferable to anticipate and plan for such an eventuality while recognising that any decisions on a particular course of action are likely to depend on what has been disclosed by the witness during the course of the interview.

Recording the planning process

3.157 A full written record should be kept of the decisions made during the planning process and of the information and rationale underpinning them. This record should be referred to in the statement of evidence subsequently made by the interviewer in relation to the planning, preparation and conduct of the interview, and should be revealed to the PPS under the requirements of the Criminal Procedure and Investigations Act 1996.

Preparing the witness for an interview

3.158 Vulnerable witnesses should always be prepared for an interview. In some cases, this preparation might be fairly brief but some vulnerable witnesses may be very unused to speaking to strangers and may well need to spend time getting to know the interviewer before they are ready and/or willing to take part in an investigative interview. This familiarisation process may take some time (e.g. hours in some cases) and, therefore, in their preparation, interviewers need to consider whether one (or more) meetings with a witness should be planned to take place prior to the investigative interview.

3.159 In some instances, it may be helpful to arrange a familiarisation visit to the interview suite for the witness as part of the preparation process.

3.160 The preparation of the witness should include an explanation of the purpose of the interview and the reason for visually recording it (including who might subsequently view it), the role of the interviewer(s) and anybody else to be present, the location of the interview and roughly how long it is likely to take. The interviewer(s) should also outline the general structure of the interview and provide some explanation of the ground rules that apply to it (including the witness not making any assumptions about the interviewer's knowledge of the event). Substantive issues relating to the evidence should not be discussed while preparing a witness for an interview.

3.161 Where appropriate, the witness's carer(s) should also be provided with suitable information at this stage. In particular, they should be discouraged from discussing the details of the alleged offence(s) with the witness or any other individual who may be involved in the investigation but must be able to reassure the witness who wishes to talk or express anxieties. They should be asked to document carefully any discussions they have with the witness or other persons regarding the allegation or investigation (e.g. who was present, date/time and setting, what exactly was said). The witness should never be offered inducements for complying with the investigative process. Carer(s) should also be encouraged to provide emotional support to the witness such as physical comfort and reassurance. They should be given information about what further role, if any, they may have in planning the interview or in being present while it is conducted (or given reasons why the interviewer(s) would prefer them not to be present). Where possible, any support needs of the carer(s) that are identified should be brought to the attention of the relevant authorities/agencies.

3.162 Any issues or concerns raised by the witness or their carer(s) should be addressed while preparing them for the interview (e.g. welfare issues or concerns about the possibility of a later court appearance).

3.163 Most witnesses will be anxious prior to an investigative interview and few will be familiar with the formal aspects of this procedure. It is, therefore, important that the interviewer uses the time spent preparing a witness for an interview to build up a rapport with the witness. The nature and the extent of rapport building required very much depends on what has been established about the witness during the planning phase of the interview.

3.164 Vulnerable witnesses might need to spend more time getting to know the interviewer(s) before they are ready and/or willing to take part in an investigative interview. The interviewer(s) should consider whether one or more meetings with a witness should be planned to take place prior to the interview because this familiarisation process may take some time.

3.165 Some witnesses may feel that their initial, lawful co-operation with a person who subsequently commits an offence may make them blameworthy and vulnerable witnesses may assume that they must have done something wrong simply because they are being interviewed. The interviewer might need to try to reassure the witness on these points but promises or predictions should not be made about the likely outcome of the interview. So far as possible, the interview should be conducted in a 'neutral' atmosphere, with the interviewer taking care not to assume, or appear to assume, the guilt of an individual whose alleged conduct may be the subject of the interview.

3.166 Some witnesses may be unhappy or feel shame or resentment about being questioned especially on personal matters. In the rapport phase, and throughout the interview, the interviewer should convey to the witness that they have respect and sympathy for how the witness feels. A witness may be apprehensive about what may happen after the interview if they do provide an account of what happened. Such worries should be addressed.

3.167 Initial discussions with the witness could focus on events and interests not thematically related to the investigation: sport, television programmes, and so on. Sometimes, where the witness and the interviewer have had some previous contact this can be quite brief. At other times, especially when the witness is nervous or has been subject to threats from the alleged abuser, a much longer period of rapport-building when the witness is prepared for the interview may be warranted.

3.168 Rapport-building while the witness is prepared for the interview can also serve to set the tone for the style of questions to be used by the interviewer during the interview. It is, therefore, important that the witness is encouraged to talk freely through the extensive use of open-ended questions because this can help to encourage the witness to give detailed accounts; a style of communication wholly consistent with the guidance set out in this document.

3.169 In some instances, it might be helpful to conduct a practice interview while preparing the witness for the interview. In these circumstances, the witness could be asked to recall a personal event unrelated to the issue of concern (e.g. a birthday or a holiday). This serves to provide the witness with an example of the kind of detail that will be required in relation to the issue of concern and to practise extended verbal responses. Such practice interviews might be particularly useful with learning disabled witnesses who might not appreciate the demands of a witness interview for detailed and context information.

3.170 Rapport-building while the witness is prepared for the interview also gives the interviewer the opportunity to build on their knowledge of the witness's communication skills and degree of understanding of vocabulary. The interviewer can then adjust their language use and the complexity of their questions in the light of the witness's responses.

3.171 It may prove problematic to attempt to proceed with an interview until rapport has been established. Should establishing rapport when the witness is prepared for the interview proves difficult, it may be preferable to postpone the interview rather than proceeding with an interview that may well turn out to be of no benefit.

3.172 Assistance should be sought if necessary from interview supervisors and interview advisers concerning the issues that might arise during the preparation of a witness for an interview.

3.173 Full written notes must be kept of the preparation of a witness for an interview and must be given to the PPS on request. The information obtained to plan the interview should be reviewed and revised if necessary in the light of any additional information that arises from preparing the witness for the interview.

Part 3B: Interviewing vulnerable adult witnesses

General advice on interviewing vulnerable adult witnesses

3.174 What follows is a recommended procedure for interviewing based on a phased approach. This treats the interview as a process in which a variety of interviewing techniques are deployed in relatively specific and discrete phases, proceeding from free narrative to open and then to more closed forms of questioning. It is suggested that this approach is likely to achieve the basic aim of allowing the witness to provide an account. This structure should also result in a hierarchy of reliability of the information elicited. However, inclusion of a phased approach in this guidance should not be taken to imply that all other techniques are necessarily unacceptable or to preclude their development. Neither should what follows be regarded as a checklist to be rigidly worked through. Nevertheless, the sound framework it provides should not be departed from by interviewers unless they have discussed and agreed the reasons for doing so with their senior manager(s) or an interview adviser (tier 5 of the Association of Chief Police Officers' (ACPO's) National Investigative Interviewing Strategy (ACPO, 2009)).

3.175 Much more professional experience and published research now exist on the topic of conducting appropriate investigative interviews with children than with other vulnerable groups. Nevertheless, as for all witnesses, interviews with vulnerable witnesses should normally consist of the following four main phases:

- establish rapport;
- seek free narrative recall;
- ask questions; and
- closure.

Each phase will be described in greater detail below. These phases are compatible with and underpin the PEACE interview framework advocated by ACPO.

3.176 The additional planning phase, which will have occurred prior to the actual interview and which will often need to be extensive, should provide guidance to the interviewer about what might be achieved in each of the four main phases of the interview (e.g. 'Is the witness able to communicate via free recall?'). No interview should be conducted without there having been prior, proper planning.

3.177 Although currently our knowledge is limited concerning how best to interview vulnerable witnesses, some of the difficulties that research and good practice have noted for vulnerable witnesses illustrate the less obvious difficulties that ordinary witnesses experience. Interviewing practices and procedures that diminish difficulties for ordinary witnesses are likely to do so for vulnerable witnesses and vice versa. While Chapter 2 focuses specifically on child witnesses, the learning and approaches captured there have a transferable application to vulnerable witnesses in general.

3.178 While research has found that the accounts of some types of vulnerable witnesses are less complete than those of other witnesses, these are not necessarily less accurate if the interviewing is conducted appropriately. A fundamental consideration when interviewing vulnerable witnesses is to determine whether the necessary communication aids are in place. Otherwise, it may be wrongly decided that the person does not have the communication skills necessary to proceed.

3.179 The interviewer will need to pitch the language and concepts used (see below) to a level that the witness can clearly understand while the focus should be on recognising and working with the witness's capabilities rather than limitations.

Interviewer behaviour

3.180 Many interviewers will not be very familiar with the various types of vulnerable witnesses. Research has made it clear that when people meet others with whom they are unfamiliar their own behaviour becomes abnormal. This unusual behaviour is often noted by vulnerable people who may view it as a sign of our discomfort. When planning an interview, interviewers should always plan to monitor their own behaviour throughout the interview and to try to keep it as normal as circumstances allow. The planning should, in this regard, especially focus on how the interviewer will manage the opening minutes of the interview. The planning should also have dealt with the issue of the interviewer being conversant with the appropriate terms to use with witnesses for various vulnerabilities/disabilities so that interviewers will not be uneasy/tense about using such terminology (when necessary) in the presence of the witness and so that the witness will not be caused unease by inappropriate use of terminology.

3.181 Interviewers must be aware that, in order to gather accurate information from a vulnerable witness, they have to be sensitive not only to the communication needs of the witness but also to their own impact on the interview. They should try to focus on the witness as a person rather than on the vulnerability. For many people with disabilities, the disability is not central to their self-concept. Interviewers should try to avoid being uncomfortable or unsure how to behave with someone who has a disability that they have not encountered before. Interviewers will often need to behave in a reassuring and sympathetic way but they should avoid behaving in ways that vulnerable witnesses may find demeaning, insincere or patronising.

3.182 Some vulnerable witnesses may choose to place themselves nearer to or further away from the interviewer than other witnesses do, and interviewers need to be aware of their own reactions to this. They also need to be aware that, while they may intentionally try to act in a friendly and helpful way to vulnerable witnesses, they may at the same time unwittingly be giving off contradictory signals of unease, embarrassment, anxiety, insecurity, and so on, including feelings about their own incompetence. Furthermore, some vulnerable witnesses may present circumstances in which the interviewer's usual methods of social interaction are likely to fail.

3.183 Consideration should be given to the different forms of bodily expression and communication that many vulnerable witnesses will have. A proportion of vulnerable witnesses will be experienced at communicating with strangers. Interviewers can benefit from this expertise by asking such witnesses for advice concerning how they (i.e. the interviewers) should behave. Doing so will also allow the witness to feel empowered by their exerting some control in the interview. Feelings of empowerment by the witness may have the added benefit of reducing over-compliance during questioning.

Pace and breaks

Pace

3.184 Many vulnerable witnesses will require that their interviewers go at a slower pace than other witnesses. This is because many of them will have a slower rate of understanding, thinking and/or replying than other witnesses. Both research and good practice have found that interviewers will need to:

- slow down their speech rate;
- allow extra time for the witness to take in what has just been said;
- provide time for the witness to prepare a response;
- be patient if the witness replies slowly, especially if an intermediary is being used;
- avoid immediately posing the next question;

- avoid filling in the answers to questions for the witness; and
- avoid interrupting.

The interview should go at the pace of the witness.

Breaks

3.185 Not only will interviews with vulnerable witnesses typically be conducted at a slower pace than with other witnesses, these interviews will usually involve more breaks and pauses. Many vulnerable witnesses will not be able to concentrate for as long a time as can other witnesses and some of them will also require regular comfort breaks. Where appropriate, the interviewer should agree with the witness a simple sign (e.g. the use of a special card) that the witness can use to request a break. This will also help to empower the witness and might help to reduce any power differential that they perceive in the interaction.

Phase one: establishing rapport (including engaging and explaining)

Explaining the formalities

3.186 Firstly, it is necessary when video recording the interview to check that the equipment is turned on and that all people in the room can be clearly seen on the monitor through the camera with the wide-angle lens where two cameras are in use and that the witness is appropriately framed in the main camera image (see Appendix E). Next, the interviewer should say out loud the day, date, time and place (not the detailed address) of the interview and give the relevant details of all those present.

Building rapport

3.187 A substantial rapport phase will allow the interviewer to become more familiar with the witness's preferred method of communicating and to become more competent with this method. The focus should be on the witness's ability rather than disability. This phase should allow earlier decisions made during the planning phase to be revised as necessary. Explanation can be provided as to the nature of a video recorded interview, and the role of the interpreter or intermediary if they are to be present.

3.188 Another major aim of the rapport phase is to help the witness, and indeed the interviewer, to relax and feel as comfortable as possible. Typically, the witness should be invited to discuss 'neutral' events in their life (for example, interests

or hobbies where this is appropriate for that witness). The use of open-ended questions at this stage, if appropriate, should help the witness understand at the outset that detail is required. It will encourage them to talk at length. It is at this stage in the interview that the interviewer can supplement their knowledge of the witness's social, emotional and cognitive development. This should help an interviewer to adapt their style (questions and use of language) of interviewing to the needs of the witness. As interviewers become more familiar with interviewing vulnerable witnesses, they may become tempted to shorten their rapport phases. This temptation should be resisted since, while the interviewer may now be more familiar with such interviews, the witnesses will not be.

3.189 Within the main body of the interview and, if an interview is being video recorded, it is important that any discussion of neutral topics in the rapport phase is completed within a relatively short space of time. Interviewers should remember that a lengthy rapport phase may result in some vulnerable witnesses getting:

- tired before they are asked to provide an account. This could have an adverse impact on the quality of their evidence; and
- confused about the purpose of the interview. This could increase in their anxiety.

3.190 If the interview plan suggests that discussing neutral topics for a lengthy period of time may be beneficial (e.g. with witnesses with a learning disability or some traumatised witnesses), it should take place as part of witness preparation before the interview commences.

3.191 Interviewers should be aware that it is neither desirable nor essential to discuss neutral topics in every interview. Where a vulnerable witness is anxious to begin their account of the alleged incident(s) as soon as possible, a discussion of neutral topics could be counterproductive by needlessly prolonging the rapport phase thus increasing their anxiety levels. In any event, rapport should not be regarded as something that is confined to the first phase of an interview: it begins when the interviewer first meets the witness and continues throughout the interview.

3.192 At an early point in the rapport phase the interviewer should briefly mention the reason for the interview in a way that does not refer directly to an alleged offence. For example, it could be appropriate for the interviewer to say that they would like to talk about something that the witness has already told someone else or because something seems to have been making the witness unhappy. Interviewers should be aware that, while some witnesses will from the outset be very clear concerning what the interview is about, others will not.

3.193 Some witnesses may feel that their initial, lawful co-operation with a person who subsequently committed an offence may make them blameworthy. The interviewer should also bear in mind that some vulnerable witnesses will assume that, because they are being interviewed, they must have done something wrong. The interviewer might need to reassure the witness on this point but promises or predictions should not be made about the likely outcome of the interview. So far as possible, the interview should be conducted in a 'neutral' atmosphere with the interviewer taking care not to assume, or appear to assume, the guilt of an individual whose alleged conduct may be the subject of the interview.

3.194 Being interviewed is an unusual occurrence for most people who, in addition, are probably unused to conversing with someone who could be questioning what they are communicating. This is particularly so in an interview with a stranger who is also in authority. A witness could enter the interview confused about its purpose, anxious about its process and outcome, and possibly distressed by prior events. Also, some witnesses may not comprehend why they are being interviewed about embarrassing, painful experiences they may have been told to keep quiet about.

3.195 Some witnesses may be unhappy, or feel shame or resentment about being questioned, especially on personal matters. In the rapport phase, and throughout the interview, the interviewer should convey to the witness that they have respect and sympathy for how the witness feels. A witness may be apprehensive about what may happen after the interview if they do provide an account of what happened. Such worries should be addressed.

3.196 It may be that some vulnerable witnesses do not perceive the need to produce full and detailed accounts of their experiences since this may not normally be required by the people around them in their normal environment. Therefore, the need for a full account should be explained without putting undue pressure on the witness. When discussing 'neutral' events, the witness can be encouraged, if appropriate, to provide free recall and to appreciate that it is the witness who has the information. It may well prove problematic to attempt to proceed with an interview until rapport has been established. Some witnesses are not used to relating to strangers. Indeed, many are taught not to do so. Should establishing rapport prove difficult, it may be preferable to postpone the interview rather than proceeding with an interview that may well turn out to be of no benefit.

Ground rules

3.197 The interviewer should provide an explanation of the outline of the interview that is appropriate to the abilities of the witness. Typically, the outline will take the form of the interviewer asking the witness to give a free narrative account of what they remember and following this with a few questions in order to clarify what has been said. Witnesses should also be told that:

- if the interviewer asks a question they do not understand or asks a question that they do not know the answer to, they should say so; and
- if the interviewer misunderstands what they have said or summarises what has been said incorrectly then they should point this out.

3.198 It should be explained that the interviewer might take a few brief notes.

3.199 It should be made clear that the witness can ask for a break at any time. These may be required more frequently than with other witnesses. Practice suggests that 20 minutes is likely to be the maximum period that most witnesses with learning disabilities are able to concentrate. In order for witnesses to have some control over a request for a break and yet not have to make a verbal request, a 'touch card' can be useful; that is, a card is placed beside witnesses which they can touch when they want a break. The break can provide an opportunity for refreshment. Such breaks should never be used as an inducement to witnesses.

3.200 Interviewers should be aware that asking someone to provide information frankly and in detail about personal matters (e.g. involving sex) is asking the person to discuss something in a manner they have learned to avoid. The interviewer should inform the witness why they are being asked to give a detailed account and that doing so, in that situation, is not breaking with convention. Interviewers should also be aware that some witnesses may prefer, initially, to write rather than say aloud sensitive words or phrases. The witness should be advised of the option to write things down at certain points of the interview.

Oaths and the importance of telling the truth

3.201 Where a decision is taken to record an interview with a vulnerable witness on video, there should not be an attempt to get the witness to swear an oath, either before or after an interview. If the witness goes on to give evidence at court, the court will decide whether an oath should be administered retrospectively or whether the witness is to give unsworn evidence.

3.202 Where there is an issue as to whether the vulnerable witness understands the value and importance of telling the truth, the interviewer can obtain assurances from the witness on these points, as is current practice for child witnesses. Note that these procedures should only be employed where questions regarding witness competency might be raised at trial. This is not an issue for all adult witnesses who have disabilities or a mental disorder.

3.203 In those cases where discussion of truth and lies is appropriate, it is important to demonstrate that the witness understands the difference between the two. The witness could be asked to give examples of truth and lies. If this is not possible, the interviewer can ask some questions about this difference. If such questions are asked, they should follow the guidance set out elsewhere on styles of questioning and focus on an intent to deceive rather than mere mistakes (NB: where the use of the examples set out in Chapter 2 is contemplated, they should be modified in a way appropriate to the witness's communication). After such questions, it is appropriate to conclude with a statement like: 'Please tell me all you can remember about what happened. Don't make anything up or leave anything out. It is very important to tell the truth'.

Phase two: initiating and supporting a free narrative account

3.204 Witnesses will normally expect the interviewer, who is usually an authority figure to them, to control the interview. However, a witness interview requires that information flows from the witness to the interviewer. Some vulnerable witnesses will be under the false impression that the interviewer already knows much or all that happened and that their role, being eager to please, is merely to confirm this. It is crucial that interviewers inform witnesses, in ways that the they understand, that (i) they were not present at the event(s), (ii) they do not yet know what occurred, and (iii) supplying detail is important.

3.205 If it is deemed appropriate, having established rapport, to continue with the interview then the witness should be asked when possible to provide in their own words an account of the relevant event(s) (note that the purpose of the interview should have been appropriately explained to the witness during the rapport phase). Only the most general open-ended questions should be asked in this phase as guidance to the witness concerning the general area of life experience relevant to the investigation (e.g. 'Do you know why you are here today?'; 'Is there anything that you would like to tell me?'). This type of question is one that enquires in a non-specific manner. If the witness responds in a positive way to such questions then the interviewer can encourage the witness to give a free narrative account of events. During this phase, the interviewer's role is to act as a facilitator not an interrogator. Research findings consistently have shown that improper questioning

of vulnerable witnesses is a greater source of distortion of their accounts than are memory deficits. Therefore, it is essential to avoid using improper questioning in the early parts of an interview. Every effort must be made to obtain information from the witness that is spontaneous and uncontaminated by the interviewer.

3.206 In the free narrative phase, the interviewer should encourage witnesses to provide an account 'in their own words' by the use of non-specific prompts such as 'Did anything else happen?', 'Is there more you can tell me?' and 'Can you put it another way to help me understand better?'. Verbs like 'tell', 'explain' and 'describe' are likely to be useful. The prompts used at this stage should not include information known to the interviewer concerning relevant events that have not yet been communicated by the witness. Research has found that in their free narrative accounts vulnerable witnesses usually provide less information than other people. Nevertheless, this information may be no less accurate. However, it is vulnerable witnesses whose accounts are likely to be most tainted by inappropriate questioning.

3.207 Many witnesses when recalling negative events may initially be more comfortable with peripheral matters and may only want to move on to more central matters when they feel this to be appropriate. Therefore, interviewers should resist the temptation prematurely to 'get to the heart of the matter'. They should also resist the temptation to speak as soon as the witness appears to stop doing so, and should be tolerant of pauses, including long ones, and silences. They should also be tolerant of what may appear to be repetitious or irrelevant information from the witness. Above all, interviewers must try to curb their eagerness to determine whether the interviewee witnessed anything untoward.

3.208 A form of active listening is needed, letting the witness know that what they have communicated has been received by the interviewer. This can be achieved by reflecting back to the witness what they have just communicated, for example: *'I didn't like it when he did that'* (witness); *'You didn't like it'* (interviewer). The interviewer should be aware of the danger of subconsciously or consciously indicating approval or disapproval of the information just given.

3.209 If the witness has communicated nothing of relevance regarding the purpose of the interview, the interviewer should consider, in the light of the plans made for the interview, whether to proceed to the next phase of the interview (i.e. questioning). The needs of the witness and of justice must both be considered. Exceptionally, consideration may be given to now concluding the interview by moving directly to the closure phase.

Compliance

3.210 Some vulnerable witnesses may be particularly compliant in that they will try to be helpful by going along with much of what they believe the interviewer 'wants to hear' and/or is suggesting to them. This is particularly so for witnesses who believe the interviewer to be an authority figure. Some witnesses may also be frightened of authority figures. This may also be linked to cultural attitudes in relation to authority, for instance for someone from an older generation or from another culture. Interviewers should be alert to this issue in cases where the witness originates from a country where there is a more authoritarian state particularly where the witness is a refugee or asylum seeker. This issue is also relevant in cases of sexual exploitation involving adults and children. In addition, this warrants consideration in a Northern Ireland specific context where, despite the progress of recent years, there will still be a variety of views about and reaction to the police or those who are seen to represent 'the State'. The interviewer should, therefore, try not to appear too authoritative but should be confident and competent as a means of reassuring the witness that they can be relied on.

3.211 Many vulnerable witnesses are very concerned to present themselves in the best possible light and many might try to appear as 'normal' as possible by, for example, pretending to understand when they do not. This is something we all do. Even though they may not understand a question, vulnerable witnesses may prefer to answer it than to say that they do not understand. Saying that one does not understand a question can be taken to be implying that the interviewer or witness is at fault. Given that some vulnerable witnesses will prefer to avoid these implications, it is appropriate to reassure them by re-emphasising the ground rules at appropriate points during the interview.

3.212 An emerging finding is that witnesses who feel empowered may well have less of a need to demonstrate compliance. This is one reason why allowing the witness some control of the interview is likely to be beneficial.

3.213 Interviewers should clearly explain in the rapport phase that because they were not present at the event(s) they may unwittingly ask questions that witnesses do not understand or questions that they cannot answer. They should explain that if they do ask such questions they would be very happy for witnesses to indicate (perhaps by the use of a red card) that they do not understand, remember or know the answer. Vulnerable witnesses may benefit from practice at this before the interview commences. Interviewers should also make it clear that, if the witness does not know the answer to a question, 'I don't know' responses are welcome. This will also help to avoid witnesses feeling under pressure to confabulate (i.e. to fill in parts of the event that they did not witness or cannot remember) which is otherwise likely to be the case for some vulnerable witnesses.

3.214 If communication becomes difficult, it may be helpful, where appropriate, for the interviewer to say 'Can you think of a way to tell me more?', 'Can you think of a way to show me what you mean?' or 'Is there a way I can make this easier for you?'.

3.215 If the witness has communicated something that the interviewer feels needs to be clarified but the witness at present seems reluctant or unable to do so, it may be better that the interviewer returns to the point later in the interview rather than be insistent.

Acquiescence

3.216 Research has consistently found that many vulnerable witnesses acquiesce to 'yes/no' questions. That is, they answer such questions affirmatively with 'yes' regardless of content. This can occur even when an almost identical 'yes/no' question is asked subsequently but this time with the opposite meaning. This tendency to respond positively to every question occurs particularly frequently with some witnesses with a learning disability. However, it is not solely due to the witness's vulnerability. The way that the interview is conducted (e.g. in an overly authoritative way) and the nature of the questions asked (e.g. suggestive or too complex) will also influence the extent of unconditional positive responding.

3.217 Sometimes 'nay-saying' (repeatedly responding with 'no') will occur particularly for questions dealing with matters that are socially disapproved of or are social taboos.

3.218 Acquiescence is one of the major reasons why interviewers should do their very best to avoid using 'yes/no' questions even though they are used frequently in everyday conversations. Questions that have a 'yes/no' format can very often be transformed into questions that have an 'either/or' format. Research has found that 'either/or' questions, by avoiding 'yea-saying' or 'nay-saying', more frequently elicit reliable responses from vulnerable witnesses than do 'yes/no' questions. Even so, a small proportion of witnesses seem always to choose the latter of the two alternatives offered by 'either/or' questions. If a witness appears to be doing this, the interviewer should phrase some of the 'either/or' questions so that the first alternative is the one that is more likely to fit in with the account the witness is giving.

3.219 Similarly, if some 'yes/no' questions have to be used, they should be phrased so that sometimes 'yes' and sometimes 'no' would be the response that fits in better with the account the witness is giving.

Phase three: questioning

Prior to the questioning phase of the interview

3.220 Before asking the witness any questions, it may be beneficial to outline for them what is expected of them in this phase of the interview. It is helpful for the interviewer to tell the witness that they will now be asking them some questions, based on what they have already communicated in the free narrative phase, in order to expand and clarify on what they have said. It is also beneficial to reiterate a number of the ground rules outlined in the rapport phase of the interview, for example to explain to the witness that detail is required or this is a difficult task which requires a lot of concentration, and to point out that it is acceptable to say 'I don't know' or 'I don't understand' to a question.

General approach

3.221 During the free narrative phase of an interview, most witnesses will not be able to recall everything relevant that is in their memory. Many vulnerable witnesses because, for example, they are frightened or stressed, or have a learning disability, will not be that skilled at accessing their own memory as is required by the free narrative phase. Therefore, their accounts could greatly benefit from the asking of appropriate questions that assist further recall. However, both research and good practice have found that vulnerable witnesses may well have great difficulty with questions unless these:

- are simple;
- do not contain jargon;
- do not contain abstract words and/or abstract ideas;
- contain only one point per question (see Chapter 4 for more information about multiple questions);
- are not too directive/suggestive; and
- do not contain double negatives.

3.222 In addition, interviewers need fully to appreciate that there are various types of question which vary in how directive they are. The questioning phase should, whenever possible, commence with open-ended questions and then proceed, if necessary, to specific-closed questions. Forced-choice questions and leading questions should only be used as a last resort. When questioning a witness, interviewers may wish to ask the various types of question about one issue before proceeding to ask questions about another. This would be good practice in terms of how memory storage is organised. When this occurs, the questioning on each issue should normally begin with an open-ended question although some particularly vulnerable witnesses may not be able to cope with such questions and specific-closed questions might be necessary.

3.223 When posing questions, interviewers should try to make use of information that the witness has already provided and words/concepts that the witness is familiar with (e.g. for time, location, persons). Some vulnerable witnesses have difficulty understanding pronouns (e.g. he, she, they); in these circumstances it is better for interviewers to use people's names wherever possible.

3.224 Some vulnerable witnesses will experience difficulty if, without warning, the interviewer switches the questioning to a new topic. To help witnesses, interviewers should indicate a topic change by saying, for example, 'I'd now like to ask you about something else.'.

3.225 Many vulnerable witnesses will have difficulty with questions unless they are simple, contain only one point per question, do not contain abstract words or double negatives, and lack suggestion and jargon. Some vulnerable witnesses may well misinterpret terms that the interviewer is familiar with. For example, they may think that someone 'being charged' involves payment or that 'defendant' means a person who defended themselves against an assault.

3.226 It is important that interviewers check that witnesses understand what has just been said to them by asking the witness to convey back to the interviewer (where this is possible) what they understand the interviewer to have just said. Merely asking the witness 'Do you understand?' may result simply in an automatic positive response. If they do not understand a question, some vulnerable witnesses will nevertheless attempt to answer it to the best of their ability by guessing at what is meant possibly producing an inappropriate reply.

3.227 Some vulnerable witnesses will respond to a question from, or a comment made by, an interviewer by repeating the last few words in the utterance (echolalia). Appropriate methods for managing this depend on the individual. Interviewers should take appropriate advice (e.g. from a carer) on how to manage it while planning the interview.

3.228 If, for the sake of clarity, interviewers decide to repeat one or more questions later on in the interview, even with changed wording, they should explain that it does not indicate that they were unhappy with the witness's initial responses but that they just want to check their understanding of what the witness said (for example, 'I just want to make sure that I've understood what you said about the man's jacket. What colour did you say it was?'). Otherwise, some vulnerable witnesses may believe that the questions are being repeated solely because their earlier responses were incorrect or inappropriate, or that they were not believed.

3.229 Some vulnerable witnesses may also have a limited understanding of the relationship between negative events, their causation, and who is responsible.

3.230 Even if an event was an unforeseeable accident or 'an act of God', some vulnerable witnesses will believe that someone must be held responsible. Some may even take the blame, thinking that the interviewer (an authority figure) will like them more if they do.

3.231 The questioning of vulnerable witnesses requires extensive skill and understanding on the part of interviewers. Incompetent interviewers can cause vulnerable witnesses to provide unreliable accounts. However, interviewers who are able to put into practice the guidance on questioning contained in this document will provide witnesses with much better opportunities to present their own accounts of what really happened.

Open-ended questions

3.232 Open-ended questions are ones that are worded in such a way as to enable the witness to provide an unrestricted response. These also allow the witness to control the flow of information. This type of questioning minimises the risk that interviewers will impose their view of what happened. Such questions usually specify a general topic which allows the witness considerable freedom in determining what to reply. Research and practice show that the most reliable and detailed answers from witnesses of all ages are secured from open-ended questions. It is important, therefore, that the questioning phase should begin with open-ended questions and that this type of question should be widely employed throughout the interview.

3.233 Questions beginning with the phrase 'Tell me' or the words 'Describe' or 'Explain' are useful examples of this type of question. 'You said you were… Tell me everything that you remember' is an example of an open-ended question.

3.234 Open-ended questions can also be used to invite the witness to elaborate on incomplete information provided in the preceding free narrative phase. For example, 'You've already told me that the person who hit you was a man. Describe him for me.'. For a witness who has communicated very little in the free narrative phase, a helpful question could be of the form 'You said you were not happy. Tell me what makes you unhappy?'.

3.235 If the witness responds to open-ended questions, the interviewer should try to avoid interrupting even if the witness is not providing the expected type(s) of information. Interrupting the witness disempowers them and suggests that only short answers are required. If a witness is communicating information that the interviewer does not understand, this should be returned to only when the witness has finished responding to that question.

3.236 When being questioned, some witnesses may become distressed. If this occurs, the interviewer should consider moving away from the topic for a while and, if necessary, reverting to an earlier phase of the interview (e.g. the rapport phase). Shifting away from and then back to a topic the witness finds distressing and/or difficult may need to occur several times within an interview.

3.237 Some vulnerable witnesses may not have the usual understanding of time. Wherever possible, the planning phase should have focused on the witness's likely grasp of time, for example in terms of times of day, days of the week or the length of a week, month or year. Interviewers can assist witnesses by using words/phrases for time that they understand. If a relevant event may have occurred repeatedly, some witnesses might find it easier to describe the general pattern of these events before recalling in detail specific episodes. Their account of the general pattern may well facilitate recall of specific episodes. Therefore, interviewers should not prematurely ask questions about specific episodes. Most witnesses, whether vulnerable or not, will recall correct information about events that are not in the same time order as things actually happened. Some vulnerable witnesses may not have needed to rely in their everyday lives on a good sense of time and, therefore, questions about time will need to be put to them in ways they can understand, for instance by reference to fixed points in their own lives such as meal breaks, public festivals or holidays.

Specific-closed questions

3.238 A closed question is a question that closes down a witness's response and, therefore, allows only a relatively narrow range of responses to be obtained where the response usually consists of one word or a short phrase. Closed questions can, therefore, be appropriate or inappropriate in nature depending on the quality of the information likely to be obtained from the witness. Specific-closed questions are appropriate and serve to ask in a non-suggestive way for extension or clarification of information previously supplied by the witness. Specific-closed questions vary in their degree of explicitness and it is always best to begin with the least explicit version of the question. Therefore, a vulnerable adult witness in a sexual assault investigation may have responded to an open-ended prompt by mentioning that a named man had climbed into his bed. A specific-closed but non-leading, follow-up question might be 'What clothes was he wearing at the time?'. If this yielded no clear answer, a further, more explicit question might be 'Was he wearing any clothes?'.

3.239 Specific-closed questions can ask in a non-suggestive way for extension and/or clarification of information previously provided by the witness. For example, for a witness who has already provided information that a young man in the high street was wearing a jacket, a specific yet non-suggestive question could be 'What colour was the man's jacket?'.

3.240 Examples of specific-closed questions are those that begin 'Who', 'What', 'Where', 'When', and 'Why'. Questions involving the word 'why' (or similar utterances, e.g. 'So how come...?') may be interpreted by vulnerable witnesses as attributing blame to them and should, therefore, be avoided wherever possible. Also to be avoided is repeating a question soon after the witness has provided an answer to it (including 'Don't know'). Witnesses may well interpret this as a criticism of their original response and accordingly they may provide a different response closer to what they believe the interviewer wants them to give.

3.241 Although some particularly vulnerable witnesses may not be able to provide information in a free narrative phase nor be able to respond to open-ended questions, they may be able to respond to more specific questions. However, interviewers must be aware that specific-closed questions should not unduly suggest answers to the witness. An example of a specific-closed, yet non-leading, question for an institutionalised witness who has, as yet, provided no relevant information could be 'What happens at bath time?'.

3.242 For some vulnerable witnesses, open-ended questions will not assist them that much to access their memory, whereas specific-closed questions may well do so. One problem here is that the more narrow and focused specific-closed questions become, the easier it is for them to be suggestive.

Forced-choice questions

3.243 Forced-choice questions are ones that provide the witness with a limited number of alternative responses. For example, 'Was the man's jacket black, another colour, or can't you remember?'. As long as the question provides a number of sensible and equally likely alternatives, it would not be deemed suggestive. Some vulnerable witnesses may find such closed questions particularly helpful. However, at the beginning of the use of forced-choice questions, interviewers should try to avoid using ones that contain only two alternatives (especially yes/no questions) unless these two alternatives contain all possibilities (e.g. 'Was it daytime or night-time?'). If questions containing only two alternatives are used, these should be phrased so that they sometimes result in the first alternative being chosen and sometimes in the second alternative. It should be remembered that a third alternative, such as "can't you remember?" or "don't you know?" can be offered with all forced choice questions as there may be occasions where there are only two possible alternatives but the witness cannot recall or remember.

3.244 Some vulnerable witnesses may only be able to respond to forced-choice questions that contain two alternatives. Even in such circumstances it should still be possible for interviewers to avoid an investigative interview being made up largely of such questions. However, such interviews are likely to require special expertise and extensive planning especially regarding the questions to be asked.

3.245 If forced-choice questions are to be used, it is particularly important to remind the witness that 'Don't know', 'Don't understand' or 'Don't remember' responses are welcome and that the interviewer does not know what happened. If a witness replies 'I don't know' to an 'either/or' question (e.g. 'Was the car large or small?'), interviewers should try to avoid then offering a compromise 'yes/no' question (e.g. 'If it wasn't large or small, would you say it was medium size?') that the witness may merely acquiesce to.

Leading questions

3.246 Put simply, a leading question is one that implies the answer or assumes facts that are likely to be in dispute. Of course, whether a question is leading depends not only on the nature of the question (where the answer is implicit in the way the question is worded) but also on what the witness has already communicated in the interview. An example of a question that is leading by virtue of the very nature of the words used would include 'I bet that hurt, didn't it?'. An example of a leading question that depends on what the witness has already communicated in the interview would include 'Where did he punch you?' when the witness said previously in the interview that a male assailant 'hit' them without using the word 'punch'.

3.247 When a leading question is improperly put to a witness giving evidence at court, opposing counsel can make an objection to it before the witness replies. This is not usually possible during video- or audio-recorded interviews but subsequent objections could be made which may result in parts of the recording being edited out.

3.248 In addition to the legal objections, psychological research indicates strongly that witnesses' responses to leading questions tend to be determined more by the manner of questioning than by valid remembering. Some vulnerable witnesses may be more willing to respond to 'yes/no' questions with a 'yes' response. Therefore, if questions permitting only a 'yes' or 'no' response are asked, these should be phrased so that those on the same issue sometimes result in a 'yes' response and sometimes a 'no' response.

3.249 It cannot be overemphasised that responses to leading questions referring to central facts of the case that have not already been described by the witness in an earlier phase of the interview are likely to be of very limited evidential value in criminal proceedings. If a leading question produces an evidentially relevant response, particularly one that contains relevant information not led by the question, interviewers should take care not to follow this up with further questions that might have the effect of leading the witness. Instead, they should revert to the 'neutral' modes of questioning described above.

3.250 There are circumstances in criminal proceedings where leading questions are permissible. For example, a witness is often led into their testimony by being asked to confirm their name or some other introductory matter as these matters are unlikely to be in dispute. More central issues may also be the subject of leading questions if there is no dispute about them. However, at the interview phase, it may not be known which facts will be in dispute.

3.251 Courts also accept that it may be impractical to ban leading questions. This may be because the witness does not understand what they are expected to tell the court without some prompting as may be the case for a witness with a learning disability.

3.252 As the courts become more aware of the difficulties of obtaining evidence from vulnerable witnesses and of counteracting the pressures on witnesses to keep silent, a sympathetic attitude may be taken towards leading questions deemed necessary. A leading question that succeeds in prompting a witness into spontaneously providing information beyond that led by the question will normally be acceptable. However, unless there is absolutely no alternative, the interviewer should never be the first to suggest to the witness that a particular offence was committed or that a particular person was responsible. Once such a step has been taken, it will be extremely difficult to counter the argument that the interviewer 'put the idea into the witness's head' and that their account is, therefore, tainted.

3.253 However inappropriately leading or suggestive some questions might be, some vulnerable witnesses will go along with them and may produce nonsensical replies. Such incompetence by the interviewer will inappropriately call into question the competency of the witness.

Understanding what the witness is trying to convey

3.254 Some vulnerable witnesses will have speech or other means of communication that other people find difficult to understand. At appropriate points in the interview, and especially in the closure phase, the interviewer should provide the witness with a recap of what the interviewer believes the witness to have communicated. When the meaning of a witness's communication is unclear, they could be asked, for example, to 'Put it another way' or 'Can you think of another way of telling me?'.

3.255 Interviewers need to be aware that the common human frailty of ignoring information contrary to one's own view may be even more likely to affect their interviews with vulnerable witnesses whom they are having difficulty understanding and/or may believe to be less competent than other people. Research on interviewing has consistently found that interviewers ignore information that fails to fit in with their assumptions about what may have happened. One important role for the second interviewer is to check that the lead interviewer does not ignore important information provided by the witness.

Topic selection

3.256 Within the questioning phase of the interview, the interviewer should subdivide the vulnerable witness's account into manageable topics or episodes, and seek elaboration on each area using open-ended and then specific-closed questions as outlined in the previous paragraphs. Each topic/episode should be systematically dealt with until the witness is unable to provide any more information. Interviewers should try to avoid topic-hopping (i.e. rapidly moving from one topic to another and back again) as this is not helpful for the witness's remembering processes and may confuse them.

3.257 Good questioning should also avoid the asking of a series of predetermined questions. Instead, the sequence of questions should be adjusted according to the witness's own retrieval processes. This is what 'witness-compatible questioning' means. Each individual will store information concerning the event in memory in a unique way. Therefore, for maximum retrieval/information gain, the order of the questioning should resemble the structure of the witness's knowledge of the event and should not be based on the interviewer's notion or a set protocol. It is the interviewer's task to deduce how the relevant information is stored by the witness (via the free narrative account) and to organise the order of questions accordingly.

Misleading statements

3.258 Vulnerable witnesses can on occasion provide misleading accounts of events; these are often the result of misunderstandings or misremembering rather than deliberate fabrication. The most common cause of these misunderstandings is the interviewer failing to ask appropriate types of question or reaching a premature conclusion that the interviewer then presses the witness to confirm.

3.259 Vulnerable witnesses, like any other witness, can on occasion be misleading in their statements, either by fabricating allegations or by omitting evidentially important information from their answers. Where inconsistencies in the witness's account give rise to suspicion, interviewers should explore these inconsistencies with the witness after they have completed their basic account. Witnesses should only be challenged directly over an inconsistency in exceptional circumstances and even then only when it is essential to do so. Rather, such inconsistencies should be presented in the context of puzzlement by the interviewer and the need to be quite clear what the witness has said. On no account should the interviewer voice their suspicions to the witness or label a witness as a liar: there may be a perfectly innocuous explanation for any inconsistency.

3.260 In evaluating the witness's account, interviewers should not rely on cues from the witness's behaviour as guides to the reliability or otherwise of the witness's statements.

3.261 Where a witness with a learning disability uses language or knowledge, particularly of sexual matters, that appears to be inappropriate for them, specific questions can be asked to try to locate the source of that knowledge. Similarly, if it is suspected that a witness alleging sexual abuse may have been exposed to sexually explicit films, videos, internet sites or magazines, specific questions should be used to explore whether parts of the witness's account could conceivably be derived from such sources. It is important that all such questions should be reserved for the end of the formal questioning so as not to disrupt the witness's narrative.

Phase four: closing the interview

3.262 In this final main phase, interviewers should provide an account of what the witness has said during the interview. This should be done as much as possible in the witness's own words. This allows the witness to check the interviewer's recall of what they have said for accuracy. Care should be taken not to convey any impression of disbelief. The interviewer must explicitly tell the witness to correct them if they have missed anything out or have got something wrong. The interviewer should not "over summarise". Where summaries have been conducted appropriately throughout the interview, there is no need to provide a complete summary at the closing phase.

Closure

3.263 The interviewer should always try to ensure that the interview ends appropriately. Although it may not always be necessary to pass through each of the above phases before going on to the next, there should be good reason for not doing so. Every interview must have a closure phase. In this phase, it may be a useful idea to discuss again some of the 'neutral' topics mentioned in the rapport phase.

3.264 In this phase, regardless of the outcome of the interview, every effort should be made to ensure that the witness is not distressed but is in a positive frame of mind. Even if the witness has provided little or no information, they should not be made to feel that they have failed or disappointed the interviewer. However, praise or congratulations for providing information should not be given.

3.265 The witness should be thanked for their time and effort, and asked if there is anything more they wish to communicate (e.g. by saying to the witness 'Is there anything else you want to say?', 'Is there anything you think you've missed out?' or 'Is there anything else you think I should know?').

3.266 An explanation should be given to the witness of what, if anything, might happen next but promises that cannot be kept should not be made about future developments.

3.267 The witness should always be asked if they have any questions and these should be answered as appropriately as possible. It is good practice to give the witness (or, if more appropriate, an accompanying person) a contact name and telephone number in case the witness later decides that they have further matters they wish to discuss with the interviewer.

3.268 Not only in closing the interview but also throughout its duration, the interviewer must be prepared to assist the witness to cope with the effects on themselves of giving an account of what may well have been greatly distressing events (and about which the witness may feel some guilt).

3.269 The aim of closure should be that, as far as possible, the witness should leave the interview in a positive frame of mind. In addition to the formal elements, it will be useful to revert to neutral topics discussed in the rapport phase to assist this. It is normal to complete a video recorded interview by stating the end time.

Evaluation

3.270 Evaluation should take two primary forms:

- evaluation of the information obtained; and
- evaluation of the interviewer's performance.

Evaluation of the information obtained

3.271 After the interview has concluded, the interview team will need to make an objective assessment as to the information obtained and evaluate this in light of the whole case. For example, are there any further actions and/or enquires required, or what direction should the case take?

Evaluation of interviewer's performance

3.272 The interviewer's skills should be evaluated. This can take the form of self-evaluation with the interviewer examining the interview for areas of good and poor performance. This should result in a development plan. The interview could also be assessed by a supervisor and/or someone who is qualified to examine the interview and give good constructive feedback to the interviewer, highlighting areas for improvement. This should form part of a staff appraisal system (see tier 4 of ACPO's National Investigative Interviewing Strategy (ACPO, 2009)).

Post-interview documentation and storage of recordings

3.273 The interviewer should complete the relevant paperwork as soon as possible after the interview is completed including the Index to Video Recorded Interview referred to in Appendix G. A statement dealing with the preparation and conduct of the interview should be made while the events are still fresh in the interviewer's mind.

3.274 Recordings should be stored as recommended in Appendix H.

Further interviews

3.275 One of the key aims of video recording early investigative interviews is to reduce the number of times a witness is asked to tell their account. However, it may be the case that even with an experienced and skilful interviewer, the witness may provide less information than they are capable of divulging. A supplementary interview may, therefore, be necessary and this, too, should be video recorded, if possible. Consideration should always be given to whether holding such an interview would be in the witness's interest. The reasons for conducting supplementary interviews should be clearly articulated and recorded in writing. The PPS should be consulted if necessary.

3.276 With particularly vulnerable witnesses, a decision could be made at the planning phase to divide the interview into a number of sections to be conducted by the same interviewer on different days or at different times on the same day with rapport and closure being achieved each time.

Identification procedures

3.277 Where a video recorded interview has been conducted by virtue of this chapter, the production of facial composites using E-FIT or other systems, or the production of an artist's impression should also be video recorded. This will enable the court to hear the evidence from the witness in the same medium as the main evidence in chief and show how any new evidence has come about. This would give confidence to the evidence-gathering process and reducing the need for the witness to give additional evidence in chief in the witness box or by live link. Staff carrying out these procedures should be suitably trained to interview and record the evidence in line with this guidance (see Appendix J).

Therapeutic help for vulnerable adult witnesses

3.278 While vulnerable adult witnesses may be judged by the investigating team and/or by those professionals responsible for their welfare, to require therapeutic help prior to giving evidence in criminal proceedings, it is important to recognise the individual's right to exercise choice. It is vital that professionals undertaking therapy with prospective vulnerable adult witnesses prior to a criminal trial adhere to the official guidance contained in Chapter 8.

3.279 The PPS and those involved in the prosecution of an alleged offender do not have authority to prevent a vulnerable adult witness from receiving therapy. Whether a witness should receive therapy before the criminal trial is not a decision for the police or the PPS. However, the police and the PPS must be made aware that therapy is proposed, is being undertaken or has been undertaken so that consideration can be given as to whether or not the provision of such therapy is likely to impact on the criminal case. At all times, the importance of not coaching or rehearsing the witness in matters of direct evidential value must be borne in mind by the professional undertaking therapeutic work with the witness (see Appendix D).

Special interviewing techniques

3.280 At present, not a lot is known about techniques other than those described in this guidance that may further assist vulnerable witnesses. Witnesses who find verbal communication difficult may sometimes benefit from acting out or drawing the information that they wish to convey. However, in such instances it is very important that the interviewer checks in an appropriate way with the witness that the interviewer has correctly understood what the witness was trying to convey.

3.281 The use of items similar to those involved in the to-be-remembered event may assist recollection. However, they may also cause the witness distress. Furthermore, it may not be certain which items were actually involved and the introduction of incorrect items may mislead and/or confuse the witness. Similarly, models or toy items may be misleading if the objects they represent were not, in fact, part of the event. Some vulnerable witnesses may not realise the link between a toy or model, and the real-life object it is supposed to represent.

3.282 Whatever special techniques are being considered for use in an interview, the emphasis must be on assisting witnesses to retrieve information from their own memories rather than on suggesting things to them. Research has found that the cognitive interview procedure does seem to assist witnesses with mild learning disabilities to recall more correct information. However, this procedure should only be conducted by those who have been appropriately trained in its use including what to do if the person's recall is so vivid and powerful as to cause them (and possibly others present) distress.

The cognitive interview (CI)

3.283 This interviewing procedure was developed by cognitive psychologists and it contains, as well as procedures based on good communication skills (many of which have been described above), a number of procedures specifically designed to assist witnesses to access their memories. These procedures are usually referred to as:

- mental reinstatement of context;
- report everything;
- change the temporal order of recall; and
- change perspective.

3.284 A number of professionals who have worked with vulnerable adult witnesses recommend use of the cognitive interview (CI). However, research has found that, unless the training of interviewers who attempt to use a CI has been appropriate,

they will fail to use this technique effectively and could confuse the witness. Some witnesses may not be able to benefit from all of the CI procedures (e.g. witnesses with autism may well not be able to 'change perspective').

3.285 Interviewers and their managers need to be aware that techniques that assist witnesses to produce more recall will result in interviews that last longer. Surveys of those who use the CI have found that they often report it to be effective. However, their workloads and their supervisors put them under pressure not to conduct interviews that are time-consuming. Such pressures should be resisted for interviews with vulnerable witnesses.

3.286 Further information about the procedures contained in the CI can be found in Part 4B of this guidance.

Other interview techniques

3.287 Other techniques to assist witnesses to give accounts are being developed. These could be used in interviews carried out for the purposes of this guidance provided that evidential considerations are borne in mind, interviewers have been specifically trained to use them, and agreement is given by senior managers or an interview adviser (tier 5 of ACPO's National Investigative Interviewing Strategy (ACPO, 2009)) after discussion of the issues involved.

3.288 A process of supportive reconstruction may be very helpful in assisting some witnesses with mental disorder to recall situations and memories. This involves working through repeatedly the context of the memory, reflecting back what has been established so far and cueing witnesses to relate what happened next (the phenomenological approach, i.e. events perceptible to the senses and relating to remarked phenomena or events). If this technique is employed, it is essential that the interviewer follows and does not lead the witness.

3.289 When free narrative and questioning have produced little information of relevance but suspicion remains high, a facilitative style of questioning could be used with witnesses who are particularly reticent. This can involve asking about nice/nasty things, good/bad people, what the witness would like to change in their life, or similar techniques. For those who have been put under pressure not to disclose certain matters, an open-ended discussion of secrets may be introduced. Such methods may be very successful for those trained in these styles of questioning. If the interviewer avoids any suggestive questioning and succeeds in encouraging the witness to give an account, there should be no reason why evidence gained in this way should not be considered by the courts.

Witnesses who become suspects during the interview

3.290 It may happen that a witness who is being interviewed comes under suspicion of involvement in a criminal offence, perhaps by uttering a self-incriminating statement. Any decision on an appropriate course of action in these circumstances should involve taking into account the seriousness of the crime admitted and weighing it against the seriousness of the crime under investigation.

3.291 Where the priority is to obtain evidence from the person as a witness, the interview can proceed.

3.292 If it is concluded that the evidence of the witness as a suspect is highly relevant to a particular case, the interview should be terminated and the witness told that it is possible that they may be interviewed concerning these matters at a later time. Care should be taken not to close the interview abruptly in these circumstances. Instead, the witness should be allowed to complete any statement that they wish to make.

3.293 Any admission by a witness in the course of an investigative interview may not be admissible as evidence in criminal proceedings against them. Normally, a further interview would need to be carried out in accordance with the relevant provisions of the Code for the Detention, Treatment and Questioning of Persons by Police Officers (Code C of the Police and Criminal Evidence (NI) Order 1989). The Code provides, among other matters, for the cautioning of a suspect.

3.294 A witness who confesses to a criminal offence during the course of an interview may ask the interviewer for some guarantee of immunity. On no account should any such guarantee be given, however remote the prospect of criminal proceedings against the witness might seem. If the witness is to be interviewed in accordance with Code C of the Police and Criminal Evidence (NI) Order 1989), they must be cautioned and the purpose of the interview made clear.

4 Planning and conducting interviews with intimidated witnesses

Part 4A: Planning and preparing for interviews

What follows is a recommended procedure for planning and preparing for interviews with intimidated witnesses. Part 4B covers the interview itself and treats the interview as a process in which a variety of interviewing techniques are deployed in the framework of a phased approach. While what follows in this part and Part 4B should not be regarded as a checklist to be rigidly worked through, the sound framework that it provides should not be departed from by interviewers unless they have discussed and agreed the reasons for doing so with their senior manager or an interview adviser (tier 5 of the Association of Chief Police Officers' (ACPO's) National Investigative Interviewing Strategy (ACPO, 2009)). Any such agreements and the rationale underpinning them should be recorded. It may subsequently be necessary to explain such departures in court.

While this chapter deals specifically with interviewing intimidated witnesses, it should not be read and used in isolation from Chapters 2 and 3. This guidance has been written so that Chapters 2 - 4 form a complementary whole. For example, issues in relation to disability and intimidation will have an application across all vulnerable witnesses.

In preparing for interview, investigating officers must take note of the paragraph on gathering physical evidence in Chapter 1.

The importance of planning

4.1 The purpose of an investigative interview is to ascertain the witness's account of the alleged event(s) and any other information that would assist the investigation. A well-conducted interview will only occur if appropriate planning has taken place. The importance of planning cannot be overstated. The success of an interview and, therefore, an investigation could hinge on it. Even if the circumstances necessitate an early interview, an appropriate planning session that takes account of all the information available about the witness at the time, and identifies the key issues and objectives is required. Time spent anticipating and covering issues early in the criminal investigation will be rewarded with an improved interview later on. It is important that, as far as possible, the case is thoroughly reviewed before an interview is embarked upon to ensure that all issues are covered and key questions asked since the opportunity to do this will in most cases be lost once the interview(s) have been concluded.

4.2 Although the Public Prosecution Service (PPS) is not part of the investigating team and does not direct the investigation, an early meeting between the police and PPS to discuss special measures may be appropriate. The police may also seek advice from the PPS at an early stage about any other evidential issues that may affect the way in which the investigation is conducted. In some exceptional cases, the PPS may select suitably qualified counsel to advise from a very early stage.

4.3 In some cases, it may useful to obtain the assistance of an interview adviser to develop a witness interview strategy (see National Investigative Interviewing Strategy, Association of Chief Police Officers 2009).

Initial contact with intimidated victims and witnesses

4.4 The need to consider a video recorded interview will not always be immediately apparent, either to the first police officer who has contact with the witness or to other professionals involved prior to the police being informed. Even where it is apparent, the need to take immediate action in terms of securing medical attention and making initial decisions about the criminal investigation plan might be such that some initial questioning is necessary.

4.5 Any initial questioning should be intended to elicit a brief account of what is alleged to have taken place. A more detailed account should not be pursued at this stage but should be left until the formal interview takes place as described in Part 4B. Such a brief account should include where and when the event is alleged to have taken place, and who was involved or otherwise present. This is because this information is likely to influence decisions made in respect of the following aspects of the criminal investigation plan:

- forensic and medical examination of the victim;
- scene of crime examination;
- interviewing of other witnesses;
- arrest of alleged offender(s); and
- witness support.

4.6 In these circumstances, any early discussions with the witness should, as far as possible, adhere to the following basic principles:

- listen to the witness;
- do not stop a witness who is freely recalling significant events;
- where it is necessary to ask questions, they should, as far as possible in the circumstances, be open-ended or specific-closed rather than forced-choice, leading or multiple;
- ask no more questions than are necessary in the circumstances to take immediate action;
- make a comprehensive note of the discussion, taking care to record the timing, setting and people present as well as what was said by the witness and anybody else present (particularly the actual questions asked of the witness);
- make a note of the demeanour of the witness, and anything else that might be relevant to any subsequent formal interview or the wider investigation; and
- fully record any comments made by the witness or events that might be relevant to the legal process up to the time of the interview.

Availability for cross-examination: the legal position

4.7 A video recorded interview is usually only admissible as evidence in chief at trial where the person who made it is "available for cross-examination". However, there are exceptions to this general rule. The judge has discretion to allow the court to hear the pre-trial statements of witnesses who are unable to give evidence for various specified reasons. These include the fact that the witness is dead, "by reason of his bodily or mental condition unfit to attend as a witness" or does not give evidence at trial "through fear or because he or she is kept out of the way". It must be remembered, however, that the judge has the final word on whether or not the video recorded statement will be admitted.

Planning information

Overview

4.8 The planning phase of an interview with a witness involves some consideration of three types of information:

- information about the witness;
- information about the alleged offence(s); and
- information important to the investigation.

4.9 At this stage, interviewers need to have differing amounts of knowledge about each type of information. In a general sense, they need to know as much as is possible in the circumstances about the witness and a little about the alleged offence and information important to the investigation.

Definition

4.10 The statutory definition of an intimidated witness is set out in Article 5 of the Criminal Evidence (NI) Order 1999. Intimidated witnesses are those likely to experience fear or distress about testifying to such an extent that special measures are necessary to maximise the quality of their evidence.

Preliminaries

Cases involving intimidated witnesses

4.11 Cases that are likely to give rise to intimidated witnesses include:

- sexual offences (including those alleged by adults in relation to events said to have taken place in their childhood);
- domestic violence;
- murder and other serious assaults;
- culpable road deaths;
- racially motivated crime;
- homophobic crime;
- crime motivated by the perceived religious or political views of the victim;
- offences where the alleged perpetrator has a relationship of care to, or authority over, the witness;
- offences where the witness is related to the alleged perpetrator;
- offences where the witness lives in close proximity to the alleged perpetrator, or their family or associates;
- offences where the witness is elderly and/or frail;

- offences that form part of a series of incidents in which there is evidence of repeat victimisation;
- offences where the alleged perpetrator is influential in the criminal fraternity (this should not be based solely on anecdotal evidence);
- offences where the violent nature of the alleged perpetrator, or their family or associates suggests an increased likelihood of intimidation;
- offences where the alleged perpetrator, or their family or associates, have the intention and the ability to influence or interfere with the witness; and
- offences where witnesses have been, or are likely to be, subject to intimidation as a result of the behaviour of the alleged perpetrator, or their family or associates, or anyone else who is likely to be a defendant or a witness in the proceedings.

This is not intended to be an exhaustive list and each case should be judged on its merits.

4.12 While being the victim of an offence is in itself likely to increase the witness's fear and distress, it is unlikely to be sufficient on its own to categorise a witness as 'intimidated'. However, that a witness is also the victim of the alleged offence should be taken into account along with the other circumstances of the case (such as those listed above).

Support for intimidated witnesses prior to the interview

4.13 Intimidated witnesses need to feel safe, and may require support and encouragement to participate in an interview. Such witnesses should be appraised at an early stage about the possibility of having a supporter present during the interview where this is appropriate and about the pre-trial support that can be made available to them (see Chapter 5).

4.14 Intimidated witnesses should also be informed about the protection that might be available to them, including witness protection schemes where appropriate.

4.15 Where there is risk of intimidation, witnesses should be offered information about where rapid help and support can be obtained. A leaflet listing names, addresses and telephone numbers of relevant individuals and agencies should be available in each locality for distribution to witnesses.

4.16 The special measures that intimidated witnesses might be given access to at the trial should be outlined and their views ascertained in respect of them. Their views about the possibility of having a supporter present while they are giving evidence should also be sought. While interviewers are seeking these views, it is essential that the witness understands that, while their views will be listened to, access to

special measures during the trial is very much a decision for the court based on an application by the legal representative, and as such should not be taken for granted. Further details of special measures are set out in Chapter 6.

4.17 Investigators need to be alert to the possibility that a witness may not be intimidated at the time the offence is reported but that subsequent events may give rise to fear and distress later on in the criminal process that would qualify the witness for consideration for special measures.

4.18 Intimidated witnesses should be prepared for an interview as appropriate.

Consent

4.19 It is a general principle that all witnesses should freely consent to be interviewed and to have the interview video recorded. For this reason, interviewers should explain the purpose of a video recorded interview to the witness. Such an explanation should include:

- the benefits/disadvantages of having/not having the interview video recorded; and
- who may see the video recorded interview (including the alleged offender).

4.20 Interviewers should note that it is not necessary for the witness to give their consent in writing and that they should make a record of the action taken to obtain consent for a video recorded interview.

4.21 The witness should be told that, should the case proceed, whether a video recording is made or not, they may be required to attend court to answer further questions (i.e. cross-examination). Where an application is granted by the court, cross-examination may take place using a live link facility.

Information about intimidated witnesses

4.22 While circumstances will sometimes limit what can be found out about the witness prior to the interview taking place (for example, as a result of time constraints where the alleged perpetrator is in custody), as much of the following information should be obtained about the witness as is possible:

- age;
- gender;
- sexuality (where the alleged offence might contain a homophobic element);
- community or (perceived) political background (where the alleged offence might have been motivated by this);
- preferred name/mode of address;

- domestic circumstances (including whether the witness is currently in a 'safe' environment);
- relationship of the witness to the alleged perpetrator;
- any medication being taken and its potential impact on the interview;
- current emotional state (including trauma, distress, shock, depression, fears of intimidation/recrimination and recent significant stressful events experienced);
- likely impact of recalling of traumatic events on the behaviour of the witness;
- current or previous contact with public services (including previous contact with the police, or health and social care services); and
- any other relevant information or intelligence known.

Race, gender, culture and ethnic background

4.23 The witness's race, gender, culture, ethnicity and first language must be given due consideration by the interviewing team. They have a responsibility to be informed about, and take into account, the needs and expectations of witnesses from the specific minority groups in their local area. The interviewing team's knowledge of the witness's religion, culture, customs and beliefs may have a bearing on their understanding of any account given by the witness, including the language and allusions the witness may make, for example, to reward and punishment. Political beliefs should also be considered and interviewing teams should be alert to issues relating to sectarianism.

4.24 The investigating team needs to bear in mind that some witnesses may have experienced discrimination and/or oppression through their contact with government agencies and local authorities. Their experiences of racism, for example, may result in them distrusting the professionals involved in an investigative interview. Asylum-seeking witnesses and refugees may have a fear of disclosing abuse because of what may happen to them and their family.

4.25 It is also important that the investigating team considers the complexities of multiple discrimination, e.g. a homosexual witness from a minority ethnic community, and individuals' experiences of discrimination. The specific needs and experiences of dual-heritage witnesses must also be taken into account.

4.26 Some possible relevant considerations include the following (although this list is not intended to be exhaustive):

- customs or beliefs that could hinder the witness from participating in an interview on certain days (e.g. holy days) or may otherwise affect the witness's participation (e.g. when fasting);
- the relationship to authority figures within different minority ethnic groups. For example, witnesses from some cultures may be expected to show respect to authority figures by not referring to them by their first names, and by not correcting or contradicting them;
- the manner in which love and affection are demonstrated; and
- issues of shame. For example, witnesses from some cultures may be inhibited from talking about a sexual assault for fear of shaming their family.

4.27 A witness should be interviewed in the language of their choice. If a witness is bilingual, this may require the use of an interpreter. The interpreter should be selected from the PSNI register of translators and interpreters.

Other life experiences

4.28 Where the witness may have experienced abuse, neglect, domestic violence and/or discrimination based on race or disability, the interviewers must consider its potential impact on the interview. There is no single 'diagnostic' symptom of abuse or discrimination but some of the possible effects on vulnerable adult witnesses are set out in Boxes 4.1 to 4.3. When considering the possibility of abuse or discrimination, it must be understood that intimidated witnesses who have experienced it will not necessarily exhibit all, or indeed any, of the behaviours set out in these boxes.

Box 4.1 Some possible effects of abuse and neglect

These include:

- poor self-esteem;
- post-traumatic stress disorder;
- self-injury and suicidal behaviour;
- increased emotional problems, e.g. anxiety and depression;
- decreased cognitive functioning;
- sexualised behaviour; and
- negative social behaviour, e.g. increased aggression, non-compliance and criminal activity.

Box 4.2 Some possible effects of racism

These include:

- fear;
- poor self-esteem;
- fear of betrayal of community;
- mistrust of people from outside own community;
- difficulty in establishing positive (racial) identity; and
- increased vulnerability to racist abuse.

Box 4.3 Some possible effects of domestic violence

These include:

- fear for safety of self and others in family;
- sadness/depression, possibly reflected in self-harm or suicidal tendencies;
- anger, which may be demonstrated in aggressive behaviour;
- negative impact on health (e.g. asthma, eczema or eating disorders); and
- negative impact on behaviour (e.g. aggression).

4.29 It is important for interviewers to consider these matters in relation to each individual witness rather than work from assumptions based on stereotypes. Being sensitive to such factors should contribute towards a safe and non-judgmental interview environment for the witness. It is essential that the interview process itself does not reinforce any aspects of discriminatory or abusive experiences for the witness.

Information about the alleged offence(s)

4.30 It is preferable (though not always necessary or essential) that interviewers know little detail of the alleged offence(s) for the purposes of the interview. However, in order to plan and prepare for the interview, interviewers will need a little general knowledge about:

- the type of alleged offence(s);
- the approximate time and location of the alleged offence(s);
- the scene of the alleged offence(s) (note: this should only be enough general knowledge to help the interviewer understand what might be said during the interview);
- how the alleged offence came to the notice of the police; and
- the nature of any intimidation.

4.31 Where the interviewer is also the investigating officer or has been interviewing other witnesses during the course of an investigation, it is accepted that circumstances and practical resource considerations might be such that they are likely to know more about the alleged offence(s) than is set out above. In this situation, interviewers should try to avoid contaminating the interview process with such knowledge.

4.32 It is also accepted that circumstances and resource considerations might be such that it could be necessary for an interviewer to interview more than one witness during the course of an investigation. In such a situation, care should be taken to avoid asking questions of a witness based on the responses of previous interviewees, because this could contaminate the witness's account.

4.33 Nothing in this guidance is intended to limit operational decision-making in cases where the nature of the investigation, the context of the interview and the circumstances as they are known at the time make it necessary for interviewers to have a more detailed knowledge of the offence than the general information outlined in the paragraphs above.

Information important to the investigation

4.34 While obtaining an account of the alleged event is essential, other matters might need to be covered during the interview in order to progress the investigation. These matters can be regarded as 'information important to the investigation'. Obtaining a complete picture of all the relevant issues within an interview is essential because it will provide the investigating officer with the information necessary to conduct a comprehensive investigation. It could also prove beneficial in discussions with the PPS if the subject of witness assessment is raised. Information important to the investigation falls into two categories: general investigative practice and case-specific material. Where such information important to the investigation has not already been covered as part of the witness's account, interviewers should consider introducing it either in the latter part of the questioning phase or in a subsequent interview session, depending on the complexity of the case and what is alleged to have been witnessed by the interviewee.

4.35 The amount of knowledge that interviewers have about information important to the investigation prior to the interview depends on what they know about what is alleged to have been witnessed by the interviewee. It is preferable that interviewers know little detail of the alleged offence(s) before the interview. Only a little knowledge that could form the basis of potential questions about information important to the investigation is, therefore, likely to be available to the interviewer at this point in time. However, while planning the interview, interviewers should apply what they know of the alleged offences to determine the areas of general

investigative practice that might need to be covered in the interview. More case-specific material could either be made available to the interviewer (from the investigating officer, interview monitor or recording equipment operator) after an attempt has been made to elicit and clarify the witness's account, or be included in the planning information for a later interview to avoid potential contamination of the process.

Information important to the investigation relating to general investigative practice

4.36 Information important to the investigation relating to general investigative practice includes:

- points to prove any offence(s) alleged; and
- information that should be considered when assessing a witness's identification evidence, as suggested in R v Turnbull and Camelo ([1976] 63 Cr App R 132) and embodied in the mnemonic ADVOKATE (Practical Guide to Investigative Interviewing (National Centre for Policing Excellence, 2004)):

  A Amount of time under observation
  D Distance from the eyewitness to the person/ incident
  V Visibility – including time of day, street lighting, etc.
  O Obstructions – anything getting in the way of the witness's view
  K Known or seen before – did the witness know, or had they seen, the alleged perpetrator before?
  A Any reason to remember – was there something specific that made the person/incident memorable?
  T Time lapse – how long since the witness last saw the alleged perpetrator?
  E Errors or material discrepancies;

- anything said by the witness to a third party after the incident (evidence of first complaint etc.); and
- any other witnesses present.

This is not intended to be an exhaustive list. The nature of the information important to the investigation pertaining to general investigative practice varies according to the circumstances of the case.

Information important to the investigation relating to case-specific material

4.37 Information important to the investigation relating to case-specific material includes:

- how and where any items used in the commission of the offence (e.g. clothing, vehicles, weapons, cash, documents or other property) were disposed of, if the vulnerable adult witness might have some knowledge of this;
- access by the witness and suspect to electronic media including computers and mobile telephones;
- relevant financial transactions by the witness and suspect;
- any background information relevant to the witness's account (e.g. matters that might enhance or detract from the credibility of the witness's evidence, such as the amount of any alcohol consumed);
- any lifestyle information relevant to the witness's account;
- where the witness has knowledge of an alleged victim or a suspected perpetrator, an exploration of their relationship, background history, places frequented, and any events related or similar to the matter under investigation; and
- any risk assessment issues that the witness might know about that concern the likely conduct of the alleged perpetrator, their family or associates (this should be dealt with after the witness's account has been covered to avoid confusion).

This is not intended to be an exhaustive list. The nature of any case-specific material varies according to the circumstances of the alleged offence, the nature of any relationship between the witness and the alleged perpetrator, and what is alleged to have been seen, heard or otherwise experienced.

4.38 Significant evidential inconsistencies and significant evidential omissions (case-relevant information) are discrete categories of case-specific material.

Significant evidential inconsistencies

4.39 During the course of an investigation, it may be necessary to ask a witness to explain a significant evidential inconsistency between what they have said during the interview and other material gathered during the course of the investigation. Such inconsistencies would, for example, include significant differences between the account provided by the witness during the interview and:

- what the witness is reported to have said on a previous occasion;
- the accounts of other witnesses; and
- injuries sustained either by the alleged victim or the alleged offender.

4.40 There are a number of reasons for significant evidential inconsistencies between what a witness says during an interview and other material gathered during the course of an investigation. Many of these reasons are perfectly innocent in their nature (e.g. genuine mistakes by the witness, reasons stemming from a memory-encoding or recall failure, or sub-conscious contamination of their memory by external influences), but occasions may arise where the witness is motivated either to fabricate or exaggerate their account of an event.

4.41 Whatever the reason for the significant evidential inconsistency, occasions may arise where it is necessary to ask the witness to explain it. The following principles should be taken into account when considering whether, when and how to solicit such an explanation:

- explanations for evidential inconsistencies should only be sought:
  - where the inconsistency is a significant one;
  - after careful consideration has concluded that there is no obvious explanation for them; and
  - the witness's account has been fully explored, either at the end of the interview or in a further interview, as appropriate;
- interviewers should always be aware that the purpose of asking a witness to explain an evidential inconsistency is to pursue the truth in respect of the matter under investigation. It is not to put pressure on a witness to alter their account;
- explanations for an evidential inconsistency should take account of the extent to which the witness may be vulnerable to suggestion, compliance or acquiescence; and
- questions intended to elicit an explanation for an evidential inconsistency should be carefully planned, phrased tactfully and presented in a non-confrontational manner.

Significant evidential omissions

4.42 During the course of an investigation, it may be necessary to ask a witness about relevant information that they have not mentioned in their account. This may arise, for example, where others say that the alleged offender was carrying an object; that the alleged offender's behaviour was unusual; or that there was something particular about the alleged offender's description or vehicle but this is not mentioned by the witness. There are a number of reasons why this type of information can be omitted from an account and situations may arise where it is important to seek an explanation from the witness. In these circumstances, it may be necessary to ask a question to establish if the witness has knowledge of the information. Such a question should only be asked after the witness's account has been fully explored at the end of the interview (or in a further interview if necessary).

4.43 When planning such a question, the interviewer should consider:

- whether the information omitted by the witness is likely to be important enough to be worthy of explanation;
- the extent to which the witness may be vulnerable to suggestion, compliance or acquiescence; and
- which type of question is most likely to elicit the information in a manner that will not have an adverse effect on the value of any answer.

4.44 A plan for soliciting an explanation for the omission of case-relevant information from a witness's account must consider the reliability of any answer. For example, a useful starting point might be to ask the witness a specific-closed question such as 'What else can you tell me about the incident?'. If the witness's answer:

- includes the case-relevant information but lacks sufficient detail, the interviewer should ask the witness to provide a more detailed response by means of an open question (e.g. 'Tell me about…'). When the case-relevant information has been covered, the witness should be tactfully asked to explain its omission from their account unless the reason for its omission is apparent from the witness's response or the circumstances of the case; or
- does not include the case relevant information, a further decision will need to be made as to whether it is necessary to ask a question that might be regarded as leading (e.g. 'Do you recall seeing/hearing…?'). It should be noted that if the answer to such a leading question contains the case-relevant information, it is likely to be of limited evidential value. The evidential value of such an answer may, however, be enhanced if the interviewer then asks the witness to provide a more detailed response by means of an open question (e.g. 'Tell me about…'), followed by questions intended tactfully to elicit an explanation for its omission from their account (unless the reason for the omission is apparent from the witness's response or the circumstances of the case).

4.45 Where the witness cannot recall the case-relevant information, this may be due to not attending to the information or to memory loss.

Use of planning information

Overview

4.46 The planning information should then be used to:

- set aim and objectives for the interview;
- determine the techniques used within the phased interview;
- decide: the means by which the interview is to be recorded;
    - who should conduct the interview and if anybody else should be present (including support for the witness);
    - if anybody should monitor the interview (e.g. investigating officer, supervising officer, specialist/interview adviser, etc.);
    - who will operate the equipment;
    - the location of the interview;
    - the timing of the interview;
    - the duration of the interview (including pace, breaks and the possibility of more than one session); and
    - what is likely to happen after the interview.

Aim and objectives

4.47 The aim of the interview should be to achieve all the objectives that are set for it while being as concise as reasonably possible.

4.48 Setting clear objectives is important because they give direction to the interview and contribute to its structure. The interview objectives should focus on:

- the alleged incident or event(s);
- any case-specific information important to the investigation.

Techniques

4.49 The kind of techniques used within the phased structure set out in Part 4B will vary according to what is known about the witness and the offence when planning the interview, as well as how the witness behaves and what emerges during the interview itself. For example, it is likely to be productive to make use of some of the cognitive mnemonics within the phased interview approach with an eyewitness who is able and willing to participate in the process. However, such techniques are unlikely to be productive while a witness remains hostile and less co-operative. In such cases, an approach based on communication management is likely to be more productive.

How the interview is to be recorded

4.50 To make an application for the record of an interview with an intimidated witness to be played as evidence in chief, the interview must be video recorded. In the event of such a witness being reluctant to have their interview video recorded, the possibility of an application being made to the court for the recording to be edited in such a way as to minimise the identification of the witness (for example, by pixilation of the witness's face and by adjusting the tone of the witness's voice) should be considered. Where this possibility is discussed, it should be made clear to the witness that such anonymity cannot be guaranteed but that it is rather a matter to be determined by the court.

4.51 Regardless of how the interview is recorded, notes should always be taken that are sufficiently detailed to assist the investigating officer to determine any further lines of enquiry that might be necessary, and to brief the custody officer and any other interviewers where a suspected perpetrator is in custody. Responsibility for the compilation of such notes should be agreed during the planning phase of the interview. This responsibility should fall to the second interviewer, where they are in the adjoining room with the monitoring equipment, or the recording equipment operator. While interviewers should consider taking brief notes to assist them during the free narrative phase of the interview where this is appropriate, they should not be responsible for taking notes for the purposes of briefing others because this is likely to distract the witness, obstruct the flow of recall and slow the interview process down, therefore hindering the maximum retrieval of information.

Interviewers and others present at the interview

The interviewer

4.52 Consideration should be given to who is best qualified to lead the interview. A special blend of skills is required to take the lead in video recorded interviews. The lead interviewer should be a person who has established, or is likely to be able to establish, rapport with the witness, who understands how to communicate effectively with witnesses who might become distressed, and who has a proper grasp of the rules of evidence and criminal offences. The lead interviewer must have good knowledge of information important to the investigation, including the points needed to prove particular offences.

4.53 In addition to taking account of the prospective interviewer's skills, the following factors should be taken into consideration when considering who should conduct the interview:

- the experience of the prospective interviewer in talking to witnesses in respect of the type of offence under investigation and any other skills that they possess that could be useful;
- any personal or domestic issues that the prospective interviewer has that might have an adverse impact on the interview; and
- whether any previous experience that the prospective interviewer has with the witness is likely to either inhibit rapport building or give rise to challenges of coaching, prompting or offering inducements.

4.54 The witness's gender, race, culture and ethnicity must always be given due consideration and advice sought where necessary. However, stereotypic conclusions about who is to conduct the interview should be avoided.

4.55 Where the witness expresses a particular preference for an interviewer of either gender or sexual orientation, or from a particular race, cultural or ethnic background, this should be accommodated as far as is practical in the circumstances.

4.56 The interviewer should consider the appropriate mode of dress for the particular witness. For example, research shows that a person's perceived authority can have an adverse effect on the witness, especially with respect to suggestibility.

4.57 Exceptionally, it may be in the interests of the witness to be interviewed by an adult in whom they have already put confidence but who is not a member of the investigating team. Provided that such a person has appropriate professional qualifications, is independent and impartial, is not a party to the proceedings, is prepared to co-operate with appropriately trained interviewers and can accept adequate briefing (including permitted questioning techniques), this possibility should not be precluded.

The second interviewer

4.58 The presence of a second interviewer is desirable because they can help to ensure that the interview is conducted in a professional manner, can assist in identifying any gaps that emerge in the witness's account and can ensure that the witness's needs are kept paramount. Careful consideration needs to be made with regard to whether the second interviewer is present in the interviewing room itself or in the adjoining room with the monitoring equipment. The possibility that the witness might feel intimidated by the presence of too many people in the interview room should be taken into account in determining where a second interviewer is situated, particularly where an interview supporter and interpreter are also to be present in the interview room.

4.59 Regardless of who takes the lead, the interviewing team should have a clear and shared remit for the role of the second interviewer. Too often this role is subjugated to the need for someone to operate the video equipment, when, in reality, the second interviewer has a vital role in observing the lead interviewer's questioning and the witness's demeanour. The second interviewer should be alert to interviewer errors and to apparent confusions in the communication between the lead interviewer and the witness. The second interviewer can reflect back to the planning discussions and communicate with the lead interviewer as necessary. Such observation and monitoring can be essential to the overall clarity and completeness of the video recorded account, which will be especially important at court.

Equipment operators

4.60 The equipment should always have an operator for the duration of the interview. This will allow the view recorded by the camera to be adjusted if the witness moves. It should also provide an opportunity for the interviewer to be alerted at the earliest possible moment in the event of an equipment failure rather than such a failure only being discovered at the end of the interview (see also Appendix C).

Interpreters

4.61 Witnesses should always be interviewed in the language of their choice unless exceptional circumstances prevail (for example, in respect of the availability of interpreters). This will normally be the witness's first language unless specific circumstances result in their second language being more appropriate. Interviewers should be aware that some witnesses could be perfectly fluent in English but might use their first language to express intimate or more complex concepts. As a result, the possibility of using an interpreter should be considered while planning the interview even where a witness is bilingual.

4.62 Interpreters should be appropriately accredited and trained so that they understand the need to avoid altering the meaning of questions and replies. They should normally be selected from the PSNI register of translators and interpreters. If it is not possible to select an interpreter from these registers then the interpreter may be chosen from some other list provided that the interpreter meets standards at least equal to those required for entry onto the registers in terms of academic qualifications and proven experience of interpreting within the criminal justice system. While the familiarity of the interpreter to the witness is not a bar to use and may indeed facilitate communication, all interpreters need to be independent, impartial and unbiased. Family members or other close relatives should not be used either during the interview or when preparing the witness for it.

4.63 Interpreters should be involved in the planning process. They should have a clear understanding of the objectives of the interview, its structure and the function served by any specific techniques used (e.g. those of the cognitive interview). It should be remembered that some words in English might not have an exact equivalent in other languages and communication systems. This possibility should, therefore, be discussed while planning the interview with a view to developing strategies to address what might otherwise be a problem.

4.64 If interviewers are working with an interpreter, it is important to have clarified at the outset who will lead the interview in terms of maintaining direct communication with the witness. If the witness is communicating via an interpreter, the lead interviewer should identify themselves as such while maintaining appropriate eye contact with the witness so that the witness understands that they should address the interviewer not the interpreter. However, if a signer is being used to communicate with a witness who has a hearing impairment, it may be more important for the signer to maintain the direct communication with the witness.

4.65 Where an interpreter is present, they must be clearly identified at the beginning of the interview. Whenever possible, they should also be visible in one of the shots recorded.

4.66 Where a sign-language interpreter is being used to interpret for a witness with a hearing impairment, a camera should be used to record the signer's hand movements as well as those of the witness. In some interview suites, it might be necessary to make use of a portable camera, in addition to the static equipment already set up in the suite, for this purpose. Interviewers should also emphasise to the signer that it is important to avoid inadvertently leading the witness by presenting only one particular option when some of the more generic signs are used, e.g. the signs for 'weapon' and 'touch' depend on the context so it may be important to present the witness with a number of alternatives.

4.67 Where a signer is to be used, it is important to remember that the energy involved in signing is such that the hands of the signer and the witness are likely to get tired. The interview plan should, therefore, take account of the need for breaks to give the signer and the witness an opportunity to rest their hands.

Interview supporters

4.68 It may often be helpful for a person who is known to the witness to be present during the interview to provide emotional support (the 'interview supporter'). However, in some circumstances it has been found that the use of a person who is well-known to the witness as an interview supporter can prove counterproductive by inhibiting the disclosure of information (e.g. as a result of embarrassment arising from sensitive information being disclosed in the presence of a person seen by the witness on a day-to-day basis). For this reason, discussions as to the identity of any potential interview supporter should take account of the nature of their relationship with the witness and its potential impact on the interview process. Wherever possible, the views of the witness should be established prior to the interview as to whether they wish another person to be present and, if so, who this should be.

4.69 Other witnesses in the case, including those giving evidence of an early complaint, cannot act as interview supporters.

4.70 If an interpreter is included then they will need to be distinct from the interview supporter and these different functions should not be vested in one person.

4.71 Interview supporters must be clearly told that their role is limited to providing emotional support, and that they must not prompt or speak for the witness especially on any matters relevant to the investigation.

4.72 Where an interview supporter is present, they must be clearly identified at the beginning of the interview. Whenever possible, they should also be visible in one of the angles recorded. Good practice would be for the interview supporter to make sure they are outside of the witness's line of vision, for example by sitting on the opposite side of the witness to the interviewer.

Location of the interview

4.73 Active consideration should be given to the location of the interview and the layout of the room in which it is to take place. In the planning phase, the interviewer should attempt to determine where the witness would prefer to be interviewed. Some witnesses may be happy to be interviewed in an interview suite while others might prefer to be interviewed in a setting familiar and comfortable to them. Whatever the decision, the location should be quiet enough to avoid a situation in which background noise is likely to interfere with the quality of the sound on any video or audio record, and free from interruptions, distractions, and fear and intimidation, so the interviewer and witness can concentrate fully on the task in hand – the interview.

4.74 Interviewers should ensure that sufficient pens and paper are available for use where a witness's recall could be assisted by drawing a sketch/plan.

4.75 In the event of a witness being interviewed at their home address, care should be taken to avoid saying anything or video recording any background material that might lead to the location being identified (the use of background screens should be considered if necessary).

Timing of the interview

4.76 The decision on when to conduct an interview needs to take account of the demands of the investigation (e.g. a suspected perpetrator being in custody) as well as the potential effects of trauma and/or stress. Trauma and stress can interfere with the process of remembering but this should be determined by asking the witness rather than by the application of an arbitrary period of time. Some witnesses will want to be interviewed relatively quickly while others might wish to be interviewed at a later date. It should always be borne in mind that the potential for memory contamination taking place increases with the delay.

4.77 Interviews should not take place at a time when the witness is likely to be suffering from the effects of fatigue (other than in the exceptional circumstances mentioned in the paragraph below). The effect on the witness's routine and the potential impact of any medication, as well as their views, must be taken into account in determining the best time to conduct the interview.

4.78 In the event of circumstances being such that it is absolutely essential for a witness to be interviewed at a time when they are likely to be suffering the effects of fatigue (for example, where an alleged offender is in police custody for a serious offence and an interview is necessary to secure potentially vital evidence), consideration may be given to conducting a brief interview in the first instance which sets out the witness's account and addresses any issues on which immediate action needs to be taken. Where it is necessary to conduct a brief interview, the principles set out at the beginning of this Part should be adhered to. A more substantial interview can then be arranged at an appropriate time.

Duration of the interview (including pace, breaks and the possibility of more than one session)

4.79 The interview should go at the pace of the witness. Some witnesses will require regular comfort breaks (for example, elderly and frail witnesses). Whenever possible, the interviewer should seek advice from people who know the witness about the likely length of time that the witness can be interviewed before a pause or break is offered while planning the interview.

4.80 Some witnesses who have experienced a traumatic event may find that the interview is 'too much' for them, especially if emotional matters are being discussed. Ways of assisting these witnesses may include planning for breaks in the interview and/or pauses in which the interviewer moves the conversation on to more neutral topics such as those mentioned in the rapport phase before returning to the matter under investigation.

4.81 In some circumstances, it might be necessary to conduct the interview over more than one session (for example: in complicated cases; where allegations of multiple offences are involved; where the witness is elderly and frail; or where the witness is taking medication likely to make them sleepy). These sessions might be separated by a matter of hours or, if necessary, could take place over a number of days. When this occurs, care must be taken to avoid repetition of the same focused questions over time, which could lead to unreliable or inconsistent responding in some witnesses and interviews being ruled inadmissible by the court.

Planning for immediately after the interview

4.82 Although interviewers cannot predict the course of an interview, planning discussions should cover the different possible outcomes and consider the implications for the witness. This should include the possibility of a medical examination (where this has not taken place before the interview), the possible need for alternative accommodation, and any other steps necessary to protect the witness or reduce the possibility of harassment.

Witnesses who might become suspects

4.83 So far as is practicable, consideration should be given in the planning phase as to how interviewers will deal with any confessions to criminal offences made by the witness in the course of the interview. Any decision on an appropriate course of action will involve taking into account the seriousness of the crime admitted and weighing it against the seriousness of the crime under investigation.

4.84 It is preferable to anticipate and plan for such an eventuality while recognising that any decisions on a particular course of action are likely to depend on what has been disclosed by the witness during the course of the interview.

Recording the planning process

4.85 A full written record should be kept of the decisions made during the planning process, and of the information and rationale underpinning them. This record should be referred to in the statement of evidence subsequently made by the interviewer in relation to the planning, preparation and conduct of the interview, and should be revealed to the PPS under the requirements of the Criminal Procedure and Investigations Act 1996.

Preparing the witness for an interview

4.86 Witnesses should always be prepared for an interview. In some cases, this might be fairly brief and take place immediately prior to the interview, while in other instances it might be necessary to take more time and/or for it to take place several hours or days before the interview.

4.87 The preparation of the witness should include an explanation of the purpose of the interview and the reason for video recording it (including who might subsequently view it); the role of the interviewer(s) and anybody else to be present; and the location of the interview and roughly how long it is likely to take. The interviewer(s) should also outline the general structure of the interview and provide some explanation of the ground rules that apply to it (including the witness not making any assumptions about the interviewer's knowledge of the event). Substantive issues relating to the evidence should not be discussed while preparing a witness for an interview.

4.88 Any issues or concerns raised by the witness should be addressed while preparing them for the interview (for example, welfare issues or concerns about the possibility of a later court appearance).

4.89 Most witnesses will be anxious prior to an investigative interview and few will be familiar with the formal aspects of this procedure. It is, therefore, important that the interviewer uses the time spent preparing a witness for an interview to build up a rapport with the witness. The nature and the extent of rapport building required very much depends on what has been established about the witness during the planning phase of the interview.

4.90 Witnesses who are intimidated might need to spend more time getting to know the interviewer before they are ready and/or willing to take part in an investigative interview. Interviewers should consider whether one (or more) meetings with a witness should take place prior to the interview because this familiarisation process may take some time.

4.91 Some witnesses may feel that their initial, lawful co-operation with a person who subsequently commits an offence may make them blameworthy. The interviewer might need to try to reassure the witness on these points but promises or predictions should not be made about the likely outcome of the interview. So far as possible, the interview should be conducted in a 'neutral' atmosphere, with the interviewer taking care not to assume, or appear to assume, the guilt of an individual whose alleged conduct may be the subject of the interview.

4.92 Some witnesses may be unhappy or feel shame or resentment about being questioned especially on personal matters. In the rapport phase, and throughout the interview, the interviewer should convey to the witness that they have respect and sympathy for how the witness feels. A witness may be apprehensive about what may happen after the interview if they do provide an account of what happened. Such worries should be addressed.

4.93 Initial discussions with the witness could focus on events and interests not thematically related to the investigation: sport, television programmes, and so on. Sometimes, where the witness and the interviewer have had some previous contact this can be quite brief. At other times, especially when the witness is nervous or has been subject to threats from the alleged abuser, a much longer period of rapport-building when the witness is prepared for the interview may be warranted.

4.94 Rapport-building while the witness is prepared for the interview can also serve to set the tone for the style of questions to be used by the interviewer during the interview. It is, therefore, important that the witness is encouraged to talk freely through the extensive use of open-ended questions because this can help to encourage the witness to give detailed accounts; a style of communication wholly consistent with the guidance set out in this document.

4.95 In some instances, it might be helpful to conduct a practice interview while preparing the witness for the interview. In these circumstances, the witness could be asked to recall a personal event unrelated to the issue of concern (e.g. a birthday or a holiday). This serves to provide the witness with an example of the kind of detail that will be required in relation to the issue of concern and to practise extended verbal responses.

4.96 It may prove problematic to attempt to proceed with an interview until rapport has been established. Should establishing rapport when the witness is prepared for the interview proves difficult, it may be preferable to postpone the interview rather than proceeding with an interview that may well turn out to be of no benefit.

4.97 Assistance should be sought if necessary from interview supervisors and interview advisers (see tiers 4 and 5 of ACPO's National Investigative Interviewing Strategy (ACPO, 2009)) with the issues that might arise during the preparation of a witness for an interview.

4.98 Full written notes must be kept of the preparation of a witness for an interview and given to the PPS on request.

4.99 The plan for the interview should be reviewed and revised if necessary in the light of any additional information that arises from preparing the witness for the interview.

Part 4B: Interviewing intimidated witnesses

General advice on interviewing intimidated witnesses

4.100 Over the years, many professionals have recommended the use of the phased approach of interviewing, starting with a free narrative phase and then gradually becoming more and more specific in the nature of the questioning in order to elicit further detail. This structure results in what is termed a 'hierarchy of reliability' of information with the opening phases resulting in good quality recall. However, as the interview becomes more specific, the quality of information elicited may reduce. Research has shown that the free narrative phase of the interview typically is incomplete but more accurate. When witnesses are questioned about a 'to-be remembered' event, more information is elicited but the accuracy tends to be lower with the more direct questions resulting in higher error. Therefore, interviewers have to be particularly careful about the types of questions used and where in the interview to use particular questions.

4.101 However, inclusion of a phased approach in this guidance should not be taken to imply that all other techniques are necessarily unacceptable or to preclude their development. Neither should what follows be regarded as a checklist to be rigidly worked through. Flexibility is the key to successful interviewing. Nevertheless, the sound framework it provides should not be departed from by interviewers unless they have discussed and agreed the reasons for doing so with their senior manager(s) or an interview adviser (tier 5 of the Association of Chief Police Officers' (ACPO's) National Investigative Interviewing Strategy (ACPO, 2009)).

4.102 For all witnesses, interviews should normally consist of the following four main phases:

- establish rapport;
- seek free narrative recall;
- ask questions; and
- closure.

Each phase will be described in greater detail below. These phases are compatible with and underpin the PEACE interview framework advocated by ACPO.

4.103 The phased approach is at the heart of the cognitive interview (CI)/enhanced cognitive interview (ECI). Essentially, if all the cognitive 'special' instructions are taken away and not used, what is left is the phased interview. The CI was initially developed in an attempt to improve witness memory performance by using various techniques derived from cognitive psychology to gain as much correct information as possible without jeopardising the quality of the information reported. The original CI comprised a set of four instructions given by the interviewer to the witness: (i) report everything; (ii) mentally reinstate context; (iii) recall events in a variety of different temporal orders; and (iv) change perspective. Subsequently, the originators found that real-life police interviewing of witnesses lacked much that the psychology of interpersonal communication deemed important. Therefore, they developed the ECI, which incorporated several new principles from memory research and the social psychology of communication. As a result, the ECI consists of the original CI techniques noted above plus some additional techniques (e.g. transfer of control and witness-compatible questioning).

4.104 Therefore, the following discussion will also describe the 'special' cognitive mnemonics that aim to help elicit specific details that witnesses may have difficulty remembering. Some interviewers think that use of the ECI is an all-or-nothing affair – that they have to use all the techniques or none at all. Instead, it would be preferable to use one technique well rather than all of its techniques poorly. As noted above, if you take away all the 'special' techniques of the ECI, you are left with the phased interview. So, rather than it being a decision to use the ECI or not, the questions are: 'Which ECI technique(s) should I use?', 'With whom should I use each?', 'When should I use each?' and 'How should I present each?'. It is important, therefore, for interviewers to use the appropriate technique at the appropriate time with the appropriate witness. This is not an easy task. As a result, interviewers should be trained and be competent to the appropriate tier (2 or 3) of ACPO's National Investigative Interviewing Strategy (ACPO, 2009) in order to do this appropriately.

4.105 The CI/ECI mnemonics typically can only be used with co-operative witnesses. If the witness is not co-operative then the interviewer should resort to either the phased interview or, as the next step, an approach based on communication management.

Phase one: establishing rapport (including engaging and explaining)

Opening the interview: explaining the formalities

4.106 Firstly, it is necessary when video recording the interview to check that the equipment is turned on and that all people in the room can be clearly seen on the monitor through the camera with the wide-angle lens where two cameras are in use and that the witness is appropriately framed in the main camera image (see Appendix E). Next, the interviewer should say out loud the day, date, time and place (not the detailed address) of the interview and give the relevant details of all those present.

Opening the interview: personalising the interview, building rapport and engaging the witness

Personalising the interview

4.107 The opening phase of an interview will often determine the success of the interview as a whole. At the outset, it is necessary to establish trust and lay the foundations for successful communication. The interviewer is often a person who is unfamiliar to the witness and, therefore, in order to reduce possible tension and insecurity felt by the witness, it is essential that the interviewer should introduce themselves by name and greet the witness by name (i.e. personalise the interview). Greeting should occur as it is at the heart of effective rapport development which is the next step of the interview process.

4.108 Paying attention to the appropriate form of address at this initial greeting phase can help send a message of equality both now and throughout the interview. This is essential as it reduces the perceived authority differential between interviewer and witness so that they are less likely to comply with leading questions. As no interview can be perfect, it is essential to build resistance against inappropriate questions which may unwittingly be used by an interviewer later in the interview.

4.109 The interviewer needs to treat the witness as an individual with a unique set of needs as opposed to being 'just another interviewee'. Obtaining maximum retrieval is a difficult task requiring deep concentration. A witness, therefore, needs to feel that they are an integral part of the interview in order to be motivated to work hard.

4.110 As noted above, the interviewer needs to present themselves as an identifiable person. This is because people dislike the unknown and prior to the interview may draw on past experiences and knowledge about the police and interviews to help them think about what to expect. This information may be obtained from media

representation and, as a result, may not be particularly favourable. Therefore, it is the job of the interviewer at the outset, and throughout the interview, to lessen any 'stereotypes' the witness may have. This can start through personalising the interview. Interviewers who are in uniform may have to spend more time on this and the next phase of the interview to overcome any barriers set up by their clothing.

4.111 First impressions count so the clothing an interviewer wears is a matter that should be considered before an interview. For example, interviewers in too formal attire may have more difficulty in personalising the interview and developing rapport especially when interviewing younger individuals.

Building rapport and engaging the witness

4.112 Rapport is essential, and good rapport between interviewer and witness can improve both the quantity and quality of information gained in the interview. Rapport, therefore, has a direct impact on the interview process itself. Rapport is especially important where the type of information required is highly personal.

4.113 The witness's anxiety, whether induced by the crime and/or the interview situation (or otherwise), needs to be reduced for maximum remembering. This is because people only have a limited amount of processing power available and the aim is to have the witness's full power devoted to retrieving as much information as possible. Anxiety may detract from this. The interviewer, therefore, needs to start to create a relaxing atmosphere and to make the witness feel secure and confident both with the interviewer and with the interview situation. One way to achieve this is to start by asking some neutral questions not related to the event which can be answered positively and, therefore, create a positive mood.

4.114 Within the main body of the interview and, if an interview is being video recorded, it is important that any discussion of neutral topics in the rapport phase is completed within a relatively short space of time. Interviewers should remember that a lengthy rapport phase may result in some intimidated witnesses getting:

- tired before they are asked to provide an account. This could have an adverse impact on the quality of their evidence; and
- confused about the purpose of the interview. This could increase in their anxiety.

4.115 If the interview plan suggests that discussing neutral topics for a lengthy period of time may be beneficial (e.g. with some traumatised witnesses) it should take place as part of witness preparation before the interview commences.

4.116 Interviewers should be aware that it is neither desirable nor essential to discuss neutral topics in every interview. Where an intimidated witness is anxious to begin their account of the alleged incident(s) as soon as possible, a discussion of neutral topics could be counterproductive by needlessly prolonging the rapport phase thus increasing their anxiety levels. In any event, rapport should not be regarded as something that is confined to the first phase of an interview: it begins when the interviewer first meets the witness and continues throughout the interview.

4.117 Rapport requires that the interviewer interacts meaningfully with the witness contributing as an interested party and not simply asking a list of predetermined short-answer questions. Standardised phrases should be avoided as their use will convey to the witness that they are 'just another interviewee' which is likely to depersonalise the interview. It is a good idea for the interviewer to talk about themselves too as this openness can serve as a model to demonstrate what is required of the witness and help to further personalise the interview by making the interviewer more identifiable.

4.118 The use of open-ended questions in the developing of rapport will help the witness understand at the earliest phase in the interview what will be required later, i.e. elaborated responses. The interviewer should encourage the witness to speak without interruptions when they are describing a familiar event (e.g. a recent holiday).

4.119 Witnesses have different levels of language and skilful interviewers tailor their own communication level to that of the witness. It is in this rapport phase of the interview that the interviewer can assess the witness's communication abilities (this should also occur in planning and preparation), and this will allow the interviewer to develop an interactive model of interviewing determined and defined by the witness. This is easier to do when examining the witness's responses to open-ended questions. For example, it is often useful to count how many words on average a witness uses per sentence and use this figure as a guide to the length of sentences/questions the interviewer should use.

4.120 A guiding principle for developing rapport is to communicate empathy. Here the interviewer needs to demonstrate a willingness to try to understand the situation from the witness's perspective. Some witnesses may be unhappy, or feel shame or resentment about being questioned especially on personal matters. In the rapport phase, and throughout the interview, the interviewer should convey to the witness that they have respect and sympathy for how the witness feels.

4.121 A witness may be apprehensive about what may happen after the interview if they provide an account of what happened. While every effort should have been made to address these concerns while preparing the witness for the interview, they should be addressed during this phase if they emerge again.

4.122 At the start of the interview, the interviewer could allow the witness to vent their concerns and emotions about the incident(s) in question. These in turn can be used to explain the interviewer's needs. This can help to initiate the next phase of describing the aims of the interview (i.e. setting the ground rules).

Opening the interview: explaining the ground rules

4.123 It is important to explain to the witness what is to be expected from them as for most witnesses an investigative interview is an alien situation. People typically fear the unexpected but by describing the interview process this fear can be reduced.

Interview factors

4.124 There are some details concerning the interview itself that need to be explained to the witness. The reason for the interview needs to be given which in turn will make its focus clearer. The interviewer, however, needs to be careful not to comment on the nature of the offence as this can be seen as leading the witness. Questions such as 'Do you know why you are here today?' have been found to help at this stage of the interview.

4.125 The interviewer needs to give an explanation of the outline of the interview. Typically the outline will take the form of the interviewer asking the witness to give a free narrative account of what they remember and following this with a few questions in order to clarify what the witness has said. Witnesses should also be told that:

- if the interviewer asks a question that the witness does not understand or asks a question that the witness does not know the answer to, they should say so; and
- if the interviewer misunderstands what the witness has said or summarises what has been said incorrectly then they should point this out.

In addition, it should be explained that the interviewer might take a few brief notes.

4.126 There should not be an attempt to get the witness to swear an oath during an interview. If the witness goes on to give evidence at court, the court will administer an oath retrospectively.

Focused retrieval

4.127 Memory recall at the most detailed level requires focused attention and intense concentration. If there are too many distractions then the witness will find it very difficult to retrieve from the detailed level of memory. The interviewer should inform the witness that the task is not an easy one but one that will require considerable concentration. Witnesses also need to feel that they have an unlimited time for recall so that they can search their memory effectively at their own pace and provide elaborate, detailed responses. If there is a restricted time, witnesses may shorten their responses accordingly and shorter responses are usually less detailed.

Transfer of control

4.128 This instruction is an ECI technique which would be helpful in almost all interviews. The witness may expect the interviewer, usually an authority figure, to control the interview. Therefore, a witness may well be expecting an active interviewer asking a series of questions to a more or less passive witness whose only task is to answer these questions and wait for the next one. This is not the typical behaviour of a skilful interviewer. Instead their role is as a facilitator, a person to help the witness remember, to facilitate retrieval and to help the witness, as and when they require it, to recall as much information as possible. It is the witness who has been witness to the event and who has all the information. Consequently, the main person in this exercise is the witness and not the interviewer.

4.129 The interviewer should, therefore, pass the control of the information flow to the witness. After all, it is the witness who holds the necessary information. Therefore, at the start of the interview the witness needs to be informed explicitly of this. It is the witness who should do most of the mental work and most of the communicating throughout the course of the interview.

4.130 Another reason why this instruction is so important is because detail is not often required in everyday communication. For example, when asking a colleague who has just returned from holiday 'Did you have a good time?', only limited detail from them is actually sought. The reason for asking this question is generally a polite, common courtesy. This is because we learn from a young age what is termed the 'maxim of quantity' which states that detail in general communication is not required and may even be seen as rude. However, in an investigative interview the witness needs to give extensive detail and should do most of the communicating. Unless directly told this, the witness will not give such detail automatically as they will have learned from years of experience of communicating that to give detail is not necessary and to dominate the conversation is rude.

Report everything

4.131 This final instruction in this sub-phase of the interview is also an ECI instruction that would be useful in almost all interviews. As noted above, witnesses are unlikely to volunteer a great amount of detailed information unless told to do so. Interviewers, therefore, should explicitly state their need for detail. Therefore, as with the transfer of control instruction, the 'report everything' instruction encourages witnesses to report everything they remember without any editing even if witnesses think the details are not important or trivial, or cannot remember completely a particular aspect of the event.

4.132 There are a number of reasons thought to be responsible for the effectiveness of this instruction. Many witnesses may believe that the interviewer already knows a lot about the event in question. As a result, witnesses may not mention things they think are unimportant or which seem obvious as witnesses do not want to be seen to be wasting interviewer time. Some witnesses may (erroneously) believe that they themselves know what types of information are of value and, therefore, may only report what they believe to be important. In some cases, this may result in witnesses mistakenly withholding relevant information. Therefore, the instruction to report everything is likely to result in the reporting of information which otherwise may be held back by the witness. Witnesses may also withhold information if they cannot remember it completely. However, the recall of partial information may help the interviewer gain a more complete picture of the incident (for example, if a witness recalls a few characters of a number plate and other witnesses each recall one other character).

Phase two: initiating and supporting a free narrative account

4.133 In this phase of the interview, the interviewer should initiate an uninterrupted free narrative account from the witness through the use of an open-ended invitation. The interviewer can also use this phase as the planning phase for the questioning phase of the interview. This is because the free narrative account allows the interviewer an insight into the way in which the witness holds the information about the event in their memory. Therefore, brief note-taking is recommended at this stage. However, if the interviewer takes too many notes, this may well distract the witness, hindering the flow of recall. In addition, if the interviewer slows the witness down in order to take detailed notes, this again hinders maximum retrieval. In this regard, it is always helpful to give thorough consideration to the need for a second interviewer at the planning phase.

4.134 It is essential not to interrupt the witness during their narration to ask questions – these should be kept for later.

4.135 In the free narrative phase, the interviewer should encourage witnesses to provide an account in their own words by the use of non-specific prompts such as 'Did anything else happen?', 'Is there more you can tell me?' and 'Can you put it another way to help me understand better?'. Verbs like 'tell', 'explain' and 'describe' are likely to be useful. The prompts used at this stage should not include information known to the interviewer concerning relevant events that have not yet been communicated by the witness.

4.136 Many witnesses, when recalling negative and emotional events, may initially be more comfortable with peripheral matters and may only want to move on to more central matters when they feel this to be appropriate. Therefore, interviewers should resist the temptation to 'get to the heart of the matter, prematurely'. They should also resist the temptation to speak as soon as the witness appears to stop doing so, and should be tolerant of pauses, including long ones, and silences. They should also be tolerant of what may appear to be repetitious or irrelevant information from the witness. Above all, interviewers must try to curb their eagerness to determine whether the interviewee witnessed anything untoward.

4.137 A form of active listening is needed, letting the witness know that what they have communicated has been received by the interviewer. This can be achieved by reflecting back to the witness what they have just communicated; for example, 'I didn't like it when he did that' (witness) then 'You didn't like it' (interviewer). The interviewer should be aware of the danger of subconsciously or consciously indicating approval or disapproval of the information just given.

Context effects, memory and the mental reinstatement of context

Context effects and memory

4.138 Research has demonstrated that context can have a powerful effect on memory. It is sometimes easier to recall information if you are in the same place or context as that in which the encoding of the information took place. This helps us to explain why we are overcome with a surge of memories about our past life when we visit a place we once knew (e.g. a school you used to attend). The context in which an event was encoded is itself thought by some to be one of the most powerful retrieval aids. For example, Crimewatch reconstructions attempt to reinstate the physical context of the event in order to jog people's memories of the event itself.

4.139 Research has demonstrated the effects physical context can have on memory. For example, participants learned a list of words either on land or 20 feet under water. Later the participants had to recall the previously learned list of words either on land or under water, i.e. in the same context where they learned the list or in a different context. It was found that those who learned the words on land recalled more of the words when they were also on land and those who learned the words under water recalled more of the words under water. Recall was approximately 50 per cent higher when the learning and recalling contexts were the same.

4.140 In a practical sense, physically reinstating the context of the event (i.e. taking a witness back to the scene of a crime) may not be possible or advisable (though sometimes this is a strategy that can be used in the correct circumstances). There are a number of reasons why taking someone back physically to the incident scene is inappropriate. From a police operational perspective, if it is a recent crime, the scenes of crime officers may still be present and taking someone back to the scene could contaminate the crime scene itself. Also, the witness/may become too traumatised and anxiety may interfere with the process of remembering. Furthermore, the crime scene may have actually changed. For example, the weather may be different, or people and objects, which were at the crime scene, are unlikely to have remained the same. Therefore, taking someone back may be counterproductive if the scene is drastically different. In addition, physically taking someone back to the scene is expensive and time-consuming, and, if the interview is being video recorded, the logistics of doing this at the scene may be problematic (e.g. if the scene is outside and it is raining).

4.141 Context, however, need not be external to the person remembering. Our internal state can also act as a contextual cue. For example, a person who was feeling happy when experiencing an event may be better placed to remember the event in that state. Recollection of an experience is likely to be most successful when a retrieval cue reinstates a person's subjective state at the time of an event including thoughts and feelings.

4.142 Research has shown that the mental reinstatement of the context of the event, both the physical and the internal context, can be as effective as taking someone back physically.

The mental reinstatement of context

4.143 The context reinstatement instruction is part of the ECI and it asks witnesses to reconstruct in their minds the context, both physical (environmental) and internal (i.e. how they felt at the time), of the witnessed event. Any aspect of an environment in which an event is encoded can, in theory, serve as a contextual cue. For example, the interviewer could say to the witness: 'Put yourself back to the same place where you saw the assault. Think of where you were. How were you feeling at the time? What could you hear? What could you smell? Think of any people who were present. Think about the objects there. Now tell me everything you can remember without leaving anything out.'. The statements should be given using the past tense and should not be leading. This instruction can be used before obtaining the first free narrative account or to obtain a second free narrative. Again, this will depend on the witness.

4.144 The use of sketch plans may also be helpful here. The witness could be asked to draw the layout of the event and describe who was where, etc. This will also help the witness reinstate the context, and could be a useful tool for the questioning phase of the interview to help focus the witness and structure topic selection. In addition, this is a useful investigative tool in ensuring that the R v Turnbull and Camelo rules are comprehensively covered.

4.145 Context reinstatement can be a useful technique and, like any procedure that enhances recall, it can recreate feelings associated with the event. Interviewers, therefore, need to be appropriately trained in the use of this instruction and what to do if the recalling of a negative event upsets the witness.

Active listening and appropriate non-verbal behaviour

4.146 Appropriate non-verbal behaviour during the interview is just as important for a successful interview as are the verbal instructions.

Proxemics

4.147 Proxemics refers to the physical distance between individuals (e.g. interviewer and witness) and the effects of this on them. Everyone has around them a personal 'bubble' of space which usually extends to about an outstretched arm's length around them though cultural differences in this do occur. It has been found that an invasion of a person's personal space, especially by a stranger, can be emotionally disturbing and may well result in gestures indicative of stress. Therefore, it is imperative to be aware that an interviewer's own behaviour can affect the behaviour of the witness.

Posture and orientation

4.148 The angle or orientation at which people stand or sit in relation to one another can convey information about attitude, status and affiliation. Although cultural differences do occur, positive conversation tends to take place most comfortably at a 120-degree angle (or a 'ten-to-two' position). Confrontation tends to occur in a face-to-face orientation. Therefore, positions in an interview room can affect the interview outcome even before any verbal interaction has taken place. If the interviewer sits in a non-confrontational orientation (e.g. a 'ten-to-two' position), this can start to promote a relaxed atmosphere in the interview.

The principle of synchrony

4.149 In a two-person interaction, which is progressing well, each person's behaviour will tend over time to mirror that of the other person – the principle of synchrony. Interviewers can make use of this to influence the witness's behaviour simply by displaying the desired behaviour themselves. Therefore, by speaking slowly in a calm, even voice and behaving in a relaxed way, the interviewer can guide the witness to do so as well. The interviewer should encourage the witness to speak slowly as rapid speech (which is common in anxious witnesses) becomes a problem for memory retrieval. 'Mirroring' can also help build and maintain rapport in that intended behaviours can be demonstrated by the interviewer and may in turn be mirrored by the witness. If an interviewer sits and speaks in a relaxed manner, the witness is more likely to demonstrate relaxed behaviour as well.

Pauses and interruptions

4.150 The interviewer also needs to give the witness time to give an elaborate answer and should use pauses so that the witness can conduct a thorough search of their memory. Witnesses pause during a free narrative account for a variety of reasons. The witness may be seeking feedback from the interviewer on the quality of the response. For example, the witness may be thinking 'Have I given enough information or do I need to continue?' or 'Have I been talking too long?'. The witness may also pause in order to organise the rest of the narration or when trying to access information. Any interruption during these pauses may preclude further information being produced and this information may be lost.

4.151 Interviewers can promote extensive answers during these pauses by remaining silent or by expressing simple utterances (gurgles) conveying their expectation that the witness should carry on (e.g. 'mm hmm'). This non-verbal behavioural feedback should not be qualitative (e.g. saying 'right') as this may give the witness the

impression that the information they have already given is the type of information required and may, therefore, be judged by the courts as inappropriately rewarding certain types of utterance. Instead, interviewers should praise the witness for their efforts in general and do so between interview phases. Similarly, the interviewer should not display surprise at information as this could be taken as a sign that the information is incorrect. Repeated interruptions soon teach witnesses that they have only a limited time to reply and this often leads to shortened responses to future questions.

Phase three: questioning

4.152 During the free narrative phase of an interview, most witnesses will not be able to recall everything relevant that is in their memory. Therefore, their accounts could greatly benefit from the interviewer asking appropriate questions that assist further recall.

4.153 Interviewers need to appreciate fully that there are various types of questions that vary in how directive they are. The questioning phase should, whenever possible, commence with open-ended questions and then proceed, if necessary, to specific-closed questions.

Prior to the questioning phase of the interview

4.154 Before asking the witness any questions, it may be beneficial to outline for them what is expected of them in this phase of the interview. It is helpful for the interviewer to inform the witness that they will now be asking them some questions based on what they have already communicated in the free narrative phase in order to expand on and clarify what they have said. It is also beneficial to reiterate a number of the ground rules outlined in the rapport phase of the interview. For example, it is helpful to explain to the witness that detail is required, to explain that this is a difficult task which requires a lot of concentration, and to point out that it is acceptable to reply 'I don't know' or 'I don't understand' to a question.

Types of question

4.155 Different types of question produce different types of answer with respect to quality and quantity, and it is essential that particular classes of question are used in the correct order. There are some types of question that have a tendency to produce erroneous information.

Open-ended questions

4.156 An open-ended question is the best kind of question from the point of view of information-gathering (i.e. gaining good quality information). Therefore, this type of question should be used predominantly during the interview. Open-ended questions are framed in such a way that the witness is able to give an unrestricted answer which in turn enables the witness to control the flow of information in the interview. This questioning style also minimises the risk that the interviewer will impose their view of what happened on the witness. Open-ended questions elicit responses similar to those obtained by the free narrative account which has been found to be the most accurate form of remembering. Open-ended questions can also be used to elaborate on incomplete information provided in the free narrative account.

4.157 Questions beginning with the phrase 'Tell me' or the word 'Describe' are useful examples of this type of question. Examples of open-ended questions are: 'You said you were at the scene of the incident this morning. Tell me everything you remember.' 'You said that there was a man with a knife. Describe him for me.'

Specific-closed questions

4.158 A specific-closed question is one that allows only a relatively narrow range of responses. Specific-closed questions are the second-best type of question, and should be used to obtain information not provided by the witness in the free narrative account and not elicited through the use of open-ended questions. This is because the use of specific-closed questions allows the interviewer to control the interview and minimise irrelevant information being provided. However, they may cause witnesses to be passive and decrease their concentration, and, therefore, can result in less recall. Also, specific-closed questions can produce more incorrect responses than open-ended questions. Open-ended questions are, therefore, preferable because they elicit more elaborate and more accurate responses.

4.159 In answering the open-ended question given above that requested a description of the perpetrator, the witness may have omitted hair colour; therefore, a subsequent specific-closed question could be: 'What colour was his hair?'.

4.160 An interview is a learning experience especially if the witness has limited or no knowledge of the interview situation. As a consequence, any interviewer behaviour is likely to have an immediate effect on the interview process (e.g. on an answer given). The witness will also learn from this behaviour what is to be expected and will try to adjust their behaviour accordingly. Therefore, if an interviewer opens an interview by using a succession of specific-closed questions, which do not allow the

witness to give full answers, they will expect this to occur throughout the interview. As a result, the witness will give short answers even if the interviewer may request long responses from the witness later in the interview using open-ended questions. This is the reason why open-ended questions should be used first with specific-closed questions as a back-up option.

4.161 Some authors define open-ended questions by their opening word: 'Who', 'What', 'Where', 'When' and 'Why'. Although these questions can be framed as open-ended questions, they are much more commonly used as specific-closed questions. For example:

Q. 'Who said that?'
A. 'John Smith.'
Q. 'What did he say?'
A. 'He said...'
Q. 'Where were you standing?'
A. 'Outside the bedroom.'
Q. 'When was that?'
A. 'About 11.'

4.162 An example of such a question framed as an open-ended question is 'What happened next?'. However, its effect depends on where in the interview this question is asked. If 'What happened next?' is used within predominately open-ended questions, it should elicit an open-ended response from the witness. However, if it is embedded among a large number of specific-closed questions, it is unlikely to elicit a lengthy response because the witness is not used to giving detail.

4.163 A 'Why' question, although it may produce a response, can create more problems than it solves particularly if the question seeks an explanation of behaviour. This is because people often do not know, with any degree of accuracy, what their own motivation is, let alone what motivates others. 'Why did he do that?' may well be a closed question but it is also a question that the witness cannot possibly answer with 100 per cent accuracy. In addition, 'Why' questions also tend to promote the feeling of blame. Victims often partly blame themselves for what happened and so 'Why' questions may strengthen this belief. This will not help the witness or the remembering process.

Wording of specific-closed questions

4.164 The interviewer needs to tailor the language of each individual question to each witness and should avoid using grammatically complex questions. Interviewers should also avoid using questions that include double negatives. The key is to keep questions as short and simple as possible including only one point per question.

4.165 If the interviewer is seeking elaboration on what the witness mentioned in their free narrative account, the interviewer should as far as possible try to use the same words that the witness used. Negative phrasing should also be avoided as this suggests a negative response which it often receives (for example, 'You can't remember any more, can you?').

4.166 In addition, jargon and technical terminology should not be used as these reduce the witness's confidence and may alienate them. Moreover, a witness may just respond in the affirmative to avoid embarrassment if they do not understand.

4.167 Specific-closed questions should not be repeated 'word for word' because the witness may feel that their first answer was incorrect and change their response accordingly. When a question is not answered or the answer is not understood, it should be reworded instead of repeated. Also, if the witness has been unable to answer a number of questions in succession, the interviewer should explicitly change to an easier line of questioning with a short break in the interim otherwise the witness may lose self-confidence.

Forced-choice questions

4.168 This and the following are further types of question that should be avoided if at all possible and only be used as a last resort.

4.169 This type of question can also be termed a selection question: it gives witnesses only a small number of alternatives from which they must choose and which may, in fact, not include the correct option (e.g. 'Would you like tea or coffee?'). The result of asking this type of question is that witnesses may guess the answer by selecting one of the options given. Witnesses may also answer in the affirmative, and the interviewer must then either assume to which part of the question this reply corresponds (which may be an incorrect assumption) or rephrase the question.

Multiple questions

4.170 A multiple question is one that asks about several things at once. For example: 'Did you see him? Where was he? What was he wearing?'. The main problem with this type of question is that witnesses do not know which part of it to answer. The witness has to remember all the sub-questions asked while trying to retrieve the information required to answer each sub-question. Moreover, when an witness responds to such a question, misunderstandings can occur as the interviewer may wrongly assume that the witness is responding to sub-question one when actually they are responding to sub-question two.

4.171 Less obvious examples of this type of question include those questions that refer to multiple concepts, for example 'What did they look like?'. This question asks the witness to describe two or more people and, therefore, may not only limit the amount of retrieval per person but also may confuse the interviewer as to who the witness is currently describing. Misunderstandings could, therefore, occur.

Leading questions

4.172 A leading question is one that implies the answer or assumes facts that are likely to be in dispute. For a question to be construed as leading will depend not only on the nature of the question but also on what the witness has already said in the interview. When a leading question is put improperly to a witness giving evidence at court, opposing counsel can make an objection before the witness replies. This, of course, does not apply during recorded interviews but it is likely that, should the interview be submitted as evidence in court proceedings, portions might be edited out or, in the worst case, the whole recording ruled inadmissible (see Appendix F).

4.173 In addition to legal objections, research indicates that witnesses' responses to leading questions tend to be determined more by the manner of questioning than by valid remembering. Leading questions can serve not merely to influence the answer given but may also significantly distort the witness's memory in the direction implied by the leading question. For these reasons, leading questions should only be used as a last resort where all other questioning strategies have failed to elicit any kind of response. On occasion, a leading question can produce relevant information which has not been led by the question. If this does occur, interviewers should take care not to follow up this question with further leading questions. Rather, they should revert to open-ended questions in the first instance or specific-closed questions.

4.174 A leading question that prompts an witness into spontaneously providing information which goes beyond that implied by the question will normally be acceptable to the courts.

4.175 Furthermore, witnesses who do not provide distorted information in response to such questions are nevertheless likely to become irritated by questions that imply the anticipated answer especially if they know that answer to be incorrect.

4.176 Leading questions come in a number of different forms, some being more suggestive than others. The leading questions thought to be the most suggestive are tag questions such as 'You did see the gun, didn't you?'. It has also been found that questions worded using 'the' compared with 'a' result in greater levels of erroneous responses. This is because 'the' presupposes the existence of an item. It should be noted that witnesses may be more likely to succumb to suggestive questioning when they see the interviewer as an authority figure. The way that interviewers structure questions can have a marked influence on the responses given by the witness. It is imperative to understand the nature of questioning in order to conduct the most effective and non-biased interview. (See also issues of suggestibility, acquiescence and compliance in Chapter 3.)

Asking questions

Topic selection

4.177 Within the questioning phase of the interview, the interviewer should subdivide the witness's account into manageable topics or episodes, and seek elaboration on each area using open-ended and then specific-closed questions. Each topic or episode should be systematically dealt with until the witness is unable to provide any more information. Interviewers can also summarise what the witness has said, using their own words, in relation to each topic or episode. Topic-hopping (i.e. rapidly moving from one topic to another and back again) should be avoided as this is not conducive to maximum retrieval.

4.178 When being questioned, some witnesses may become distressed. If this occurs, the interviewer should consider moving away from the topic for a while and, if necessary, reverting back to an earlier phase of the interview (e.g. the rapport phase). Such shifting away from and then back to a topic the witness finds distressing and/or difficult may need to occur several times within an interview.

Witness-compatible questioning

4.179 Good questioning should avoid asking a series of predetermined questions. Instead, the sequence of questions should be adjusted according to the witness's own memory processes. This is what 'witness-compatible questioning' means. Each witness will store information concerning the event in a unique way. Therefore, for maximum retrieval, the order of the questioning should resemble the structure of the witness's knowledge of the event, and should not be based on the interviewer's notion or a set protocol. It is the interviewer's task to deduce how the relevant information is stored by the witness (via the free narrative account) and to organise the order of questions accordingly.

Activating and probing images (mini-context reinstatement)

4.180 This has been used as part of the ECI. It is used to help the witness to recall more specific details of the event (a mini-context reinstatement). This begins by recreating/activating the psychological and environmental context. The context here is very specific in that it refers to a particular moment or aspect of the incident. For example, if the first aspect of the event that the witness reported in their free narrative account was the man with a knife, they can now be asked the following: 'You mentioned the man with the knife. I want you to focus on him. When did you get the best view of him? [Sketch plans can be useful here.] Think of what he looked like, his overall appearance. What was he wearing? What could you smell? What could you hear? What were you feeling? Tell me everything you can about him in as much detail as you can.'. For each aspect the interviewer should start by probing with open-ended questions to enable the witness to supply an extensive answer. The interviewer should follow up with specific-closed questions but only when the open-ended questions do not result in the desired information. Avoid using leading questions.

Extensive retrieval

4.181 This is an element of the ECI. The more attempts the witness makes to remember a particular event, the more information will be recalled. Some witnesses should, therefore, be encouraged to conduct as many retrieval attempts as possible because many witnesses terminate their memory search after the first attempt. However, simply asking the witness to repeat the same search strategy is unlikely to lead to much new information and may be de-motivating for the witness. Therefore, in addition to searching extensively, using concentration, the witness should be encouraged to use a variety of memory search strategies. One way of doing this is to get the witness to use varied retrieval strategies such as the ECI techniques of

'change the temporal order of recall' and 'change perspective'. However, it is vital at this phase in the interview to allay any fears that this is being done because the witness is not believed.

Different senses

4.182 Retrieval may also be varied by probing different senses. Typically interviewers concentrate on what the witness saw and, as a consequence, what they heard, smelt, felt and tasted are often ignored. Valuable information may, therefore, go unreported. For example, if the witness has so far not mentioned much about sounds in the event, such as conversations, an interviewer could use sound as a retrieval cue: 'What I want you to do now is to go through the event again but this time think of all the sounds [use any sounds they have mentioned earlier in the interview as an example] and tell me what you can remember.'.

4.183 At the time of the offence, victims of serious violence sometimes dissociate themselves from the attack, and may close their eyes or focus on something else to help themselves do this. As a result, they may later have limited information attained from sight and, therefore, interviewers need to probe their memory of the event using other senses.

Recall in a variety of temporal orders

4.184 When an event is freely recalled, most witnesses report the event in real time (i.e. in the order in which it took place though not completely chronological – there is usually some jumping about). When recalling in this way, witnesses use their knowledge of such events in the past to help them recall this particular event (e.g. what typically happens on a Friday night will help them remember the assault on a particular Friday night). This results in the recall of information that is in line with their general knowledge (in this case of 'typical Friday nights'). However, unusual information or occurrences may not be so readily recalled. The 'change order' instruction invites the witness to examine the actual memory record which in turn can result in the reporting of additional information which is unusual and unique.

4.185 Research has shown that witnesses who were instructed to recall an event in forward order and in reverse order remembered more total correct information than those who recalled the event twice in forward order. The additional information gained tended to concern action information (i.e. what people did), which can distinguish the event (what happened on the Friday night the assault happened) from similar events (what typically happens on Friday nights).

4.186 Therefore, once witnesses have (using free narrative account) recounted the event in their own order, the interviewer could encourage the witness to recall the event using a different order; for example, from the end to the beginning of the event (i.e. reverse order recall), and/or working backwards and forwards in time from the most memorable aspect of the event.

Change perspective technique

4.187 Witnesses have a tendency to report events from their own psychological perspective. The change perspective instruction, from the ECI, asks the witness to recall the event from a different personal perspective (not a change in location). For example, in one police investigation a secretary saw what she thought was a scuffle between two men across the road from her office as she walked to work. When initially questioned by the police, about what was in fact a murder, all she could remember about one of the men's hair was that it was blond. The victim had dark hair but another witness had also said that one of the men had blond hair. Therefore, the murderer may well have had blond hair and the secretary may have seen his hair. In her subsequent interview, the interviewer said 'So far you have said you are having difficulties retrieving details of his hair style. What could a hair stylist remember about his hair?'.

4.188 Care must be taken with this technique as witnesses may misinterpret the instruction to adopt a different perspective as an invitation to fabricate an answer. Therefore, witnesses should be explicitly told not to guess at this stage of the interview and this instruction needs to be explained clearly. It is imperative when using this instruction to tell the witness explicitly that they must only report details that they actually witnessed themselves. Note that this technique should only be used by well-trained interviewers.

Memory prompts

4.189 There are also additional memory aids used in the ECI to help the reporting of specific details concerning people (e.g. names, faces, voices, clothing, appearance) and objects (e.g. vehicles, number sequences, weapons). For example, people are often unable to remember names. To assist with this, the interviewer could request the witness to think about name frequency (common or unusual name), name length (short or long, number of syllables) and the first letter of the name by conducting an alphabetical search. Similar techniques can help in the remembering of vehicle licence plate characters.

4.190 Witnesses tend not to realise that the interviewer requires detailed descriptions, specifically of the perpetrator, and instead tend to focus on the actions in the event. As a result, descriptions tend to be short and incomplete. Therefore, interviewers need to instruct the witness to report all types of information and not just action information. In addition, witnesses often have difficulty reporting information about people. When 'people information' does exist in the witness's memory, reporting such information from that mental image often involves a translation process from a visual to a verbal medium. This is a difficult task that requires concentration and assistance from the interviewer. The following techniques may help in eliciting specific details about people involved in the event:

- Physical appearance
  Did the person remind you of someone you know?
  Why?
  Any peculiarities?
- Clothing
  Did the clothing remind you of anyone?
  Why?
  What was the general impression?
- Speech characteristics and conversation
  Did the voice remind you of anyone?
  Why?
  Think of your reactions to the conversation.

It is important to remember when using the above three techniques to always back up the question with 'Why'. This is because the response to 'Did the voice remind you of anyone?' may for example be Sean Connery but the witness may not necessarily be thinking of a Scottish accent. Therefore, asking 'Why?' is imperative.

Phase four: closing the interview

Recapitulation

4.191 Interviewers should in this final main phase provide an account of the witness's description of the event in their own words. This allows the witness to check the interviewer's recall for accuracy. The interviewer must explicitly tell the witness to correct them if they have missed anything out or have got something wrong. The interviewer should not "over summarise". Where summaries have been conducted appropriately throughout the interview, there is no need to provide a complete summary at the closing phase.

4.192 This phase also functions as a further retrieval phase. The witness, however, should be instructed that they can add new information at this point in the interview otherwise they are unlikely to stop an interviewer in the full flow of recapitulating.

4.193 If there is a second interviewer present, the lead interviewer should also check with them whether they have missed anything.

4.194 Care should be taken not to convey disbelief.

Closure

4.195 The interviewer should always try to ensure that the interview ends appropriately. Every interview must have a closing phase. In this phase, it may be useful to discuss again some of the 'neutral' topics mentioned in the rapport phase.

4.196 In this phase, regardless of the outcome of the interview, every effort should be made to ensure that the witness is not distressed but is in a positive frame of mind. Even if the witness has provided little or no information, they should not be made to feel that they have failed or disappointed the interviewer. However, praise or congratulations for providing information should not be given.

4.197 The witness should be thanked for their time and effort, and asked if there is anything more they wish to communicate. An explanation should be given to the witness of what, if anything, may happen next but promises that cannot be kept should not be made about future developments. The witness should always be asked if they have any questions and these should be answered as appropriately as possible. It is good practice to give to the witness (or, if more appropriate, an accompanying person) a contact name and telephone number in case the witness later decides that they have further matters they wish to discuss with the interviewer. It is natural for witnesses to think about the event after the interview and this may elicit further valuable information. Advice on seeking help and support should also be given.

4.198 When closing the interview, and indeed throughout its duration, the interviewer must consider the witness's mental health and be prepared to assist them to cope with the effects of giving an account of what may well have been greatly distressing events (and about which the witness may feel some guilt).

4.199 The aim of closure should be that, as far as possible, the witness should leave the interview in a positive frame of mind. In addition to the formal elements, it will be useful to revert to neutral topics discussed in the rapport phase to assist this. This point has important repercussions, one of which is that a well-managed interview can positively influence organisation –community relations. Many witnesses will tell friends, family, etc. about the skill of the interviewer and their feelings about the interview process as a whole.

4.200 Report the end time of the interview on the video/audio-recording.

Evaluation

4.201 Evaluation should take two primary forms: evaluation of the information obtained and evaluation of the interviewer's performance.

Evaluation of the information obtained

4.202 After the interview has concluded, the interview team will need to make an objective assessment of the information obtained and evaluate this in light of the whole case. Are there any further actions and/or enquiries required? What direction should the case take?

Evaluation of interviewer's performance

4.203 The interviewer's skills should be evaluated. This can take the form of self-evaluation with the interviewer examining the interview for areas of good performance and poor performance. This should result in a development plan. The interview could also be assessed by a supervisor and/or someone who is qualified to examine the interview, and give good constructive feedback to the interviewer, highlighting areas for improvement. This should form part of a staff appraisal system (see tier 4 of ACPO's National Investigative Interviewing Strategy (ACPO, 2009)).

Post-interview documentation and storage of recordings

4.204 The interviewer should complete the relevant paperwork as soon as possible after the interview is completed including the Index to Video Recorded Interview referred to in Appendix G. A statement dealing with the preparation and conduct of the interview should be made while the events are still fresh in the interviewer's mind.

4.205 Recordings should be stored as recommended in Appendix H.

Supplementary interviews

4.206 One of the key aims of video recording early investigative interviews is to reduce the number of times a witness is asked to tell their account. However, it may be the case that, even with an experienced and skilful interviewer, the witness may provide less information than they are capable of divulging. A supplementary interview may, therefore, be necessary and this too should be video recorded. Consideration should always be given to whether holding such an interview would be in the witness's interest and the PPS should be consulted if necessary. The reasons for conducting supplementary interviews should be clearly articulated and recorded in writing.

Identification procedures

4.207 Where a video recorded interview has been conducted by virtue of this chapter, the production of facial composites using E-FIT or other systems, or the production of an artist's impression should also be video recorded. This will enable the court to hear the evidence from the witness in the same medium as the main evidence in chief and show how any new evidence has come about, giving confidence to the evidence gathering process and reducing the need for the witness to give additional evidence in chief in the witness box or by live link. Staff carrying out these procedures should be suitably trained to interview and record the evidence in line with this guidance (see Appendix K).

Therapeutic help for intimidated witnesses

4.208 An intimidated witness may be judged by the investigating team, and/or by the witness, to require therapeutic help prior to giving evidence in criminal proceedings. It is vital that professionals undertaking therapy with prospective intimidated witnesses prior to a criminal trial adhere to the official guidance contained in Chapter 8.

4.209 The PPS and those involved in the prosecution of an alleged offender do not have authority to prevent an intimidated witness from receiving therapy and whether a witness should receive therapy before the criminal trial is not a decision for the police or the PPS. However, the police and the PPS must be made aware that therapy is proposed, is being undertaken or has been undertaken so that consideration can be given to whether or not the provision of such therapy is likely to impact on the criminal case. At all times, the importance of not coaching or rehearsing the witness in matters of direct evidential value must be borne in mind by the professional undertaking therapeutic work with the witness (see Appendix D).

Safeguarding intimidated witnesses

4.210 Although witnesses may be willing to report or give information about an offence, this does not mean that they do not fear reprisals. Intimidated witnesses may be reluctant to provide a formal statement preferring instead to merely tell the police about the offence they have witnessed. Some witnesses may explicitly claim that they have been or are likely to be intimidated but others will not.

4.211 Some offences are more likely than others to give rise to the intimidation of witnesses. Research has shown that assaults, domestic violence, stalking (which by its nature involves repeated victimisation) and racially motivated crimes are particularly likely to lead to intimidation. When the witness is also the victim, the risks may increase further. Victims of sexual offences are also particularly vulnerable to intimidation. This vulnerability is heightened when the victim is a child and is further heightened when they do not have strong family support structures in place as is the case for many children in care who might have been sexually exploited. Such children can often experience a real and tangible fear as to what might happen if they report the abuse. This fear can be based on explicit or implicit threats. It is not only the nature of the offence, however, that may indicate the possibility of intimidation. Investigators need to be aware of the culture and the lifestyles of not only the witness but those who live with and around them. On some medium- and high-density housing estates, for instance, there may be a history of drug problems and/or anti-police feeling. A culture of fear and silence as regards criminal behaviour may exist in these areas. Equally, those who live in small, close-knit communities may have an increased risk of intimidation. Extended family networks may mean that the witness lives, shops and works near relatives and associates of the offender.

4.212 More specific factors might give rise to actual or perceived intimidation risks for the witness such as the witness's age, gender, sexual orientation, disability, cultural or ethnic background, religious and political beliefs. Careful attention must always be paid to issues that may relate to sectarianism. Vulnerable witnesses, particularly those with mental impairment or ill health (paranoia or chronic anxiety, for instance), may perceive that they are at risk. More substantive indicators of risk may concern the nature of the relationship between the witness and the accused. For example, it may be that the alleged perpetrator is in a position of authority over the witness (such as a carer in a residential home) or that the alleged perpetrator is the witness's violent ex-partner. Interviewers need to be aware of whether the witness has been intimidated in the past, and whether the alleged perpetrator or their relatives and associates have a history of intimidation and violent behaviour. The local influence of the alleged perpetrator, whether this is in terms of their position within the criminal fraternity or their socio-economic status, is a further issue that requires investigation.

4.213 In some instances intimidation may occur only later in the investigative process. If this happens, the intimidated witness should still qualify for special measures.

4.214 There are a number of steps that may be taken to provide protection, reassurance or assistance to intimidated witnesses at the interview phase. A police visit to the witness's home should be avoided as far as possible. Instead, the police should consider following alternative procedures, while leaving the choice of arrangements, within reason, to the witness. Interviews could take place on 'neutral ground', such as a relative's home out of the locality or the witness's place of work, where appropriate.

4.215 Procedures that may serve to alleviate the witness's fears when an offence has first been reported include:

- inviting the witness by telephone (or, if no telephone is available, by letter) to visit the police station to make a statement;
- delaying the visit to the witness's home until the next day, preferably sending a plain clothes officer; and
- conducting a number of house-to-house calls at adjacent properties, so that the witness is not singled out.

It is important that the witness's visits to the police station are planned to avoid encounters between the witness and the suspect and their associates.

4.216 Additional guidance in respect of the treatment of intimidated witnesses is available in Working with Intimidated Witnesses: A Manual for Police and Practitioners Responsible for Identifying and Supporting Intimidated Witnesses (Office for Criminal Justice Reform, 2006).

Witnesses who become suspects during the interview

4.217 It may happen that a witness who is being interviewed comes under suspicion of involvement in a criminal offence, perhaps by uttering a self-incriminating statement. Any decision on an appropriate course of action in these circumstances should involve taking into account the seriousness of the crime admitted and weighing it against the seriousness of the crime under investigation.

4.218 Where the priority is to obtain evidence from the person as a witness, the interview can proceed.

4.219 If it is concluded that the evidence of the witness as a suspect is highly relevant to a particular case, the interview should be terminated and the witness told that it is possible that they may be interviewed concerning these matters at a later time. Care should be taken not to close the interview abruptly in these circumstances. Instead, the witness should be allowed to complete any statement that they wish to make.

4.220 Any admission by a witness in the course of an investigative interview may not be admissible as evidence in criminal proceedings against them. Normally, a further interview would need to be carried out in accordance with the relevant provisions of the Code for the Detention, Treatment and Questioning of Persons by Police Officers (Code C of the Police and Criminal Evidence (NI) Order 1989). The Code provides, among other matters, for the cautioning of a suspect.

4.221 A witness who confesses to a criminal offence during the course of an interview may ask the interviewer for some guarantee of immunity. On no account should any such guarantee be given, however remote the prospect of criminal proceedings against the witness might seem. If the witness is to be interviewed in accordance with Code C of the Police and Criminal Evidence (NI) Order 1989), they must be cautioned and the purpose of the interview made clear.

5 Witness support and preparation

Introduction

5.1 Support and preparation by providing victims and witnesses information about the court process, explaining special measures to them, and giving them an opportunity to express their wishes (including identifying who they would like to accompany them in the live television room when they are giving evidence if appropriate) helps them to give better evidence and can influence their decision to proceed with the case in the first place. The additional stress of coping with an unfamiliar situation is likely to reduce the ability of witnesses to participate and to respond to questioning, or to effectively recall events in order to assist the fact-finding process of the criminal justice system. Preparation and support which are planned to fit the needs of individual witnesses can help to prevent and alleviate this problem.

5.2 Improvements have recently been introduced to improve information provision to victims and witnesses, and the identification of their support needs. The Code of Practice for Victims of Crime explains how a victim should expect to be treated by the criminal justice system. The Guide to Northern Ireland's Criminal Justice System for Victims and Witnesses of Crime builds on and complements the Code of Practice by providing a step by step guide through the criminal justice process, explaining what a victim or witness can expect at each stage. This guidance should be read in conjunction with the Code of Practice and Guide, and agencies should ensure that they deliver the requirements set out in both documents.

5.3 Vulnerable and intimidated witnesses will need greater consideration and it will be necessary to identify appropriate additional support and preparation to help them to give the best evidence they can.

5.4 'Vulnerable' witnesses are defined by Article 4 of the Criminal Evidence (Northern Ireland) Order 1999 (the 1999 Order), as amended by the Justice Act (Northern Ireland) 2011, as:

- all child witnesses (under 18 years of age); and
- any witness whose quality of evidence is likely to be diminished because they have a:
    - mental disorder (as defined by the Mental Health (NI) Order 1986); or
    - significant impairment of intelligence and social functioning (witnesses who have a learning disability); or
    - physical disability or are suffering from a physical disorder.

5.5 'Intimidated' witnesses are defined by Article 5 of the 1999 Order, as those whose quality of evidence is likely to be diminished by reason of fear or distress at the prospect of giving evidence.

5.6 Children and adults with learning disabilities might have problems with memory, vocabulary, level of understanding and suggestibility to leading questions. Some people with learning disabilities are acquiescent or compliant with the demands of those in positions of power or authority. In these cases, it may be beneficial to use an intermediary who will assess the witness's level of communication and make recommendations about how their needs can be met. In addition to these difficulties, such witnesses often lack knowledge or understanding of the criminal justice system. Consideration should always be given to using an intermediary to assist in communicating with children with learning disabilities. The defence or prosecution should ask court staff to make provision for any special needs a witness may have as a result of a disability, medical condition or age. Such difficulties can be helped by provision of appropriate information and support. National Standards have been prepared for those involved in young witness preparation (see Appendix L).

5.7 Children or adults who have been victimised may have special difficulties as witnesses in criminal proceedings. They may need help to overcome the feeling that it is they, rather than the defendant, who is on trial. The context and process of the trial itself may also bring back old memories, and patterns of reaction and response for vulnerable witnesses. They may be especially sensitive to suggestions of their own guilt or responsibility for the alleged actions of the defendant.

5.8 People with mental health issues can find the criminal justice system especially stressful. Those with post-traumatic anxiety disorders can have special problems prior to and during the trial, particularly if their problem is related to the alleged offence.

5.9 At the earliest stage in the process, the police should explain the special measures available to vulnerable or intimidated witnesses (and their parent or carer if the witness is a young witness, i.e. under 18), including the advantages/strengths and potential weaknesses/disadvantages of each. When providing such an explanation, the police should explain the role of the supporter in accordance with National Standards on Witness Supporters and make it clear to the witness that the granting of special measures and witness supporter is for the court to decide after taking their views into account.

5.10 The views of witness about which if any special measure(s) would be likely to assist them, including the identity of any supporter that they would like to accompany them in the live television link room while they give evidence if applicable, should be carefully recorded in the 'witness care report' (a standard form used by the police during case preparation to transmit confidential information to the Public Prosecution Service (PPS)) .This normally accompanies the witness's statement. In addition, once it has been established that a witness is to be involved in criminal proceedings, provided consent is given, the police officer will make a referral to the appropriate support service (VSNI Witness Service or NSPCC Young Witness Service) by completing Form PJ 19. The police and the PPS will need to consider if there is a need for a formal assessment of the witness in relation to special measures provision. In more complex cases, it may be appropriate for the police and PPS to convene a meeting to discuss special measures provision. This may need to include other relevant parties (e.g. Health and Social Care Trust, witness support services) and is likely to include the witness. Careful consideration should be given to the venue for such a meeting where a witness is to be included. The witness should be informed as soon as possible of a special measures application being granted or of any changes to the special measures being provided.

Overview of witness support and preparation

Entitlement to support and preparation

5.11 All witnesses, including those who may be vulnerable or intimidated, may require support before the trial. Witnesses, whether giving evidence for the prosecution or defence, should be given an explanation of their role at court and assistance to ensure that they are able to give their best evidence. Support is appropriate at all stages of the case. This will not involve discussing or rehearsing the witness's evidence or otherwise coaching them before the trial – witness 'training' for criminal trials is prohibited. That does not prohibit pre-trial familiarisation visits provided that broad guidance is followed – the witness can be shown the courtroom and the live link room to familiarise themselves before their day in court but there can be no discussion of the evidence (see Appendix D for relevant case law).

Nature of support and preparation

5.12 The first task is the identification of children and vulnerable and intimidated adults who need special consideration during their involvement with the criminal justice process. To ensure timely access to support, the police must take all reasonable steps to identify vulnerable or intimidated victims, and to record relevant information on the 'Witness Details Form' under the section marked 'Witness Care Report'. In practice, this approach to victims will also be extended to the identification of vulnerable and intimidated witnesses. While it is usually the police who first identify witnesses' vulnerability, it can be highlighted by anyone with knowledge of the witness or by the prosecutor following assessment of the evidence. Once a witness has been identified as either vulnerable or intimidated, there is potentially a long period of time before a court hearing takes place. During this time, preparation and support need to focus on arrangements surrounding any interviews with the witness, pre-trial arrangements and preparation for any court hearing. Providing the witness with information about the investigation and court case, and obtaining their views on which special measures they feel is most appropriate for their needs, and who they would want to accompany them into the live link room, if that is their preferred special measure, is crucial. If the case goes ahead, support will also be required during the court hearing and in the immediate aftermath. In the typical criminal case, these activities will probably occur over many months.

5.13 Box 5.1 illustrates some of the range of possible activities that can be undertaken with vulnerable and intimidated witnesses by pre-trial and court witness supporters. The key tasks for young witness preparation are described in the National Standards for Young Witness Preparation (see Appendix L) and Preparing Young Witnesses for Court – A Handbook for Child Witness Supporters (NSPCC, 1998).

5.14 Victims of sexual violence and abuse may have multiple support and safety needs because of the nature of these crimes. These may include therapeutic support, housing, treatment of injuries and infection, drugs and alcohol treatment, risk assessment and support through the criminal justice process. The Sexual Assault Referral Centre which is under construction at the time of writing will provide victims of sexual assault with medical care and counselling alongside a police investigation.

5.15 Victims of domestic abuse will also have particular support and safety needs. Women's Aid has a key support role in cases of domestic abuse. However, it should be noted that it is the Victim Support NI (VSNI) Witness Service which has a lead role in supporting victims and witnesses in domestic abuse cases in court. Where children are to be called as witnesses, there will be a role for the NSPCC Young Witness Service. The three agencies have a range of joint protocols which support the delivery of these services. The introduction of Multi-Agency Risk Assessment Conferences (MARAC) creates a partnership model for dealing with domestic abuse. These multi-agency conferences aim to provide a forum for sharing information and developing action plans which will reduce future harm to very high-risk domestic abuse victims and their children. This will also include maximising evidential opportunities throughout criminal investigations and subsequent criminal proceedings to ensure perpetrators of domestic abuse are held accountable for their actions.

Box 5.1 Activities undertaken by pre-trial supporters and court witness supporters

Depending on the supporter's role, they can:

- provide emotional support;
- educate and give information;
- understand the witness's views, wishes, concerns and any particular vulnerabilities that might affect them during the criminal process (including the witness's views on special measures), and convey these to the relevant criminal justice system agency;
- agree the manner and frequency of the provision of information;
- familiarise the witness with the court and its procedures, and with the responsibilities of the criminal justice system;
- support the witness through interviews and court hearings;
- undertake court preparation and pass on information about the trial;
- explore with the witness their preferences in respect of special measures and, if it is relevant, who they would want to accompany them into the live link room, and relay that information to the police or PPS;
- accompany the witness on a pre-trial visit to court;
- accompany the witness when their memory is to be refreshed (this should not be undertaken by a supporter who will accompany the witness while giving evidence);

- accompany the witness while they give evidence in court or the live link room (where the court approves this);
- liaise with family members and friends of the witness;
- liaise with legal, health, educational, social work and other professionals, and act as an advocate on behalf of the witness;
- liaise with those offering therapy and counselling prior to a criminal trial; and
- arrange links with experts in any of the witness's specific vulnerabilities or difficulties, e.g. communication problems, learning disabilities, or specific cultural or minority ethnic group concerns.

Different types of supporter

- Victim Support NI community services
- Victim Support NI Witness Service
- NSPCC Young Witness Service
- Women's Aid re domestic abuse
- Nexus and Rape Crisis and Sexual Abuse Centre Northern Ireland re sexual offences
- PSNI Domestic Abuse Officer, Family Liaison Officer, Child Abuse Investigation Officer etc
- Other voluntary groups as appropriate, such as NICEM (Northern Ireland Council for Ethnic Minorities) and the Rainbow Project

5.16 Different support functions may be provided at different stages. Four distinct roles or phases for witness support have been identified. They are:

- interview support – provided by someone independent of the police, who is not a party to the case being investigated. The supporter can sit in on the interview. They may be a friend or relative, but not necessarily so;
- pre-trial support – provided to the witness in the period between the interview and the start of any trial;
- court witness support – a person who may be known to the witness but who is not a party to the proceedings, has no detailed knowledge of the case or may have assisted in preparing the witness for their court appearance. A direction for evidence to be given via live link under may also provide for a supporter; and
- post-trial support – witnesses have considerable needs following a trial and it is important that practitioners are mindful of the information needs of victims and witnesses following a verdict and sentencing. The need for information is acute in discontinued cases or where lesser charges are proffered, particularly where a

plea is accepted. Agencies providing support have a key role in identifying current need; linking the witness to appropriate sources of information; helping the witness to understand the outcome of proceedings; and connecting witnesses to sources of relevant ongoing support.

5.17 The same supporter will not normally be used throughout the entire criminal justice process and indeed it is unlikely to be appropriate for the same person to be involved in all four phases since this can lead to allegations that the witness is being coached; family members and friends are unlikely to have experience of the courtroom and the pre-trial supporter must have knowledge of the court process. Research indicates that the interests of the witness, especially in terms of consistent information, are best served if pre-trial and court support are undertaken by the same person. Any supporter used during the interview, however, should not be used to prepare the witness for court nor should they offer to support the witness while they are giving evidence because they are already aware of the witness's account. However, in exceptional circumstances (such as a witness finding it difficult to adapt to change), the same supporter may be used at all stages of the process. When this happens, great care needs to be taken to brief the supporter about the limitations of their role. There needs to be certainty that the supporter will not be called as a witness either by the defence or the prosecution.

Investigative interview support

5.18 Accompanying and supporting children as well as vulnerable and intimidated witnesses can be helpful during investigative interviews. The supporter may be a friend or relative provided they are not party to the proceedings, and they are not involved in pre-trial support or in the role of supporter at trial.

Pre-trial support

5.19 Support from a trained person with knowledge of the court process can assist the witness through information provision and preparation for giving evidence. The police and PPS will provide information about the progress of the case and support requirements in preparation for court will be discussed and agreed with the witness. A supporter may be present when the witness views their video recorded statement for the purpose of memory refreshment before the trial. However, careful consideration must be given as to who this supporter should be in order to guard against future allegations of coaching the witness. Generally, any supporter present during the witness's memory refreshment would not be the same person who has supported the witness pre-trial and/or is expected to accompany the witness when giving evidence. The court should be informed of the identity of any supporter and any potential conflicts should be highlighted. A discussion should also take place

with the witness that explores their preferences in respect of special measures and, if it is relevant, who they would want to accompany them into the live link room. The witness's views in respect of special measures and support during the trial should then be conveyed to the PPS.

5.20 VSNI's Witness Service and the NSPCC Young Witness Service can arrange pre-trial visits for prosecution witnesses. The defence can make similar arrangements for defence witnesses by contacting NI Courts and Tribunals Service (NICTS). These visits should give vulnerable or intimidated witnesses information about special measures including, where applicable, the opportunity to practise using the live link facility.

Support while giving evidence

5.21 Support during the court process itself, in the live link room or when giving remote live link evidence is to be provided when it is necessary. There are evidential constraints that apply to the person providing support (see Appendix K). The identity of a supporter in the live link room or at the remote location must be the subject of an application to the court. It is normal practice in Northern Ireland courts for supporters from the VSNI Witness Service or the NSPCC Young Witness Service to accompany witnesses in the live link room. Where a supporter from either witness service is not available, a suitably trained member of Court Service staff will be available to accompany the witness in the live link room.

Evidential boundaries

5.22 The pre-trial support and/or court witness supporter must not be a witness in the case and must not be given details of the case or the evidence of the witness. However, the supporter needs to know:

- the charges against the defendant;
- the relationship between the defendant and the witness, and whether the charges involve an abuse of trust;
- the defendant's custody status and any change in this during the pre-trial period; and
- matters which may affect how preparation is conducted or how the witness gives evidence (e.g. the age of the witness, whether an intermediary has been applied for or not, and any medical needs).

5.23 Court witness supporters must not discuss the details of the case with the witness, or the evidence the witness is to give or has given. In their initial contact with witnesses, supporters must explain that they are independent of both the prosecution and the defence, and that there will be no discussion of the evidence in order to avoid allegations that the supporter has told the witness what to say. Supporters need to distinguish between providing practical, emotional help and support to the witness generally which is a key part of their role, and on the other hand expressing their own views and beliefs concerning the evidence of the witness, which is not permitted.

5.24 Court witness supporters must also explain that preparation work cannot be guaranteed to be confidential. For example, if the witness begins to talk about the evidence, the supporter must make a note – in the witness's words – of what was said, notify the police and ask the witness to speak to the person who conducted the investigative interview. Such a written record is disclosable. Further guidance on court witness supporters is described in Appendix K.

Who can provide support?

5.25 Who undertakes the range of support and preparation functions will depend on the needs of the individual witness, the availability of resources and the court's directions. In addition to general considerations, including the views of the witness, it may be appropriate to secure the assistance of a supporter who has a particular understanding of the needs of the witness, for example from the point of view of ethnic or cultural background, or disability awareness.

5.26 Assistance and support is available from VSNI through their community services and Witness Service, and from the NSPCC Young Witness Service as well as a range of other organisations, such as Women's Aid, NICEM and the Rainbow Project. VSNI's Witness Service provides pre-trial preparation and support to adult witnesses and the NSPCC Young Witness Service provides pre-trial preparation and support to witnesses under 18 years. These arrangements are covered by a series of complementary protocols between the two support service providers and the other key statutory agencies – PSNI, PPS and NICTS. All the agencies recognise that it is vital that pre-trial preparation and support begins as soon as the witness's vulnerability or intimidation is identified and the police and/or the PPS become aware that they may need to attend court.

5.27 Support and preparation work with a prosecution witness should not be undertaken without informing the police officer in charge of the case. The work should be carried out by someone who is independent and focuses purely on preparing the witness for the experience of giving evidence which they may find difficult. The supporter must also not have been involved in the detailed preparation of the case, nor must they discuss details of the prosecution case or the evidence of the witness. It is recognised that supporters could be police officers or other professionals, or volunteers. However, all must have received basic training, which may include additional information from the PPS on the criminal justice system and court processes. Supporters working with child and adult witnesses should be subject to current Enhanced Disclosure Procedures through Access NI in line with the Protection of Children and Vulnerable Adults (NI) Order 2003 (POCVA). The social worker or police officer who conducted the investigative interview is excluded from the role of supporter in the same case (see 'Government Policy on the Child Witness Supporter' in Preparing Young Witnesses for Court – A Handbook for Child Witness Supporters (NSPCC, 1998)).

What knowledge and skills are involved?

5.28 Witness support requires training. The skills involved in pre-trial preparation and support include the following:

- knowledge about, and aptitude for, working with vulnerable and intimidated individuals;
- an ability to prepare witnesses to go to court without discussing their evidence or coaching them in any way;
- knowledge and understanding of court procedures, relevant legislation and policy;
- knowledge about the information and support requirements of vulnerable and intimidated witnesses as well as the support that is available; and
- an ability to liaise with other professionals and family members.

5.29 Working with young witnesses requires additional qualities and skills which are described in the National Standards for Young Witness Preparation (see Appendix L) and in Preparing Young Witnesses for Court – A Handbook for Child Witness Supporters (NSPCC, 1998). There must be proper documentation of any support work (see Box 5.2).

Box 5.2: Documenting support work

Supporters should:

- make concise and factual records summarising all activities undertaken with witnesses including a record of all phone contacts (these should be suitable to produce to the court if required);
- make the records as soon as possible after the event;
- make a record of all liaison contacts with other professionals and the voluntary sector;
- distinguish fact from opinion when it is necessary to record opinion;
- note in the witness's own words any reference by the witness to the evidence, and notify the police accordingly; and
- keep records securely in a locked room or filing cabinet.

Identifying vulnerable and intimidated witnesses

5.30 The prosecutor and/or defence legal representatives require information about the needs and the wishes of the witness for the purpose of pre-trial preparation, planning how the witness should give evidence and in making related applications to the court. At the outset, the police should identify details of any difficulties witnesses might have in giving evidence and explain how the different special measures might assist them. Young witnesses are automatically eligible for consideration for special measures. Witnesses can then express an informed view on their preference for particular measures, which will be included in any application. Research concerning young witnesses suggests that giving them the choice of how they give their evidence has a beneficial effect on their emotional state, their experience of court and their performance as a witness. While a child's views are obviously important, it is the norm for child witnesses to give evidence via video/live link.

5.31 The police should provide the PPS with information relevant to vulnerability and intimidation. Provision of this information at this stage allows for active consideration of the steps necessary to secure the giving of a witness's best evidence as early as possible. The police must give consideration to obtaining medical or equivalent evidence from someone with professional knowledge of the witness in the appropriate discipline, as this may be required in support of a special measures application. This will be subject to the relevant permission being sought from, and explanation given to, the witness.

5.32 The police may also seek indirect information about the needs of the witness from their court witness supporter, relatives, friends or carers (provided that they are not party to the crime under investigation), or other agencies. The PPS should seek such information if it is not provided, as this will be necessary for pre-trial planning. In the case of defence witnesses, it is the responsibility of the defence lawyer to enquire about the witness's needs, refer them to appropriate support services and make appropriate special measures applications.

Preparation, support and liaison throughout the court process

5.33 Pre-trial support and preparation should begin as soon as possible, particularly if the witness has been identified as vulnerable or liable to intimidation. Vulnerability will normally have been highlighted before the first investigative interview. In the case of video recorded interviews, a pre-interview planning meeting should be scheduled at which any special difficulties are identified and plans made for relevant special measures to be taken at the interview. The police investigators are responsible for calling an early special measures meeting during the investigation with the PPS (these meetings can, in practice, be a telephone discussion). Where there is any doubt as to whether an interview should be video recorded, where an intermediary or aids to communication are involved, or where there might be an issue about the use of a supporter during an interview, the police investigator should normally undertake an early special measures meeting. The PPS may, in more serious cases, hold an early consultation with the victim prior to making a decision to prosecute and this meeting may include prosecution counsel. After the interview, the next stage involves support, further assessment of needs and liaison with others. As pre-trial hearings and the trial hearing come closer, specific preparatory work for these witnesses will be necessary. In some cases, separate pre-trial therapy or counselling work will be necessary to meet the needs of the witness (see Chapters 7 and 8). A variety of support needs must be met at the hearing itself. The period after the hearing is an important one for ensuring continuing support or treatment, through debriefing and arranging for further work with the vulnerable or intimidated witness to be carried out by other professionals. Opportunities for support occur throughout the witness's involvement with the legal process. These activities can be summarised under four phases:

- support during the investigation;
- pre-trial support, preparation and liaison;
- support at the hearing; and
- support after the hearing.

Support during the investigation

5.34 Information collected during the planning phase prior to a video recorded investigative interview, and that emerging during the interview itself, is highly relevant to later decisions concerning how witnesses may give their best evidence. It is important that the views of the witness are sought. Not all vulnerable and intimidated witnesses will be video interviewed – the majority of adult witnesses will probably give a written statement. A decision as to whether or not to video interview a witness or make a written statement will be decided by the police at this stage. However, the investigating officer may wish to consult with the PPS prior to making this decision. During the investigation, information about the witness will have been gathered from contact with the witness directly as well as from those providing care, education or specific services. The effective undertaking of the initial needs assessment by the police prior to the statement being written or the video interview recorded will also have established critical information relevant to the investigation, and about support needs up to and including the trial.

5.35 During the course of the investigation, for example in an interview, further information may emerge that may be relevant to decisions about how the witness might give their best evidence. It may become clear that further expert advice is needed in order to determine the best method of communicating with the witness, any special support or assistance which might be required and in what form the witness's evidence might best be taken. For example, it may be identified that the witness requires an intermediary.

Special requirements

5.36 Some witnesses will have special requirements. These can include communication difficulties, but also differences connected with cultural and minority ethnic values and, sometimes, religious practices that are likely to have an influence on the investigative and pre-trial support and preparation phases. For witnesses whose specific needs include culture, language and communication, consultation should take place with an appropriate adviser, interpreter or intermediary. During the course of a pre-interview planning meeting for a video recorded interview, or immediately after the interview, the police may have discovered special requirements of the witness with respect to culture or communication. Some of these issues will have been identified during the undertaking of the initial needs assessment. Members of the witness's family or friends, or their carer will often be a good source of information about these needs or requirements. The Police should consult with the witness and those who know the witness well in order to seek their advice on these matters, provided that they are not a party to the crime under investigation, or likely to undermine or interfere with the investigation. One example is those witnesses

whose first language is not English but who at first meeting appear to communicate relatively easily using English. Appropriate advice and interpretation may be needed during the interview, when providing information about the court process and when giving evidence at trial in order to prevent the witness becoming confused and to enable them to give their best evidence. The guidance in the National Agreement on Arrangements for the Use of Interpreters, Translators and Language Service Professionals in Investigations and Proceedings within the Criminal Justice System, which has been endorsed by the Association of Chief Police Officers, should be referred to.

5.37 As the hearing approaches, witness support work will become more specifically focused on preparing the witness for giving evidence at court. In some cases, therapy prior to trial will be organised as well.

Pre-trial support, preparation and liaison

5.38 The interval between the investigative interview and the final trial hearing can often be lengthy. Over the months the tasks range from initially assessing needs, either by direct enquiry or observation by the police, through gathering information from others, to providing continuing support. The pre-trial supporter may not take on all these roles (for example, therapy) and different components may be carried out by a different person. The different roles of a pre-trial supporter are considered in Box 5.3. Anyone providing support to a witness at any stage of the criminal process must be clear about which roles they are adopting and which are not compatible with their overall role or the support roles they have taken on. It is recommended that individual agencies make this clear in their own role descriptions and associated guidance for their staff and volunteers. The PSNI, PPS, VSNI Witness Service and NSPCC Young Witness Service will work together to ensure that witnesses are updated on all court hearings in their case. They will also make arrangements to continually assess the witness's information and support needs because these may change over time.

Box 5.3: Components of pre-trial preparation

Assess the needs of the witness:

- directly; or
- by obtaining information from others.

Support:

- seek the witness's views about giving their evidence and being at court, including who they want to accompany them into the live link room is that is relevant;
- provide information about the criminal process and their role within it, for example the Young Witness Pack, if applicable;
- provide support and general assistance to the witness to enable them to give their best evidence;
- liaise with others as appropriate, particularly in respect of any pre-trial court familiarisation visit;
- provide general emotional support to the witness;
- manage anxiety connected with the court process; and
- provide therapy (including counselling).

Liaise and communicate with:

- the witness;
- other professionals in connection with the legal case;
- the witness's family and friends;
- the witness's circle of professionals; and
- those providing therapy and counselling to the witness.

Preparing for the trial:

- provide information concerning courts (personnel and what will happen during the trial);
- explain the options for giving evidence;
- consider any practical needs;
- discuss the victim's wishes;
- arrange the pre-trial visits;
- refresh memory; and
- meet the legal representative.

Communication between the police and PPS

5.39 Police officers should have undertaken an initial needs assessment for the witness and recorded relevant information, which is then provided to the PPS. Additional information relevant to vulnerability and intimidation should be included in the Witness Care Report and the prosecution file. If an accused is charged by the police, any information as to the vulnerability or intimidation of the witness should be conveyed to the PPS at that time.

5.40 A meeting between the investigating officer and the PPS may be of assistance in determining which measures could assist the witness before and during the trial, taking into account the witness's own views and preferences for a particular person to act as a supporter This may require no more than a telephone call. Where appropriate, a second meeting involving the witness should be considered so that these issues can be discussed further and the needs of the witness fully assessed and appreciated.

5.41 In addition, both the prosecution and defence have a responsibility to communicate any special needs of the witness to the court either at the time the case file is reviewed or at a pre-trial hearing. The court should be made aware of what special measures will be needed at court to enable the witness to give their best evidence. It is also helpful if the court can be told in advance about any special arrangements they can make for the witness to make them feel safer e.g. entering and leaving the court by a separate entrance, or arranging separate seating in the court. In addition, it may be appropriate for the legal representatives and/or the judge to meet the witness before the trial. The investigating officer or the PPS should ensure that witnesses discussed at any such hearing (or their supporters) are informed about these hearings and the outcome.

Support before and on the day of the trial/hearing

Pre-trial hearing/review

5.42 A pre-trial hearing or review provides the opportunity for pre-trial planning and for initial decisions to be taken about the special measures available to vulnerable and intimidated witnesses under the 1999 Order, as amended, and any other provisions. At a preliminary hearing, the judge, informed by the legal representatives, with full instructions and having seen any video recordings of the witness's evidence, should be asked by the prosecution and/or the defence to consider all the issues set out below and make any necessary directions. This is to ensure that all relevant issues can be coordinated and planned in readiness for the

trial. There are advantages in completing this as early as possible as it will tend to avoid delay, and bring greater clarity and certainty to the preparation of vulnerable and intimidated witnesses. This will also assist the prioritisation of cases involving child witnesses. It is vital that there is clear communication between the legal representative and those providing support for the witness, both before and after any pre-trial hearing(s).

5.43 The judge may wish to use the list of issues set out below as a checklist to ensure that legal representatives have fully considered the needs of the witness and these have been issued as a checklist for all Crown Court judges:

- video recorded evidence;
- television links;
- screens around the witness box;
- proposals for any supporter;
- arrangements for the witness to refresh their memory;
- the witness's preparation for court (including meeting the legal representatives);
- witness attendance times;
- breaks for the witness;
- special circumstances (such as learning difficulties, hearing problems, English not being the first language, short attention span) and the arrangements made to accommodate these;
- mental or medical condition of the witness;
- views of the witness about court dress;
- scheduling and standby arrangements; and
- disclosure of third party records.

5.44 In addition, judges may wish to make use of the Equal Treatment Bench Book published by the Judicial Studies Board in England and Wales (www.jsboard.co.uk), which can be used as good practice guidance in Northern Ireland. In considering the needs of the witness, judges should be cognisant of the information that has been gathered in relation to the witness at the planning and decision making phases of the interview process as this will provide insight into the particular needs and circumstances of each witness. Legal representatives have an important role in ensuring that this information is available to judges.

Preparation for going to court

5.45 The aim of preparing witnesses for court is to make them feel more confident and better equipped to give evidence; to help them understand the legal process and their role within it; and to encourage them to reveal their fears and misapprehensions. For many witnesses, the court environment may increase their

stress and reduce their ability to provide accurate testimony. Effective preparation can assist the witness to give a more accurate and complete account, and also help secure better post-trial adjustment.

5.46 The pre-trial supporter can provide the witness with information about the court process (or can direct their carer or specialist service to it). For example, there is a witness pack available for supporters and child witnesses to use (NSPCC, 2011), including a video for 11–15-year-olds, Giving Evidence – What's it Really Like. A video for witnesses with learning disabilities has been made by Voice UK. A range of materials in different formats is available (see Appendix T).

Pre-trial visit to the court

5.47 Witnesses are likely to benefit considerably from a pre-trial court familiarisation visit. VSNI and the NSPCC will offer pre-trial visits to court as part of their witness support services. (Where an intermediary is being used to help the witness to communicate at court, the intermediary should accompany the witness on their pre-trial visit). The visit will enable witnesses to familiarise themselves with the layout of the court and make witnesses better informed about the particular special measures ordered by the court to assist them to give evidence. The following may be covered at the visit:

- location of the defendant in the dock;
- court officials (what their roles are and where they sit);
- who else might be in the court, for example those in the public gallery and press box;
- location of the witness box;
- run-through of basic court procedure;
- facilities available in the court;
- discussion of any particular fears or concerns;
- outline of the services offered by VSNI's Witness Service or the NSPCC Young Witness Service, as appropriate, on the day of trial; and
- demonstration of any special measures applied for and/or granted, for example practising on the live link and explaining who will be able to see them in the courtroom, or showing the use of screens (where it is practical and convenient to do so).

Refreshing the memory of the witness

5.48 Witnesses are entitled to see a copy of their statement before giving evidence. Where the investigative interview of the witness has been video recorded, the recording is often used to refresh the witness's memory before the trial – the equivalent of reading the statement beforehand. Viewing the video ahead of time in more informal surroundings helps some witnesses familiarise themselves with seeing their own image on the screen and makes it more likely that they will concentrate on the task of giving evidence. Arranging memory refreshment for young witnesses is particularly important.

5.49 If a video recording is ruled inadmissible by the court then legal representatives must give careful consideration to the alternative method of refreshing the witness's memory. Decisions about admissibility should be made in sufficient time to allow other steps to be taken. If the witness is to give oral evidence in chief, legal representatives should consider seeking a ruling on whether it is appropriate to allow the witness to see the video before evidence is given. Relevant supporters should be informed promptly about any decisions on video admissibility and editing.

5.50 Issues involved in planning for refreshment of a witness's memory will be raised with the court by the legal representatives. If memory refreshment is to proceed, a decision may be required as to how the vulnerable witness should be supported during the process and the implications for the supporter's role in any subsequent trial. A decision can be reached about the person who is best placed to support the witness while their memory is refreshed. Consideration will need to be given to any competing requirements for the witness supporter during the remainder of the criminal justice process. Witness supporters from VSNI and the NSPCC routinely avoid being present during memory refreshment to reduce any risk of contamination but can be available before and after memory refreshment.

5.51 Having consulted with the PPS, if appropriate, the police will arrange for prosecution witnesses to read their statements or view video recorded interviews. The relevant police officer should consult the prosecution about where this should take place, when it should take place and who should be present. A record of anything said at the viewing should be maintained. In exceptional cases, such as those involving very young children or children with learning disabilities, the prosecutor should consider whether a video recording should be made when the witness refreshes their memory from the video recorded interview.

5.52 Witnesses need to receive appropriate explanations about the purpose of watching the video before the trial and their views about this must be taken into account. Sometimes videos will be edited for legal reasons, for example if the video contains irrelevant material or inadmissible matters of fact or law. Witnesses need to be alerted to any editing so that they will not be surprised, suspicious or confused when the recording does not match precisely their recollection of the interview.

5.53 The time interval between showing the video for the purpose of refreshment and actually giving evidence should take account of the witness's needs and concentration span. Minimising delay should be balanced against the difficulty experienced by some witnesses in concentrating through two viewings on the same day. Many child witnesses may prefer to watch the video at least a day before the trial to help prepare them and reduce the stress of giving evidence on the day. It is recommended that the first viewing of the video recording should not be on the morning of the trial in order to avoid the child having to view the recording twice in one day. If the witness loses concentration or becomes distressed during the viewing, a break will be necessary.

Communication with the witness

5.54 Witnesses should be told who is responsible for keeping them informed of significant developments in their case. The PSNI, PPS, VSNI Witness Service and NSPCC Young Witness Service will work together to ensure that witnesses are kept informed. This will be the subject of formal protocols between the agencies which set out roles, responsibilities and lead agency status at different stages of the criminal justice process. It is vital to keep victims properly informed but this is particularly the case for vulnerable or intimidated witnesses.

5.55 The police or the PPS must keep the supporter informed about key decisions, for example about how the witness is to give evidence. The police and the PPS will agree how this should be done. Where an intermediary is to be used, the police should inform them that they have been appointed.

5.56 Witnesses are likely to be anxious about the progress of the case and decisions about whether and how they will give evidence. A vital ingredient therefore, for the police, in maintaining the confidence of the victim, is keeping them fully informed of significant developments in their case. Where there is a need to update a victim of a significant development during the course of an investigation, good practice indicates that the police should consider making personal contact with the victim or, if impractical, by telephone or letter. This would include where a person has been arrested on suspicion of an offence; where the person has been subsequently

released with no further action; where a person has been remanded in custody to appear before a court and details of that first court appearance; when police charge and release a person on bail to appear at court and details of that first court appearance; or where a person has been reported to the PPS for their consideration as to whether that person should be prosecuted. Victims should also be updated by the police in cases where no one has been made amenable.

5.57 The PPS has established dedicated Community Liaison Teams (CLT) who provide a range of services to victims and witnesses for the prosecution who are involved in magistrates' court cases, indictable cases until committal stage (PSNI take over responsibility post-committal) and youth court cases. CLTs provide a contact point for victims and witnesses who have queries concerning the overall prosecution process and the progress of their specific case. When it appears likely that the commission of a crime will result in a person being prosecuted, the victim (and other witnesses) should be advised of the role of the VSNI Witness Service and/or the NSPCC Young Witness Service. The PPS has responsibility for informing the witness services of the referral details of witnesses called to attend magistrates' and youth courts. In the Crown Court, the police continue to notify witnesses of when to attend and will inform witnesses required to attend the Crown Court of the services offered by both witness services.

5.58 While continuing efforts are made to minimise delays in the criminal justice system, witnesses should be forewarned at an early stage that some cases take a long time to reach trial or may be discontinued pre-trial, and that some trials may need to be adjourned. They should also be advised beforehand of the possibility of waiting to give evidence on the day of trial. Witnesses may be put on 'standby' and asked to wait at locations away from the court, to be summoned by pager when their evidence is to be heard. Vulnerable or intimidated witnesses may be able to wait somewhere near to the court until the time they need to give evidence.

Provision of therapy prior to a criminal trial

5.59 There is a concern that some witnesses are denied therapy pending the outcome of a criminal trial for fear that their evidence could be considered tainted and the prosecution lost. This may conflict with ensuring that a witness is able to have immediate and effective treatment to assist recovery. Delay in seeking treatment may worsen the prognosis. Therefore, witnesses should not be denied access to any therapeutic help prior to any criminal trial, in particular if they have a mental illness. Chapter 7 provides guidance in relation to pre-trial therapy for child witnesses and Chapter 8 provides guidance in relation to pre-trial therapy for vulnerable and intimidated adult witnesses.

5.60 Pre-trial therapy should be kept separate from preparation and support. Therapy includes both counselling and psychotherapy. The guidance in Chapter 7 has been prepared for childcare professionals as well as lawyers involved in making decisions about the provision of therapeutic help for child witnesses. It emphasises that the best interests of the child are paramount when deciding whether, and in what form, therapeutic help is given. Records of any therapeutic work should be kept because they may become relevant material at a forthcoming trial and may satisfy a test for disclosure under relevant legislation. Whenever possible, before any therapeutic work is undertaken, there should be full discussion between the various agencies and professionals, as well as clear communication and named contact points within each agency. It is recommended that a protocol is established so that the different issues involved in providing pre-trial therapy can be jointly co-ordinated and the best interests of the child held central. Chapter 8 provides similar guidance in relation to pre-trial therapy for adults where the welfare of the witness is also the paramount consideration. Record keeping, discussion between agencies and professionals before any therapeutic work is undertaken and ongoing communication are equally relevant in relation to adults.

Plans and communication concerning the trial

5.61 Applications for special measures can be made at any stage up to and including the trial itself. However, it is good practice for special measures and any related matters to be decided on as early as possible as this enables the pre-trial supporter to plan ahead with greater certainty. If the court rules that a witness is eligible for one or more special measures then this ruling and the details of the measures to be provided are binding on the trial court. Details of where, when, and how these are to be provided are set out in the form of binding directions. Frequent communication and co-ordinated planning is needed if more than one person is undertaking the pre-trial support for the witness and support during the court hearing.

5.62 Information about the witness's needs and wishes should be available to the person preparing the witness for court. This may include relevant information obtained during the investigation and recorded in the 'Witness Care Report' and/or form PJ14 in the case of a child or form AJP1 in the case of an adult, together with additional information that the pre-trial supporter has gained during the preparation for court and the pre-trial visit.

Role of the witness services

5.63 The Witness Service for adult witnesses is run by Victim Support NI. It is available in all courts for all witnesses, including those who are vulnerable or intimidated. It provides a free, independent, impartial and confidential service, adapted to individual needs. The Witness Service supports victims and prosecution witnesses, and their families and friends. The Witness Service also supports and works alongside other people who may accompany a witness, for example a carer, social worker, expert witness, interpreter, intermediary or specialist witness supporter. The Witness Service provides:

- someone to talk to (but not about the evidence);
- information about court and legal processes;
- emotional support in dealing with the impact and experience of attending court;
- pre-trial visits for witnesses so that they are familiar with the courtroom, the TV link (where appropriate) and the roles of court personnel;
- support on the day of the trial;
- support in the TV link room (where appropriate);
- practical help with completing expenses forms;
- support and information during and following sentencing;
- special support for vulnerable and intimidated witnesses;
- arrangements for defence and prosecution witnesses to be kept separate;
- liaison with other statutory and voluntary agencies;
- referral to Victim Support NI's community service or other services; and
- other arrangements such as baby changing etc.

5.64 The Young Witness Service is run by the NSPCC and performs the same role as VSNI's Witness Service for children and young people under the age of 18 years. The service is for victims and prosecution witnesses, including their families and carers. Victim Support NI and the NSPCC have a protocol in place to help them work together to maximise the support available for victims and witnesses who may have to give evidence at court.

Role of the courts

5.65 Court Service staff will assist in coordinating the provision of facilities and will liaise with other agencies. Court Service staff will provide a range of assistance which may include pre-trial familiarisation visits, liaising with the judge to ensure that the cases progress speedily, undertaking the practical arrangements on the day of trial, meeting the witness and liaising with witness services to arrange separate waiting areas where possible. A specific member of Court Service staff will ensure that the video and TV link equipment is set up and working effectively and will be available to respond to any technical difficulties.

5.66 Legal representatives, in consultation with the judiciary, should consider the order and timing of witness attendance so as to minimise inconvenience. Such an approach will benefit vulnerable or intimidated witnesses (see Appendix M).

Meeting the legal representative

5.67 On the day of the trial the prosecutor or prosecuting counsel will introduce him or herself to the witness, explain what they can expect to happen at court and answer any queries. Supports should ask witnesses whether they wish to meet their legal representative prior to giving evidence. The prosecutor or prosecuting counsel may discuss the witness's evidence and may clarify any points of ambiguity. If necessary, the prosecutor may ask the police to record a further statement.

Meeting the judge

5.68 An increasing number of judges, accompanied by the prosecution and defence legal representatives, meet young witnesses before they give evidence. Experience suggests that this can assist in demystifying the court process. Putting young witnesses more at ease helps them to give their best evidence.

Support at the hearing

5.69 The court witness supporter's role during the court hearing is principally to provide emotional support for the witness in order to reduce anxiety or stress, and therefore enable the witness to give their best evidence. If the court has approved the use of an intermediary to assist the witness, then that intermediary will be present to assist the witness in communicating their evidence to the court. Research has demonstrated that the presence of a supporter known to the witness may reduce the witness's anxiety and improve the accuracy of their recall. As is the case for all support functions, the witness supporter during the hearing must be someone who has only basic information about the witness's evidence and the supporter must avoid discussing the witness's testimony with them. In addition, the court witness supporter will not be a party to the case but will have received appropriate training, and where possible, will have a relationship of trust with the witness. It is likely that the court witness supporter will work alongside the Court Crier/Tipstaff and they will administer the oath. At court, the supporter will be with the witness while they are waiting to give evidence and will then accompany the witness to the court. The supporter will sit beside the witness and provide emotional support in a neutral but sympathetic manner; they cannot influence the court proceedings in any direct way. The court witness supporter should also be able to comfort the witness should they become distressed and should have prior arrangements agreed to enable the

supporter to alert the judge in the event of problems arising while the witness gives evidence (see Appendix K). Where the live link is being used, a specific member of Court Service staff will be available to respond to any technical difficulties.

Planning for breaks in the testimony

5.70 The court witness supporter will need to make prior arrangements to enable the court to be alerted to a vulnerable or intimidated witness's need for a break in proceedings. This may either be direct or indirect, such as through a 'touch card'. Although judges and lawyers should invite vulnerable and intimidated witnesses to tell the court when they need a break, the witness's ability to identify when this is necessary should not be relied on. Supporters should ensure that information is passed to the PPS or, in the case of a witness called by the defence, to the defendant's legal representative. This will enable the judge and legal representatives to plan breaks in the witness's testimony. Scheduled breaks are also less likely to occur at a time that would favour one side over another.

Interpreters

5.71 In some circumstances, arrangements will have been made for an interpreter to be present during the hearing. Interpreters might be required for those with limited or no understanding of English, or to assist with the use of communication devices or a form of sign language. The role of the interpreter is to facilitate communication with the witness at court and is distinct from that of the court witness supporter.

Intermediaries

5.72 The court may have approved the use of an intermediary to help the witness to give evidence. The role of an intermediary is also separate from that of the court witness supporter and they should be available during pre-trial preparation to improve the witness's understanding. An intermediary will usually have undertaken an assessment of the witness at an early stage in the proceedings and will have produced a written report for the judge, the prosecution and the defence. That report should highlight matters such as limited concentration spans and particular types of questioning that should be avoided.

Victim Impact Statements and Victim Impact Reports

5.73 Prior to sentencing victims may have the opportunity to make a victim impact statement and/or the court may request the completion of a victim impact report. A victim impact statement provides the victim with an opportunity to say what effect the crime has had on them, and to help identify their need for help and support. A victim impact report is normally completed by an appropriate professional at the request of the court to inform the judge about the impact of the crime on the victim as part of the sentencing process.

Special provisions for children

5.74 The UN Convention on the Rights of the Child and a number of European Directives emphasise the need for adults and organisations, when making decisions that affect children, to consider their best interests and their views. Reports to the PPS should always include clear information about the wishes of the child – and those of their parents or carers – about going to court. The PPS may in any event need to seek additional information from the joint investigating team.

5.75 The general points concerning pre-trial support and preparation apply to all young witnesses. Additional guidance is provided in the National Standards for Young Witness Preparation (see Appendix L) and the advice below should be read in conjunction with that document. Some additional points are made below because of the particular needs of young witnesses. The majority of these special or added points derive from the developmental immaturity of children and the need to take this into consideration so that they can give their best evidence. Central among these developmental issues are the following:

- children's understanding and appreciation of the world around them is not fully developed;
- children's language and communication skills are not as developed as those of adults;
- children are dependent on adult carers to varying degrees during childhood;
- children are used to adults being in charge of their lives, and may not appreciate or be familiar with the fact that their own views, perspectives and wishes are important; and
- children's ability to delay, postpone or inhibit their reactions to discomfort or distress may be underdeveloped.

5.76 The Young Witness Pack (NSPCC (NI), 2011) emphasises the importance of telling the truth at court. Pre-trial young witness support and preparation should include a revisiting of the difference between truth and lies. This should be in line with the guidance set out at in Chapter 2, delivered in an age appropriate manner which ensures that there is no suggestion of coaching or contamination of evidence.

5.77 Other vulnerabilities or disadvantages may compound these developmental issues, for example learning disabilities, psychological or psychiatric problems, sensory or communication difficulties, issues deriving from cultural or ethnic group differences, or extreme poverty. Furthermore, young witnesses, in addition to being developmentally immature, can be intimidated and may be subject to fear through threat, whether imagined or real. Such situations often occur in sexual abuse cases.

5.78 There may be a special vulnerability in children who have suffered maltreatment that affects their attitudes towards adults in positions of authority or power, and which might raise additional sensitivity to questions such as those which imply guilt or suggest that responsibility resides with the victim, or questions relating to a requirement to demonstrate alleged sexual activities on themselves. Child witnesses may be particularly distressed when asked to show on their own body where they were touched or to mimic sexual actions, and this should be avoided. The pre-trial supporter should discuss with the police and legal representatives whether the child may be asked to demonstrate intimate touching at court. If this is a possibility, consideration should be given to providing a doll, model or drawing to which the child can point. The judge's agreement should be sought on the use of an alternative method before the question arises.

5.79 These particular issues make children more vulnerable to adult influences in questioning. There are a number of measures that can be implemented at different stages in order to reduce the effect of these developmental issues and enable children to give their best evidence (see Boxes 5.4 and 5.5, and Chapter 6).

5.80 Prior consultation with the witness, their parent/carer and any supporter is likely to provide information which will assist the prosecution in meeting the needs of the child witness while giving evidence. It is important that the legal representative is given information from home or school about the young witness's attention span, bearing in mind that it is likely to be shorter in the stressful atmosphere of the court. This will enable the judge and legal representatives to plan breaks in the young witness's testimony.

5.81 It is important to have professionals with an aptitude and skill in being able to communicate effectively with children of different ages. The skills required include an ability to prepare the child witness to give their evidence without coaching them in any way, familiarity with court procedures and the relevant legal processes, an ability to work with children of different ages and abilities, and communication skills (see also Appendix L).

5.82 All information on prosecution witness preparation needs to be communicated to the PPS in sufficient time to enable the necessary action to be taken. The PPS would only expect the preparer to disclose information that is directly relevant to the witness giving their best evidence (e.g. the need for an intermediary). Such information can be provided separately by the police with the case file by completing the section 'Witness Care Report', through an early meeting to discuss special measures or through the NSPCC Young Witness Service. This should include the child's views on issues such as the gender and identity of a court witness supporter to accompany the child in the live link room; the wearing of wigs and gowns by judges and legal representatives; meeting the prosecution legal representative; and viewing the video statement before the trial. (See Victims and Witnesses Policy, Public Prosecution Service March 2007.)

5.83 The child's stress is likely to increase with the length of time that they have to wait to give evidence on the day of the trial. The Lord Chief Justice has recommended that a child witness should not be brought to court on the first day of trial when it is normal that the opening of the case and preliminary matters will be dealt with. Where possible, the child witness should be called as the first witness on the second day, preferably in the morning. Where such a 'clean start' to the day is intended for child witnesses, court listing officers should avoid listing other business before a child is due to give evidence (see Appendix M for details of the Lord Chief Justice's recommendations). The Lord Chief Justice stated 'I am persuaded that there are significant advantages in this procedure. Certainly it will help to reduce the pressure on the young witness or victim. It is undesirable that they should be left waiting in the environs of the court where their sense of foreboding is likely to increase. Every effort should be made to bring certainty to the timing of their evidence. That can only assist in the delivery of reliable evidence and the administration of justice'.

5.84 Cases need to be managed robustly to ensure that the case is ready for trial. There is a commitment to giving high priority to child abuse cases. Child witness cases are to be given the earliest available fixed date and trial dates should only be changed in exceptional circumstances.

Box 5.4: Measures to assist child witnesses at the hearing prior to giving evidence

- minimising waiting time at court;
- standby arrangements be on call in another location nearby;
- waiting areas appropriate to the age of the child, equipped with appropriate children's toys, books etc;
- secure waiting areas, separate from the defendant, and their families and supporters;
- entrance to the courtroom to give evidence by a side door or other arrangements so as to avoid inappropriate contact with relatives or friends of the defendant; and
- presence of a supporter throughout the waiting arrangements.

Box 5.5: Special measures and other arrangements for children at court

Part 1: Special measures

- screens – so that the witness does not have to see the defendant;
- live link – allowing a witness to give evidence from outside the courtroom, including from a live link away for the court to reduce the fear of seeing the defendant (remote link);
  - supporter in the live link room;
- video recorded evidence in chief – allowing an interview with the witness, which has been video recorded before the trial, to be shown as the witness's evidence in chief;
- evidence given in private – clearing the court of most people in sexual offence or intimidation cases (legal representatives and certain others are allowed to remain);
- removal of wigs and gowns by judges and advocates in the Crown Court;
- video recorded pre-trial cross-examination – this measure has not yet been implemented;
- intermediary – allowing an approved intermediary (a communications specialist) to help a vulnerable witness to communicate with the police, legal representatives and the court. Pending implementation of this measure in NI the courts, under their inherent jurisdiction, can grant the use of an intermediary (see Appendix B); and
- aids to communication – allowing a vulnerable witness to use communication aids such as a symbol book or alphabet boards.

Part 2: Other arrangements

- supporter;
- interpreter;
- pre-trial familiarisation visit;
- adjustments to the layout of the witness area with respect to the height of seating arrangements;
- appropriate arrangements for breaks to take into account children's greater tendency to tire and their reduced concentration span compared with adults; and
- arrangements for children with physical disabilities.

Special provisions for vulnerable adult witnesses

5.85 Vulnerable adult witnesses might be provided with various special measures (see Part 1 of Box 5.5) to maximise the quality of their evidence, as well as appropriate pre- and post-trial support. It is important that vulnerable witnesses are identified at an early stage so that investigators can establish whether they are likely to qualify for a special measures direction under the 1999 Order, as amended, taking account of the circumstances, the expressed wishes of the witness and the observations of anybody involved in the witness's care. The police should take all reasonable steps to identify vulnerable victims (see PSNI Policy Directive No. 05/2006 'Dealing with Victims and Witnesses Service Procedure, PSNI Service Procedure No.12/2006 'Vulnerable and Intimidated Witnesses, the 'Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults' and the 'Safeguarding Vulnerable Adults Regional Adult Policy & Procedural Guidance'). Vulnerable witnesses are entitled to an enhanced level of service. Witness support can be received by the witness in addition to the special measures that might be available. This support can be provided at the interview, during the pre-trial period and in court. It should be noted that the Northern Ireland Adult Safeguarding Partnership and five Local Adult Safeguarding Partnerships were set up in 2010 to coordinate and develop arrangements to safeguard vulnerable adults across Northern Ireland.

5.86 Personal qualities of vulnerable adults may put them at particular disadvantage during the investigation and court proceedings. For example, some persons with a mental disorder can be particularly sensitive to perceived challenge or criticism, or may fear recurrence of traumatic events. Similarly, people with learning disabilities might have a relative lack of adaptability. These and similar differences and vulnerabilities might lead such witnesses to require longer and more extensive support and preparation. The precise type and amount will vary according to the alleged offence, the witness's character, level of understanding and their life experience. It will also vary according to the purpose of the support, for example, whether it is designed to encourage the most reliable testimony or to reduce the trauma of proceedings on the witness, or both.

5.87 Depending on the specific vulnerability of the adult witness, it may be appropriate to adopt a similar approach to the issue of the difference between the truth and lies at the pre-trial support and preparation stage. This should be considered in relation to adults who have a learning disability or a mental/cognitive impairment, and should be assessed on a case by case basis.

5.88 Delay within the criminal justice process can add disproportionately to the stress on witnesses who are deemed vulnerable. For example, people with learning disabilities might have particular difficulty understanding the basis and reasons for a delay. For this reason, and because delay is likely to adversely affect the memory of a person with a learning disability, decision-makers should be reminded of the need to treat such cases as a priority.

5.89 Witnesses have been found to give better evidence when they have a choice about the way in which it is given. This especially applies to vulnerable witnesses, many of whom need preparation and support in order to be able to make an informed choice. Wherever possible, vulnerable witnesses should have an active role in choosing how to give their evidence. The most appropriate method of doing so will depend not only on the individual's objective capacity but also on what they wish to do, taking into account the options that are available to them. Issues of importance to those planning support for vulnerable adult witnesses are set out in Box 5.6.

Box 5.6: Issues of special importance for those planning support for vulnerable adult witnesses

- taking account of a witness's choices and views;
- use of an intermediary;
- amount of time needed to give evidence;
- time of day when they will give their best evidence;
- designing appropriate breaks;
- considering the best method of asking for a break;
- witness's level of understanding concerning courts and any prejudices they may have, such as a belief that it is the witness who is on trial;
- familiarisation with the venue for the hearings;
- explanations about the video and live link;
- short attention spans while giving evidence (especially for witnesses with learning disabilities);
- speech and communication aids; and
- planning approach to the oath and/or admonishing the witness.

Special provisions for intimidated witnesses

5.90 As with vulnerable witnesses, intimidated adult witnesses might be provided with special measures to maximise the quality of their evidence, including appropriate pre- and post-trial support. There are a number of precautions which officers can take when dealing with intimidated witnesses and, throughout the course of the case, the police should consider developing coping strategies to enable the witness to handle the threat of possible reprisals, and should give the witness appropriate information and advice. Intervention should be arranged where appropriate. Witnesses could suffer excessive fear or distress in a number of situations, such as domestic violence, assaults, sexual offences and crimes involving racism. They might also be intimidated because the alleged offence occurred over a long period of time or in the context of a close relationship with the accused. It is important to take account of government policy to respect the human rights of vulnerable adults when considering those adults who are specifically intimidated as a result of their position as witnesses. The Department of Justice and DHSSPS have developed a Tackling Violence at Home strategy and work is underway on a Northern Ireland equivalent to No Secrets – Guidance on Developing and Implementing Multi-agency Procedures to Protect Vulnerable Adults from Abuse (The Stationery Office, 2000). The PPS also have a Policy for Prosecuting Cases of Domestic Violence (2006).

5.91 In the period leading up to the trial, and during the trial, police officers will take account of the needs of witnesses and will be guided by police service policy and procedure for their protection and support, in particular, where the intimidation of witnesses is a risk (Article 2.4 Police Service of Northern Ireland Code of Ethics 2008). For some victims, specific risk assessments may be made and additional support for the victim provided, for example the introduction of MARAC in domestic abuse cases. National guidance on dealing with intimidation provides advice on what action could be taken (Working with Intimidated Witnesses: A Manual for Police and Practitioners Responsible for Identifying and Supporting Intimidated Witnesses (Office for Criminal Justice Reform, 2006), available at www.homeoffice.gov.uk).

5.92 The PACE Codes of Practice (NI) 2007 provide instruction to the police on dealing with suspected offenders where information has been given by witnesses that may lead to their identity. Video identification procedures is the preferred method of identification over live parades, group identifications and confrontations, and can serve to reduce stress on the witness. Witnesses should be kept informed of the progress of their case as a lack of knowledge (e.g. concerning the offender's whereabouts) can add to feelings of fear and uncertainty.

Post-trial support

5.93 Experience has shown that witnesses appreciate support given after the close of proceedings, a time when they may otherwise feel isolated and may have difficulty coming to terms with the court verdict. The PPS will provide victims with written notification of the outcome of proceedings. Witness services have a clear remit to provide post trial support to victims and witnesses.

5.94 Contact after the hearing also provides a useful opportunity for the supporter to identify and make arrangements for continuing support, counselling and treatment in the light of the witness's needs. The supporter can then liaise with the appropriate agency or professional to ensure that these needs are met. These tasks apply as much to those witnesses who are in the end not called to give evidence as it does to those who have provided evidence at trial.

5.95 Completion of anonymous post-trial NICTS questionnaires by the witness and the supporter will enable important feedback to be obtained for the management of future cases, and for the effectiveness and acceptability of support and preparation arrangements to be evaluated. The witness's own views, opinions and responses to the measures taken will aid the refinement of local procedures. Such feedback should complement feedback received directly by the criminal justice agencies as well as surveys such as NIVAWS (NI Victim and Witness Survey).

5.96 Where the defendant has been convicted and sentenced, the victim may benefit from participation in the NI Prison Service's Prisoner Release Victim Information Scheme, the Probation Board for NI's Victim Information Scheme or the Mentally Disordered Offenders Victim Information Scheme. Witness services, the police and PPS will all direct victims to the availability of these services when appropriate.

5.97 The Prisoner Release Victim Information Scheme provides victims with information on the final discharge and temporary release of adult prisoners sentenced to six months or more. Victims may make written representations to express their concerns when a prisoner is being considered for temporary release. The scheme is voluntary and only those who choose to register will be able to receive information and avail of the opportunity to submit views. Information can be obtained via the website www.niprvis.gov.uk or by telephoning 0845 247 0002.

5.98 The Probation Board NI Victim Information Scheme provides information to a registered victim in relation to any sentence or licence which includes Probation supervision, as follows:

- information can be provided in writing, by telephone or in a face-to-face meeting;
- victims can discuss their concerns and this may inform the offender's supervision;
- the opportunity to be involved, on a voluntary basis, in restorative contact with the offender if this would help to address issues resulting from the offence; and
- information can be obtained at www.pbni.org.uk or by telephoning 028 9032 1972.

5.99 The PBNI Victims Unit also provides reports to the Parole Commissioners. This is in relation to cases of murder where the prisoner has reached the stage of three years from tariff. These reports allow victims' families the opportunity to provide information in relation to any concerns they may have about preparation for the prisoner's release and the risk that they may pose.

5.100 The Mentally Disordered Offenders Victim Information Scheme applies in cases where the court dealing with an offender makes them the subject of a hospital order with a restriction order; or where the offender is given a transfer direction and a restriction direction while they are serving a sentence of imprisonment in respect of an offence. The scheme only applies to mentally disordered offenders sentenced in Northern Ireland. Under this scheme, victims of mentally disordered offenders, who wish to, will receive information about proposals for temporary leave of absence to facilitate the offender's treatment and also information about the offender's proposed discharge from hospital. When the offender is being considered for discharge, victims will also be invited to express their views on the effect the offender's discharge may have on their safety or well being. The definition of a victim includes the actual victim or a close family member when the actual victim has died. If the actual victim is a vulnerable person, a close family member or legal guardian may request this information on their behalf.

5.101 Further information on the scheme may be obtained from the DOJ Mentally Disordered Offenders Unit in Criminal Law Branch, Massey House, Stormont Estate, Belfast, BT4 3SX. The dedicated telephone line for the scheme is 0845 602 5488.

6 Witnesses in court

Introduction

6.1 Full and accurate information about special measures and other arrangements required to assist vulnerable and intimidated witnesses is needed to inform decision-making and pre-trial planning. In the Crown Court, it is preferable for issues to be raised and resolved as far as possible at an early pre-trial hearing (or a pre-trial review in the magistrates' and youth courts). At this hearing, initial decisions will be taken, or a date fixed for rulings to be made, about the special measures directions that are possible under the Criminal Evidence (Northern Ireland) Order 1999 (the 1999 Order), as amended by the Justice Act (Northern Ireland) 2011, and any other provisions. It is important to achieve as much certainty as possible about how the witness will give evidence and the arrangements for court attendance, preferably at an early stage in the proceedings.

6.2 Where the guidance in Chapter 5 has been followed, the needs and wishes of vulnerable and intimidated witnesses will have been identified as part of the pre-trial preparation. It is vital that legal representatives taking part in the pre-trial hearing or review are given full instructions prior to the hearing, including up-to-date information from and about the witness, so that the judge will be in a position to fully consider the need for any special measure directions or put in place any other arrangements. Judges may wish to make use of the areas outlined at paragraph 5.40 as a checklist when reviewing the arrangements for vulnerable and intimidated witnesses.

6.3 The legal representatives need to have seen any video recorded evidence in advance of the hearing/review so that decisions can be made about the admissibility of the recording and any issues, such as the need for editing, can be resolved in good time. Other issues that may depend on the admissibility of the recording, such as the steps which may be taken to refresh the witness's memory, can then be the subject of a decision by the judge in advance of trial.

6.4 New information about a vulnerable or intimidated witness may become available after the pre-trial hearing/review and before the trial. Such information may concern, among other matters, the condition of the witness (for example, an improvement in, or a degeneration of, the witness's health) or the occurrence of relevant events (for example, an act of intimidation directed at the witness or the fact that the witness has had a birthday, which is relevant to the age limits for eligibility for special measures). A witness's view may also change over time, for example a witness may become more apprehensive about confronting the defendant as the trial approaches. The steps taken by the court to enable witnesses to give their best evidence may have to be reassessed in the light of changes of this sort and legal representatives have a responsibility to keep the court informed about them. This means that procedures must be in place for channelling relevant information to the legal representatives.

6.5 Where an intermediary is appointed, a pre-trial hearing with the trial judge is essential to discuss the ground rules for intermediary use and how the examination of the witness is to be dealt with. This should cover issues such as how the intermediary will signal to the court that the witness has not understood a question or needs a break in proceedings, and how questions should be phrased in order to maximise the quality of the witness's evidence.

6.6 Where a video recording has been edited, it is important that the legal representatives should have viewed the edited version of the recording before the trial. As a general rule, material should be disclosed where it undermines the prosecution case or assists the defence. Where material meets the test for disclosure and is sensitive, the prosecutor must, after consultation with the police, assess the reasons why the material in question is sensitive, the degree of sensitivity, the significance of the material and the consequences of disclosure. The Public Prosecution Service (PPS) will consider what steps can be taken to satisfy the duty of disclosure while maintaining the confidentiality of the sensitive material. Where appropriate, this will include making an application to the court, with or without notice to the defence, for the court's authority to withhold the material from the defence.

The court's responsibilities towards witnesses

6.7 Judges have a duty to protect the interests of the defendant at trial, as they are presumed innocent until proven guilty. However, they also have a responsibility to ensure that all witnesses, including those who are vulnerable or intimidated, are enabled to give their evidence. Judges have to strike a balance under Article 6 of the European Convention on Human Rights between protecting the defendant's right to a fair trial and ensuring that witnesses who give evidence in the case are enabled to do so to the best of their ability (see the videos A Case for Balance – Demonstrating Good Practice when Children are Witnesses (NSPCC, 1997) and A Case for Special Measures (NSPCC, 2003)).

6.8 Judges are expected to take an active role in the management of cases involving vulnerable and intimidated witnesses, and to ensure that elements of the court process that cause undue distress to such witnesses are minimised. The 1999 Order, as amended, created an expectation that the court will be concerned that witnesses are enabled to give their best evidence and imposes an obligation on judges to raise of their own motion the question of whether special measures should be used if the party has not applied for them (Article 7(1)(b) of the 1999 Order). It is therefore important that they are alert to the possibility that a particular witness's evidence may be adversely affected, not just by the distress of giving evidence, but by circumstances, such as the witness's physical or mental health, that may affect that witness's ability to recall relevant matters and to deal with questions about them. The existence of such circumstances may trigger the need for a special measures direction under the 1999 Order, as amended. Such a direction may also be required in respect of a witness, the quality of whose evidence is likely to be diminished by reason of fear in connection with testifying in the proceedings. Information relating to intimidation may be potentially prejudicial to a defendant but it must be made known to a court if it is relevant to the making of a special measures direction (even if, as is likely, it is inadmissible as proof of the offence to be tried).

6.9 The responsibilities of judges to protect the interests of vulnerable or intimidated witnesses may require the making of special measures directions in appropriate cases but may also be discharged in other ways. Some witnesses may need breaks while giving their evidence, either because they are giving distressing evidence or because they have a limited span of concentration. Such breaks can often be planned in advance if the court has been given the relevant information (for example, from witness services or the intermediary's assessment report). Although judges and legal representatives should invite young and vulnerable witnesses to tell the court when they need a break, they should not rely on the witness's ability to identify when this is necessary. Planned breaks are less likely to occur at a time that would favour one side over another.

6.10 The responsibilities of judges also extend to the prevention of improper or inappropriate questioning by legal representatives (or the defendant if they are conducting their own defence). Judges should have regard to the reasonable interests of witnesses, particularly those who are in court to give distressing evidence, as they are entitled to be protected from avoidable distress in doing so. The sort of questioning likely to be ruled out is anything that lacks relevance, or is repetitive, oppressive or intimidating. Questioning may be intimidating because of its content or because of the tone of voice employed. A legal representative may be asked to rephrase a question if it is in a form or manner likely to lead to misunderstanding on the part of the witness. A young witness or a witness with learning disabilities, for example, may easily be confused by questions that contain double negatives ('Is it not true that you were not there?') or that ask two questions at the same time ('Is it true that you were there and you heard what was said?'). Judges should be alert to the possibility that a witness might be experiencing difficulty in understanding a question which, if not corrected, might lead to the giving of evidence that is not of the best quality that the witness could provide. Where an intermediary is used, their report will contain recommendations about what types of question are likely to lead to misunderstanding on the part of the witness.

6.11 In some cases, a witness, particularly a young witness, may benefit from meeting the judge before the case commences so that the witness can be put at ease. Some judges are prepared to meet young witnesses before they give evidence, provided that they are satisfied that this will not create an impression of bias in favour of the witness, as their experience suggests that this can assist in demystifying the court process. However, it is essential that the prosecution and defence legal representatives should be aware of the meeting and have the right to attend if they so wish in order to avoid any subsequent legal challenges.

The responsibilities of legal representatives towards witnesses

6.12 Legal representatives have a responsibility, when dealing with a witness who is nervous, vulnerable or apparently the victim of criminal or similar conduct, to ensure that those facing unfamiliar court procedures are put at their ease as much as possible. Meeting with the legal representative who is to call the witness to give evidence in chief in a calm environment may be an effective way of preparing a witness.

6.13 Legal representatives must assist the court, at any hearing where the matter arises, to make informed decisions about any special measures directions, or other steps which it may be necessary to take, to assist a particular witness. Both prosecution and defence legal representatives are expected to inform the judge of the special needs or requirements of any vulnerable or intimidated witnesses they intend to call.

6.14 Where applications are to be made for disclosure of relevant records held by third parties concerning a witness, they should be made at an early stage to avoid delay, in accordance with the recent Crown Court Judicial Committee Protocol (see Appendix N).

6.15 The legal representatives of the defendant have a duty to promote the best interests of the defendant by all proper and lawful means. This may include cross-examining vulnerable and intimidated witnesses about matters they may find extremely distressing. Such questioning is necessary, provided that it relates to matters that are relevant to the case, and is not done merely to insult or annoy the witness. Allegations of misconduct by a witness may not be made unless the legal representative has reasonable grounds for making them. Some legal representatives routinely ask young witnesses 'Do you tell lies?'. However, this is a practice that ought to be avoided unless the legal representative has grounds for thinking that the witness is an habitual liar (other than the fact that the witness's evidence contradicts that of the defendant). The manner in which the legal representative cross-examines a witness must not be improper or inappropriate. This may involve taking account of information about a witness's special needs. Both the legal representative calling the witness to give evidence in chief and the legal representative cross-examining the witness should strive to avoid being the cause of a misunderstanding as a result of which the witness gives evidence that is not of the best quality that they could provide. The strategies necessary to avoid such a misunderstanding may include, for example, avoiding the use of a tone of voice which is intended only to sound firm but which might be intimidating to a vulnerable witness, and following a systematic and logical sequence of questioning.

6.16 PPS legal representatives have a duty to bear in mind the needs of a vulnerable or intimidated witness who is giving evidence for the prosecution. If the defence seeks an adjournment, the legal representative for the prosecution should draw to the attention of the court any adverse effect this may have on the witness, particularly where the witness is a child or has a learning disability. The legal representative for the prosecution should also be alert to a witness's need for regular breaks and to the possibility that questioning in cross-examination of the witness may be improper or inappropriate. The prosecution legal representative should seek to protect the witness from such questioning by drawing it to the judge's attention. In the same way, a defence legal representative should seek to ensure that the court bears in mind the needs of a defence witness while they are giving evidence.

6.17 Legal representatives also have particular duties with regard to the proper handling of video recordings that are to be used in court as the evidence in chief of a vulnerable or intimidated witness. The object of these special duties is to ensure that the recording does not fall into the wrong hands and is seen only by those who have a proper interest in doing so (see Appendix H).

Competence and capacity to be sworn

6.18 All people, whatever their age, are competent to act as witnesses unless they cannot understand questions asked of them in court or cannot answer them in a way that can be understood with, if necessary, the assistance of special measures (Article 31 of the 1999 Order).

6.19 A person who has been judged not to be competent to give evidence may not appear as a witness in criminal proceedings and cannot therefore be eligible for special measures under the 1999 Order. Where a witness's competence is called into question, a decision will normally be required before the trial begins about whether they may give evidence at all and, if so, whether it should be sworn or unsworn.

6.20 It is the responsibility of the party calling the witness to satisfy the court that the witness is competent on a balance of probabilities. If the witness's competence is challenged and they need to be questioned to determine competence, questions must be asked by the court, in the absence of the jury, not by the legal representative calling or cross-examining the witness. Any such questioning must, however, be conducted in the presence of both the prosecution and the defence. When the court assesses the witness's competence, it must take into account any special measures it could grant including, for example, communication aids or the giving of evidence through an intermediary. This is to avoid a potential witness being judged not to be competent if the use of special measures would make them competent. Courts may ask for expert advice about the witness's competence, for example from a psychologist who has examined the witness or from a lay person who has special knowledge of the witness's abilities (Article 32 of the 1999 Order).

6.21 The question of whether a witness is eligible to swear an oath or to affirm may be raised by the prosecution, the defence or the court. The procedure used to determine this question is the same as the procedure outlined above for determining competence (i.e. in the absence of the jury, with the help of any necessary expert evidence and through questions from the court in the presence of the parties). A witness under the age of 14 is not to be sworn. Witnesses of 14 years and over are eligible to be sworn if they understand the solemnity of a criminal trial and that taking an oath places a particular responsibility on them to tell the truth. There is a presumption that witnesses of 14 and over are to be

sworn unless evidence is offered suggesting that they do not understand those two matters (Article 33 of the 1999 Order). If a witness's capacity to give sworn evidence is challenged, it will be for the party calling the witness to prove on a balance of probabilities that they should give sworn evidence.

6.22 Anyone competent to be a witness, but not allowed to give evidence on oath, may give evidence unsworn (Article 34 of the 1999 Order). Where a witness gives unsworn evidence in the courtroom, the judge may 'admonish' the witness to tell the truth. A convenient form of words which may be used is: 'Tell us all you can remember of what happened. Do not make anything up or leave anything out. This is very important.'. This admonition may be best given by the judge in the introductory exchange with the witness and prior to any evidence in chief or cross-examination.

6.23 Where the court decides a witness to whom Article 15 of the 1999 Order, as amended, applies is competent to take the oath, and their evidence in chief has been given in the form of a video recorded interview, there is no legal necessity for the witness to be sworn prior to the playing of the video at court. However, if the witness goes on to provide further evidence in person to the court, either in cross-examination or as supplementary evidence in chief, the oath must be administered before the evidence is heard. Again, any introductory exchange between the judge and witness provides an opportune moment for the administering of the oath. Failure to administer the oath does not render the witness's evidence inadmissible. However, the fact that it has been received unsworn may lead to it being accorded less weight than if it had been given on oath.

Special measures directions under the 1999 Order, as amended

6.24 Special measures which may be available to assist eligible witnesses in the preparation and delivery of their evidence are as follows:

- screening a witness from the accused (Article 11);
- evidence by live link (Article 12);
- evidence given in private (Article 13);
- removal of wigs and gowns (Article 14);
- video recorded evidence in chief (Article 15);
- video recorded cross-examination or re-examination (Article 16) (note: this special measure is not yet available);
- examination of a witness through an intermediary (Article 17) (note: this special measure is not yet available); and
- communication aids (Article 18).

6.25 In addition, the 1999 Order affords:

- protection of witnesses in certain cases from cross-examination by the accused in person (Articles 22 to 26); and
- restriction on evidence and questions about the complainant's sexual behaviour (Article 28).

6.26 Restrictions on the reporting by the media of information likely to lead to the identification of children under 18 and certain adult witnesses in criminal proceedings are covered in sections 44 to 52 of the Youth Justice and Criminal Evidence Act 1999.

Witness eligibility (Articles 4 and 5)

6.27 Witnesses are eligible for special measures to help them give evidence if they are vulnerable or intimidated.

Vulnerable witnesses (Article 4)

6.28 Vulnerable witnesses are defined by Article 4 of the 1999 Order, as amended, as:

- all child witnesses (under 18 years of age); and
- any witness whose quality of evidence is likely to be diminished because they have a:
  - mental disorder (as defined by the Mental Health (NI) Order 1986); or
  - significant impairment of intelligence and social functioning (witnesses who have a learning disability or autism spectrum disorders); or
  - physical disability or are suffering from a physical disorder, including deafness.

Intimidated witnesses (Article 5)

6.29 Intimidated witnesses are people whom the court is satisfied are likely to suffer fear or distress at the prospect of giving evidence, because of their own circumstances and those of the case to an extent that is expected to diminish the quality of their evidence.

6.30 In relation to intimidated witnesses, the 1999 Order lists a number of factors that the court should take into account when assessing whether the witness qualifies for any of the special measures. These include:

- the nature and alleged circumstances of the offence;
- the age of the witness;
- the social and cultural background, and ethnic origins of the witness;
- any religious beliefs or political opinions of the witness;
- the domestic and employment circumstances of the witness; and
- any behaviour towards the witness on the part of the defendant, their family or associates, or any other witness in the proceedings or co-defendant (this may be particularly relevant in cases of domestic abuse).

6.31 Particular groups of victims and witnesses who are likely to benefit from the provisions under this Article include:

- those who have experienced domestic violence;
- complainants in cases of sexual assault (as defined by Article 5(4) of the 1999 Order);
- victims of, and witnesses to, homophobic crime, racially motivated crime and crime motivated by reasons relating to religion;
- those who have experienced past or repeat harassment, stalking and bullying, or repeat victimisation;
- those who self-neglect and self-harm;
- frail older persons;
- witnesses to murder and the families of murder and manslaughter victims; and
- those who are making allegations against professionals or carers.

Quality of the witness's evidence (Article 4)

6.32 Special measures for most vulnerable or intimidated witnesses can be authorised only if they are likely to improve the quality of a witness's evidence. 'Quality' encompasses coherence, completeness and accuracy in the case of vulnerable witnesses. 'Coherence' in this sense means that the witness is able to address the questions put and give answers that can be understood, both as separate answers and when taken together as a complete statement of the witness's evidence.

6.33 The circumstances in which special measures may be invoked can therefore, range from a case where the witness's evidence would otherwise be unintelligible to cases where their evidence, though intelligible, would otherwise be of poorer quality than it could be.

Witnesses who do not qualify as eligible etc

6.34 The Crown Court has some limited inherent powers to make measures available to assist witnesses who do not qualify as eligible or who need measures for reasons other than age, incapacity, fear or distress. These powers pre-date the 1999 Order and are untouched by it. They extend, for example, to the granting of anonymity to the witness, the provision of screens and aids to interpretation, the removal of wigs and gowns, and the provision of a foreign language interpreter.

Child witnesses (Article 9)

6.35 The law presumes that child witnesses under 18 will normally give their evidence outside the courtroom by playing a video recorded interview as evidence in chief and cross-examination via live link unless this will not improve the quality of their evidence. However, subject to the agreement of the court, children may opt out of giving their evidence by either a video recorded interview as evidence in chief or by means of live link or both. If a child wishes to opt out of video recorded evidence in chief, they may give all their evidence by live link from outside the courtroom, if the court agrees. The child may also opt out of live link evidence, if the court agrees. Note that the law presumes that the child witness will then give evidence in the court room behind a screen. Should the child witness not wish to use a screen, they may also be allowed to opt out of using it. Ultimately this is a matter for the court to decide. However, the court must take the witness's views into account when making its decision on whether to approve an opt out request.

6.36 The possibility of a child witness opting out of giving evidence by video recorded statement and/or live link should be explained to all child witnesses and their carers when special measures are explained. To ensure that the child witness is able to express an informed view, it is important that the explanation of the individual special measures is clear with the advantages and disadvantages of each fully explained. In relevant cases, officers should be in a position to explain why they do not consider that it is appropriate to video record the witness's statement.

Witnesses 18 years and over (Articles 9 and 10)

6.37 If a court makes a special measures direction in respect of a child witness who is eligible on grounds of youth only and the witness turns 18 before beginning to give evidence, the direction no longer has effect. If such a witness turns 18 after beginning to give evidence, the special measures direction continues to apply (Article 9(9) of the 1999 Order).

6.38 If a witness is under 18 years when evidence in chief or cross-examination is video recorded before the trial, but has since turned 18, the video recording can still be used as evidence.

6.39 A witness who is over 18 years at the beginning of the trial but who made a video recording as their evidence in chief when they were under 18 is eligible for special measures in the same way that they would be if they were under 18, and the same presumptions apply to them.

Special measures directions (Articles 4 to 7)

6.40 Special measures directions can be made at a pre-trial hearing, before the beginning of the trial or before a 'Newton' hearing to which witnesses are called to settle the factual basis on which sentence will be passed. While it is important that directions be made in advance of trial where possible, it may be necessary for a court to react to a situation at a later stage of proceedings by making a direction to assist a witness to give evidence. New directions are needed for a retrial or appeal.

6.41 When courts decide, on application from the prosecution or defence, or of their own accord, that special measures might be appropriate for a witness, they must consider:

- whether the witness is eligible (i.e. falls within the scope of the definitions set out in Articles 4 and 5);
- whether special measures would improve the quality (meaning the completeness, coherence and accuracy) of the evidence of an eligible witness in the circumstances of the case (which take account of the witness's views and the possibility that the measures might tend to inhibit the evidence being tested effectively);
- if special measures would improve the quality of the witness's evidence, which of the measures, alone or in combination, would be most likely to maximise the quality of the witness's evidence (again, the court has to bear in mind the views of the witness and the possibility that the special measures might tend to inhibit the evidence being tested effectively); and
- the details of where, when and how the special measures specified should be provided.

6.42 The need to take account of any views expressed by the witness when resolving the issues identified in the previous paragraph underlines the necessity for the court to be provided with up-to-date information about the witness's preferences.

Binding directions (Article 8)

6.43 Special measures directions are binding until the end of the trial although courts can vary or discharge a direction if it seems to be in the interests of justice to do so. Either party can apply for the direction to be varied or discharged (or the court may do so of its own motion) but must show that there has been a significant change of circumstances since the court made the direction or since an application for it to be varied was last made. This provision is intended to create some certainty for witnesses by encouraging the party calling the witness to make applications for special measures as early as possible and by preventing repeat applications on grounds the court has already found unpersuasive.

6.44 The court must state in open court its reasons for giving, varying or discharging a special measures direction or refusing an application so that it is clear to everyone involved in the case what decision has been made and why it was made. This is intended to include, for example, the court's reasons for deciding that a witness is ineligible for help. Applications for special measures are subject to Crown Court and magistrates' court rules.

Special measures

Screening a witness from the accused (Article 11)

6.45 Screens may be authorised to shield a witness from seeing the defendant. The screen is normally erected around the witness rather than the defendant. It must not prevent the judge or jury, and at least one legal representative of each party to the case (i.e. the prosecution and each defence representative) from seeing the witness, or the witness from seeing them. If an intermediary or an interpreter is appointed to assist the witness, they too must be able to see the witness and be seen by the witness. The 1999 Order, as amended, does not specifically provide for the witness's need to see the court witness supporter (if there is one) but the court should ensure that this need is met where a screen is erected.

6.46 The court is also authorised to provide for an 'arrangement' which is not a screen, but which has the same effect of preventing a witness from seeing the defendant. An arrangement used in some older cases was to require defendants to move from the dock to a position in court where they could not be seen by the witness. Such an arrangement might have the undesirable effect of making it more difficult for the defendant to communicate with their legal representatives, which could become a factor in determining whether they were accorded a fair trial within the meaning of Article 6 of the European Convention on Human Rights. Screens erected around the defendant could also have this unintended effect. Therefore, if

such an arrangement or screens are adopted, careful consideration must be given to ensuring that the rights of the defendant are properly preserved, for example by ensuring that a break in the witness's evidence is taken in order to afford the defendant an opportunity to consult with their legal representative about any further questions which should be put in the light of what the witness has said.

6.47 Where the trial involves a jury, the judge may warn them not to be prejudiced against the defendant as a consequence. This is done as part of the judge's duty to protect the defendant from the unfairness that would ensue if, for instance, the jury were to assume that the defendant must have done something wrong to merit the erection of a screen.

Evidence by live link (Article 12)

6.48 'Live link' usually means a closed circuit television link but also applies to any technology with the same effect. The essential element of a live link is that it enables the witness to be absent from the courtroom where the proceedings are being held but at the same time to see and hear, and be seen and heard by, the judge or jury, at least one legal representative of each party to the case, and any intermediary or an interpreter appointed to assist the witness. The judge or court clerk controls the equipment. They should be comfortable with it and familiar with any likely difficulties, such as the distorted image which may appear on the witness's monitor if those in court lean too close to the camera. Judges must also ensure that the witness understands what is happening. This is most obviously of importance for a child witness or a witness who has learning disabilities but it should not be assumed that any witness is conversant with the equipment. It may be useful for the judge to inquire as to whether the witness has had a pre-trial visit to the court at which the facility has been explained and demonstrated.

6.49 There is a presumption that a witness who gives evidence by live link for a part of the proceedings will continue to give evidence by this means throughout. Where a party to the proceedings argues that the method of receiving the witness's evidence should change, the court can make a direction to this effect if the interests of justice so require.

6.50 If there are no live link facilities at the court where the proceedings would normally be held, the proceedings may be transferred to another court where a live link is available. Alternatively, if the witness is an adult and screening them is considered to be equally likely to enable them to give their best evidence, then the court may choose to screen the witness instead. A young witness, who is required by Articles 9 or 10 of the 1999 Order, as amended, to give all or part of their evidence by live link, must do so.

6.51 The 1999 Order, as amended, makes the live link available to vulnerable and intimidated witnesses whether or not their evidence in chief is presented in the form of a video recording and there may be some witnesses for whom the live link is the only special measure required to enable them to give their best evidence. Even in the case of a child witness who is subject to a presumption that a recording will be used as evidence in chief, it may be necessary to resort to the use of the live link alone if no recording is available or an available recording has been ruled inadmissible. Consideration should be given to whether use of a live link away from the court house where the trial is taking place could be used for a witness. This could be at another court or a separate 'remote' facility which has live link capability. In all cases, this will need to be agreed by the court.

Choosing between live link and screens

6.52 Where the witness who is eligible for special measures is not a young witness to whom the presumptions in Article 9 or Article 10 apply, the court making a special measures direction will be able to choose between a screen and a live link as a means of assisting the witness to give their best evidence. The live link has the advantage that the witness does not have to be physically present in the courtroom. It may also be more accessible for some witnesses with physical disabilities, including wheelchair users. However, the screen is not necessarily an inferior alternative to the live link. Screens are flexible, easy to use and permit the witness to stay in court. It is also easier for the jury or judge to gain an impression of some physical attributes of the witness where this is relevant, for example in a case where the issue is whether the defendant used reasonable force to restrain the witness. Screens can be particularly helpful in situations where the witness does not want to be seen by the defendant for reasons of fear or intimidation.

6.53 The views of the witness are likely to be of great importance in deciding which of the two very similar measures is most suitable. A witness who is greatly distressed at the prospect of being in the same room as the defendant is likely to give better evidence if permitted to use the live link. However, it should be carefully explained to the witness that the defendant will be able to see them on the television screen in the court (which may be a large plasma screen). This should be pointed out during the pre-trial visit to enable the witness to make an early and informed choice.

6.54 Where the witness is a child witness, or a witness over 18 years to whom Articles 9 or 10 apply, there is normally no choice to be made between live link and screening as live link is taken to be the more appropriate measure. The court does retain discretion to allow a child to use a screen instead where the interests of justice would be best served by so ordering.

Evidence given in private (Article 13)

6.55 The principle of open justice normally requires that evidence is given in open court; in other words, in the presence of representatives of the press and members of the public who wish to attend. There are statutory restrictions on attendance and reporting in the youth court for the protection of children and young people.

6.56 In sexual offences cases, a further exception is justified partly because the evidence may be of an intimate nature and partly because the presence of the defendant's supporters or members of the public with a prurient interest in the proceedings may make the giving of evidence exceptionally difficult. Another exception is made in cases where the court believes that someone, other than the defendant, may take advantage of their entitlement to attend the proceedings in order to intimidate the witness. In such cases, Article 13 permits the courtroom to be cleared of everyone apart from the defendant, legal representatives and anyone appointed to assist the witness. The special measures direction will describe individuals or groups of people who are excluded. The court has to allow at least one member of the press to remain if one has been nominated by the press. The freedom of any member of the press excluded from the courtroom under this Article to report the case will be unaffected unless a reporting restriction is imposed separately. Courts should give active and early consideration to this special measure due to the confidence it can give to eligible witnesses.

6.57 The court also has the power under Article 168 of the Children (NI) Order 1995 to clear the public gallery when a person under 18 gives evidence in proceedings relating to conduct that is indecent or immoral.

Removal of wigs and gowns (Article 14)

6.58 The courts have traditionally exercised a direction to dispense with the wearing of wigs and gowns by the judge and by legal representatives in the Crown Court in cases where child witnesses are concerned. The inclusion of this power as a special measure in the 1999 Order makes it clear that the same dispensation can be made in the case of vulnerable and intimidated adult witnesses. Not all witnesses want the court to depart from its traditional way of dressing: some feel more comfortable if the judge and legal representatives are dressed in the way which is most familiar to them, perhaps from watching television drama.

Video recorded evidence in chief (Article 15)

6.59 A video recorded interview can take the place of a witness's evidence in chief. References in this chapter to an 'interview' should be taken to include, where appropriate, any case where a court is also asked to receive a supplementary interview or interviews.

6.60 Video recordings can be excluded and edited if the interests of justice so require. In deciding whether any part of a recording should not be admitted, the court must weigh the prejudice to the defendant of admitting that part against the desirability of showing the whole video.

6.61 It may be contrary to the interests of justice to use a video, or part of a video, in evidence where the interviewer has neglected to follow the instructions on interviewing in this guidance. It should not be supposed that courts will exclude or edit recordings as a sanction for non-compliance with a minor detail. Before making a decision to exclude or edit a recording, a court will consider the nature and extent of any breaches which have occurred, and the extent to which the evidence affected by the breaches is supported by other evidence in the recording which is not so affected, or by other evidence in the case as a whole. If there has been a substantial failure to comply with the guidance, the consequence may well be that video evidence is excluded altogether or the relevant parts edited out. If substantial editing has occurred, the witness should be informed of this so that they are not surprised when they view the video again to refresh their memory.

6.62 An interview with a witness which is conducted entirely properly may still be excluded in the interests of justice, for example where the witness subsequently retracts the statements made in the video and it is clear that they no longer associate themselves with the views expressed in it.

6.63 Where a special measures direction has been made for a recording to be shown to the court, the court can later exclude the recording if there is not enough information available about how and where the recording was made, or if the witness who made the recording is not available for further questioning (whether by video, in court or by live link) and the parties to the case have not agreed that this is unnecessary. Such a recording might be admissible under the hearsay provisions in Article 20 of the Criminal Justice (Evidence) (NI) Order 2004, depending on the reason for not calling the witness (for example, if they have become too ill to attend as a witness – see Appendix P).

6.64 The video recording (as edited, where that is required) normally forms the whole of a witness's evidence in chief and will be watched by the witness before cross-examination takes place. The witness will usually have had an opportunity to see the recording on a previous occasion too in order to refresh their memory in preparation for the trial. Some witnesses may require breaks when watching the recording.

6.65 Where a witness gives their evidence in chief through a video recorded statement, the witness may be asked additional questions both about matters not covered in the video recorded statement and also matters that are covered in the recorded statement, provided that the court gives permission.

6.66 If a witness is asked to give further evidence, then the court can direct that the evidence will be given by the live link. As in other circumstances where a live link is provided, the 1999 Order allows temporary facilities to be authorised for magistrates' courts. In the case of witnesses who are not subject to the special rules that apply to young witnesses, the court may decide that the witness can give the further evidence in the courtroom, protected if necessary by a screen.

6.67 Witnesses aged 14 or over, who make a video recording that is intended to be their evidence in chief, are not expected to take the oath before making the recording although they will be required to do so before cross-examination or any supplementary evidence in chief. The one exception to this is if it has been decided that they will give unsworn evidence instead. The most convenient point to administer the oath may be as part of an introductory exchange between the judge and the witness. Under the 1999 Order, a witness's evidence may be received unsworn even though they are capable of giving evidence on oath so the absence of an oath at the time of the recording does not render it inadmissible.

6.68 A recording of an interview with a witness, which is not used as evidence in chief, may be used for other purposes, primarily by the other side. If a witness gives evidence at trial and has previously made a video containing statements which are inconsistent with the evidence given at trial, the video recording may be used in cross-examination to detract from the credit to be given to the evidence at trial.

6.69 The Police and Criminal Evidence Codes of Practice (NI) 2007 provide instructions on dealing with suspected offenders where information has been given by witnesses that may lead to their identity. It may be necessary to supplement the witness's video recorded evidence in order to include the outcome of such a procedure. A positive identification of a defendant by a prosecution witness may be important evidence in the case and a witness who gives evidence in chief in the normal fashion at trial would normally be asked to confirm that such identification took place. Although it is possible to prove that the identification was made by relying on

evidence other than the testimony of the witness in a case where the correctness of the identification of the defendant is contested, it is helpful if there is evidence on the point from the witness. Appendix J outlines some of the special considerations for identification parades involving vulnerable and intimidated witnesses.

6.70 Where an application to admit a video recording as evidence in chief is made under Article 15 of the 1999 Order, as amended, but is refused by the court, the police should draft a section 1 Criminal Justice (Miscellaneous Provisions) Act (NI) 1968 statement for the witness. It is essential that the video is properly reviewed as part of the drafting process to ensure consistency between what was said during the interview and what is recorded on the draft statement. The witness need not be present while the statement is drafted. After the statement has been drafted, the witness should be invited to check and sign it. The video should be readily accessible in case the witness questions whether the draft written statement correctly reflects what was said in the video interview. Where minor amendments are required, they may be incorporated into the draft statement before it is signed. If changes of a more substantial nature are required, the PPS should be consulted with a view to considering a further interview.

Video recorded cross-examination or re-examination (Article 16)

(NB this special measure had not been implemented at the time this guidance was written.)

6.71 Where the court has already decided that a video recording can be used as the witness's evidence in chief, it may also decide that the witness should be cross-examined before trial, and that cross-examination, and any re-examination, be recorded on video for use at trial.

6.72 The cross-examination is not recorded in the physical presence of the defendant although they have to be able to see and hear the cross-examination, and be able to communicate with their legal representative. This can be achieved through a live link or earpiece receiver, for example.

6.73 The video recorded cross-examination may, but need not, take place in the physical presence of the judge, and the defence and prosecution legal representatives. However, a judge has to control the proceedings. It is intended that the judge in charge of this process will normally be the trial judge. All the people mentioned in this paragraph have to be able to see and hear the witness being cross-examined, and communicate with anyone who is in the room with the witness (such as an intermediary or a witness supporter).

6.74 As with video recorded evidence in chief, a video recording of cross-examination may afterwards be excluded if there have been serious departures from the rules of evidence governing the cross-examination.

6.75 Witnesses who have been cross-examined on video are not to be cross-examined again unless the court makes a direction permitting another video recorded cross-examination. It may do so if the subject of the proposed cross-examination is relevant to the trial and something which the party seeking to cross-examine did not know about at the time of the original cross-examination (and could not reasonably have found out about by then) or if it is otherwise in the interests of justice to do so. Information that has not yet been disclosed to the other party would usually count as information that the party could not reasonably have known. It is envisaged that a direction permitting further cross-examination will occur only in exceptional cases and that the cross-examiner will make all reasonable efforts to be ready to deal with all the issues at the first attempt. The likelihood of further cross-examination will need to be taken into account if therapy is offered subsequent to the recorded cross-examination.

Choosing between video recorded and live cross-examination

6.76 The advantages of video recorded cross-examination include reducing the stress involved when a witness has to come to court to give evidence, and minimising the delay between evidence in chief and cross-examination. The witness is also not affected by postponement or adjournments in the trial itself. The matters with which the witness will be expected to deal will be the same as those dealt with in cross-examination at trial in the normal way. Witnesses who have had their cross-examination video recorded will (other than in exceptional cases where it is necessary to put further questions at a later stage) be able to put the experience behind them and take advantage of therapy without the risk of a claim being made that this will distort their evidence.

6.77 Although procedural constraints, such as the rules governing disclosure of material to the defence, may lead to the cross-examination being conducted some time after the evidence in chief was recorded, research in other jurisdictions suggests that the availability of pre-recorded cross-examination may still have the advantage that the witness's evidence is completed significantly earlier than if it were given at trial. This measure may therefore offer worthwhile advantages for those vulnerable and intimidated witnesses for whom it is an option, as well as for child witnesses in cases involving sexual offences for whom the 1999 Order provides this as the normal method of undergoing cross-examination (further rules and guidance on video recorded pre-trial cross-examination will be issued on implementation of the special measure).

Examination of a witness through an intermediary (Article 17)

(NB: implementation of this special measure was still pending at the time this guidance was written.)

6.78 Certain vulnerable witnesses may be assisted by an intermediary:

- during an investigative interview;
- during evidence in chief and cross-examination in court or via the live link; and
- during any pre-trial familiarisation visit.

6.79 The intermediary (a specialist in assessing communication needs and facilitating communication breakdowns) communicates to the witness questions asked by the court, defence and prosecution, and then communicates the answers the witness gives in reply. The intermediary is allowed to explain the questions or answers so far as is necessary to enable them to be understood by the witness, the questioner and the court but without changing the substance of the evidence. The intermediary is allowed to explain questions and answers if that is necessary to enable the witness and the court to communicate. The intermediary does not decide what questions to put. However, the intermediary will provide a written report to the court, explaining any difficulties the witness may have with certain types of questioning, to assist those putting questions to the witness. The use of an intermediary does not reduce the responsibility of the judge, or of the legal representative, to ensure that the questions put to a witness are proper and appropriate to the level of understanding of the witness.

6.80 Intermediaries must be approved by the court (retrospectively if they have assisted with the video recorded interview that is being played as the witness' evidence in chief) and declare that they will perform their function faithfully. They have the same obligation as interpreters to refrain from wilfully making false or misleading statements to the witness or the court.

6.81 The use of an intermediary is not available to witnesses eligible for special measures on the grounds of fear or distress alone. Deaf witnesses can choose to rely on administrative arrangements for the provision in court of interpreters for deaf people or, if it is more appropriate to their particular needs, to apply for an intermediary or communication aid under the 1999 Order provisions.

6.82 When an intermediary is used at trial, the judge, and at least one legal representative for both the prosecution and the defence, must be able to see and hear the witness giving evidence and be able to communicate with the

intermediary. Also, the jury have to be able to see and hear the witness unless the evidence is being video recorded, in which case they will see the recording when it is shown to them later.

6.83 Where intermediaries are used at an early stage of an investigation or proceedings, and an application is subsequently made to admit as evidence in chief a video recorded interview in which they were involved, then a special measures direction to admit the recording can be given despite the judge or legal representatives not having been present. Before the recording can be admitted, however, the intermediary must be approved by the court retrospectively.

6.84 Detailed procedural guidance will be issued when this special measure is implemented.

Communication aids (Article 18)

6.85 The use of communication aids, such as sign and symbol boards, can be authorised to help vulnerable witnesses overcome physical difficulties with understanding or answering questions. Communication aids can be used in conjunction with an intermediary. The use of a communication device is not available to witnesses eligible for special measures on the ground of fear or distress alone.

Other assistance for witnesses

The presence of a court witness supporter

6.86 The presence of a court witness supporter is designed to provide emotional support and helps reduce the witness's anxiety and stress, and contributes to the witness's ability to give their best evidence. A court witness supporter can be anyone known to the witness who is not a party to the proceedings and has no detailed knowledge of the evidence in the case. If evidence is to be given by live link, or if it is proposed that a supporter sit near the witness in court, it is a matter for the judge to determine who should accompany the witness. The identity of a supporter in the live link room or at the remote location must be the subject of an application to the court. It is normal practice for supporters from the Victim Support NI's Witness Service or the NSPCC Young Witness Service to accompany witnesses in the live link room without the need for a member of the Northern Ireland Courts and Tribunals Service (NICTS) to be present in the room. Where a supporter from either witness service is not available, a suitably trained member of Court Service staff will be available to accompany the witness in the live link room.

The address of the witness

6.87 Witnesses should not be asked to give their address aloud in court unless for a specific reason. Witnesses are not normally asked to give their address unless this is necessary. Witnesses, who are nervous about the possibility of retaliation, should be advised of this. If the witness's address is necessary for evidential purposes, it should be possible for it to be written down rather than read out in open court.

The use of a sign language interpreter

6.88 When a witness gives evidence assisted by a sign language interpreter, all persons present in the courtroom (including the defence representative) should be able to see the witness and the interpreter. If it is decided that such a witness should not give evidence in open court either the TV link should be used, ensuring the picture includes a view of the witness's hands, or screens should be used in combination with a video camera giving the defence representative a view of the witness.

6.89 Allowance should be made for proceedings to take longer than usual. Sign language interpretation is very tiring. Depending on the length of testimony and the number of witnesses using the interpreter, it will be necessary to take frequent breaks or to have more than one interpreter available.

Protection of witnesses from cross-examination by the accused in person (Articles 22 to 26)

6.90 It is a general rule in criminal trials that a defendant may choose to conduct their own defence and may cross-examine the witnesses for the prosecution. The 1999 Order provides exceptions to the principle that the unrepresented defendant (as such a defendant is called) may cross-examine prosecution witnesses. If the defendant fails to appoint a legal representative, then the court is empowered to appoint a representative to act for the defendant so that the witness's evidence will not go untested (Article 26 of the 1999 Order).

Complainants in proceedings for sexual offences

6.91 Article 22 of the 1999 Order prevents defendants charged with rape or other sexual offences from personally cross-examining the complainant of the offence. The ban is absolute in order to provide a measure of reassurance to complainants that in no circumstances will they be required to undergo cross-examination by the alleged offender. It extends to any other offences with which the defendant is charged in the proceedings. It was brought about by cases in which defendants sought to abuse their position as cross-examiner by, for example, dressing in the clothes which were worn at the time of the rape to intimidate the witness.

Complainants and other witnesses who are children

6.92 Under Article 23 of the 1999 Order, unrepresented defendants are prohibited from cross-examining in person any child who is a complainant of, or a witness to sexual offences, offences of violence, cruelty, kidnapping, false imprisonment or abduction.

6.93 The prohibition on cross-examining child witnesses extends to witnesses who were children when they gave their evidence in chief even if they have passed that age by the time of cross-examination. For the purposes of this provision, witnesses count as children if under 18 years in the case of sexual offences and if under 14 in the case of the other offences to which the provision applies.

Other cases

6.94 Article 24 of the 1999 Order gives courts the power to prohibit unrepresented defendants from cross-examining witnesses in any case other than those already covered by the mandatory ban described in the paragraphs above. Before exercising the power, the court must be satisfied that the circumstances of the witness and the case merit the prohibition, and that it would not be contrary to the interests of justice to impose it.

6.95 Article 25 of the 1999 Order provides that directions made under Article 24 are binding unless and until the court considers that the direction should be discharged in the interests of justice. Courts will have to record their reasons for making, refusing or discharging directions.

Restrictions on evidence and questions about the complainant's sexual behaviour (Articles 28 to 30)

6.96 Article 28 of the 1999 Order restricts the circumstances in which the defence can bring evidence about the sexual behaviour of a complainant in cases of rape and other sexual offences. A House of Lords' judgment (in R v A [2001] UKHL 25; [2002] 1 AC 45; [2001] 2 Cr App R 21) has subsequently qualified these restrictions. Restricting the use of such evidence serves two functions: it protects the complainant from humiliation and the unnecessary invasion of their privacy, and it prevents the jury from being prejudiced by information that might divert them from the real issues they have to consider. Their Lordships accepted the need for such restrictions but acknowledged that in some cases the evidence of a complainant's sexual behaviour might be so relevant that to exclude it would endanger the fairness of the defendant's trial. This may be particularly so where the previous sexual behaviour is with the defendant. In such a case, it would be the duty of the court to interpret Article 28 so as to admit the evidence. The courts have to find a balance between protecting the interests of the complainant and ensuring that the trial is fair.

6.97 The restrictions in Article 28 apply to all complainants in cases involving sexual offences, whether male or female, adult or child. The defence may not normally ask any questions or bring any evidence about the complainant's sexual behaviour on occasions other than those that are the subject of the charges at trial. This includes questions and evidence about the complainant's previous relationships with the defendant. Article 28 does not restrict the provision of relevant information by the prosecution about a complainant: for example, where it is the prosecution's case that the defendant raped his own wife, and his defence is consent, there would be no difficulty about informing the jury of the previous relationship between the defendant and the complainant as it would be relevant to the background of the case.

6.98 If the defence wishes to introduce evidence or ask questions about the complainant's sexual behaviour, they will have to make an application to the court. The court may grant leave in a case where:

- the evidence/question relates to a specific instance (or specific instances) of alleged sexual behaviour by the complainant;
  AND
- to refuse it might have the result of rendering unsafe a conclusion on any relevant issue (such as a conviction by a jury arrived at in ignorance of the complainant's sexual behaviour);
  AND
- one of the following four conditions is also satisfied:
  - the evidence/question is relevant to an issue in the case that is not an issue of consent (such as whether intercourse took place). The defendant's honest but mistaken belief in consent, which is currently a defence to a crime such as rape where lack of consent is an element of the offence, falls into this category, as it is not an issue of consent as such;
  - the issue is whether the complainant consented and the evidence/question relates to sexual behaviour that took place at or about the same time as the event which has given rise to the charge. This might cover cases where a couple were seen in an intimate embrace shortly before or after one is alleged to have sexually assaulted the other;
  - the issue is whether the complainant consented and the evidence/question relates to behaviour which is so similar to the defendant's version of events at or about the time of the alleged offence that it cannot reasonably be dismissed as coincidence. The House of Lords in R v A decided that this exception would have to be given a broad interpretation to cover any case where the evidence is so relevant to the issue of consent that to exclude it would endanger the fairness of the defendant's trial. It was accepted that this might involve stretching the language of the Order. The particular concern of the House in R v A was whether the defence should be able

to allude to a previous sexual relationship between the complainant and the defendant where consensual intercourse had taken place some time before the alleged rape. It was thought that there were cases where this would be necessary to ensure a fair trial even though it could not strictly be said that the previous behaviour was so similar that it could not be dismissed as coincidence. It does not follow that in every case where the defendant and the complainant have had such a relationship that it will fall within this exception. However, the House of Lords accepted that it is more likely that the court will need to be told about a previous relationship between the complainant and the defendant than between the complainant and a different person; or

- the evidence/question is intended to rebut or explain evidence advanced by the prosecution about the complainant's sexual behaviour. This might include a case where the prosecution adduce evidence to show that the complainant had no previous experience of penetrative sex and the evidence the defence wishes to bring shows the contrary.

6.99 An application for leave to ask questions/bring evidence about the complainant's sexual behaviour is made in private and the complainant is not allowed to be present, although the defendant may attend. The court must give reasons in open court for allowing or refusing an application, and specify the extent to which they are allowing any evidence to be brought in or questions to be put. This makes it clear to the complainant, as well as to the legal representatives, how far the questioning can go and in relation to which issues.

6.100 As the issue of whether evidence or questions relating to sexual behaviour can only be resolved by a court, and at a stage of proceedings where the defence case is fairly clearly defined, it is highly unlikely that any assurances can be given to a complainant that their sexual history will not be subject to cross-examination at trial. In the light of the decision in R v A, it is advisable that a complainant should be warned to expect that any claims by the defendant that they have had a sexual relationship are likely to be scrutinised by the court.

7 Provision of therapy for child witnesses prior to a criminal trial - practice guidance

Background

Witnesses are fundamental to the success of the criminal justice system. Children and other vulnerable witnesses should be able to give their best evidence in criminal proceedings with the minimum of distress. Vulnerable or intimidated witnesses, which include child witnesses, should not be denied the emotional support and counselling they may need both before and after the trial.

This guidance is based on guidance for England and Wales produced by the Department of Health, the Crown Prosecution Service and the Home Office.

The guidance is primarily for the assistance of child care professionals and legal representatives involved in making decisions about the provision of therapeutic help for child witnesses prior to a criminal trial. It makes clear that the best interests of the child are paramount when deciding whether, and in what form, therapeutic help is given. We hope that it will be helpful for all practitioners, especially those in the criminal justice system, Health and Social Care Trusts, education services, other statutory agencies, voluntary child care organisations and those in private practice.

The guidance has been produced following widespread and lengthy consultation within the criminal justice system and with those professionals who provide therapeutic help to abused children. The use of this guidance will enable children who need therapy to receive it at an appropriate time and to give their best evidence in criminal proceedings.

Introduction

7.1 Concern has been expressed that witnesses, and in particular child witnesses, have been denied therapy pending the outcome of a criminal trial for fear that their evidence could be tainted and the prosecution lost. This concern may conflict with the need to ensure that child victims are able to receive, as soon as possible, immediate and effective treatment to assist their recovery. In the context of this potential conflict, the following matters are relevant:

- many child victims express the wish to see their abuser convicted and punished;
- there is a wider public interest in ensuring that abusers are brought to justice to prevent further abuse; and
- all defendants are entitled to a fair trial.

7.2 It follows therefore that both child care professionals and forensic investigators have a mutual interest in ensuring, wherever possible, that children who receive therapy prior to a criminal trial are regarded as witnesses who are able to give reliable testimony.

Purpose and use of this guidance

7.3 The guidance is primarily aimed at therapists and legal representatives involved in making decisions in cases where the provision of therapy for child witnesses prior to a criminal trial is a consideration. However, it is hoped that the guidance will be helpful for everyone who comes into contact with child victims of abuse, particularly teachers, health visitors, counsellors, psychotherapists, social workers and the police who are often the first to hear an allegation.

7.4 It is recognised that decisions made in individual cases will depend on the particular considerations which apply to those cases. The guidance is intended to be practical in nature to avoid assumptions based on perceptions which may be unfounded. It is also acknowledged that practice will continue to evolve. The guidance simply aims to support this process by providing information based on current thinking about these issues.

7.5 In particular the guidance which follows seeks to:

- improve understanding of the difficulties for criminal prosecutions associated with the provision of therapy for child witnesses prior to a criminal trial;
- clarify the roles of those involved in making decisions about the provision of therapy prior to a criminal trial;
- explain the use of terminology and provide advice on the appropriateness of different therapeutic techniques; and
- set out a framework for good practice which highlights the important issues.

What guidance already exists on the provision of therapy for child witnesses prior to a criminal trial?

7.6 The UN Convention on the Rights of the Child states:

- Article 3. "When adults or organisations make decisions which affect children they must always think first about what would be best for the child".
- Article 12. "Children too have the right to say what they think about anything which affects them. What they say must be listened to carefully".
- Article 39. "Children who have been abused or neglected must receive assistance to promote their recovery and social reintegration. This must be done in an environment which fosters the health, self respect and dignity of the child.

7.7 Until now, this guidance has not been issued in a Northern Ireland format although the England and Wales version has been widely used to guide good practice.

7.8 Co-operating to Safeguard Children (DHSSPS, May 2003) sets out the inter-agency processes to be followed when a child is considered to be likely or is suffering significant harm. If, following enquiries under Article 66 of the Children (NI) Order 1995, there is a subsequent child protection conference and a child's name is placed on a child protection register, a child protection plan must be constructed. This plan should, along with other requirements, "describe all aspects of the needs of the child, giving particular attention to his safety and well being" (paragraph 5.72 of Co-operating to Safeguard Children). If, during this planning phase, it is known that the child is to be a witness at a criminal trial, consideration should be given to the child's therapeutic needs. This must include consideration of the possible impact the provision of therapy might have on the criminal trial, balanced with the consequences for the child of proceeding with the therapy or not (see paragraphs 7.65, 7.66 and 7.71).

7.9 Once the video recorded interview is complete, it should be possible for appropriate counselling and therapy to take place. It should be standard practice to inform the police and the Public Prosecution Service (PPS) about the nature and content of the therapy in each case. The defence may justifiably wish to know about both the nature and content of the therapy that has taken place before the child gives evidence in cross-examination. Introducing therapy before the interview is recorded has not been encouraged as the likelihood of a prosecution being jeopardised is thought to be greater, primarily due to the risk of contaminating evidence and/or the risk of coaching (perceived or actual).

7.10 The NSPCC Young Witness Pack (NSPCC (NI), 2011) focuses on the preparation of the child witness for giving evidence in a criminal trial. The first section of Chapter 6 of Preparing young witnesses for court: a handbook for child witness supporters makes the distinction between preparation and therapy prior to a criminal trial, and sets out some of the issues to be considered regarding the provision of therapy in this context.

What is therapy?

7.11 The term "therapy" covers a range of treatment approaches, including counselling, but in this context it does not include any physical treatments.

7.12 A precise definition of psychotherapy is not straightforward, but Kazdin (1990) defined it in the following way: "Psychotherapy includes interventions designed to decrease distress, psychological symptoms and maladaptive behaviour, or to improve adaptive and personal functioning through the use of interpersonal interaction, counselling or activities following a specific treatment plan. Treatment focuses on some facet of how clients feel (affect), think (cognition) and act (behaviour)".

7.13 Psychotherapies and counselling can be grouped in a number of ways (for example, psychodynamic, cognitive behavioural, systemic, experiential). They are underpinned by different models of understanding and techniques, and they vary in the context in which they are given (individual, family, group etc.) and frequency of sessions.

Types of therapeutic work undertaken prior to a criminal trial

7.14 Two broad categories of therapeutic work undertaken prior to a criminal trial can be identified:

(i) Counselling

This will address a number of issues, including:

- the impact on the child of the abuse;
- improving the self-esteem and confidence of the child;
- providing the child with information with regard to, for example, abusive relationships. The aim of this is to enable the child to seek out assistance from a trusted adult if the child feels unsafe at some stage in the future.

(ii) Psychotherapy

This will address a number of issues, including:

- treatment of emotional and behavioural disturbance, for example post traumatic stress disorder; and
- treatment of a child who has been highly traumatised and shows symptoms which give rise to concern for the child's mental health.

Both counselling and psychotherapy may require long term involvement with the child, depending on the degree of the trauma suffered and the child's cognitive ability.

Preparation for court

7.15 Preparing a child for court prior to the criminal trial commencing may be undertaken. This should be done by someone who does not have detailed knowledge of the case and is independent of the parties involved to avoid the risk of contamination or a perception of coaching. For this reason, it is advisable that counsellors and therapists do not engage in structured preparation for court but rather leave this work to the NSPCC Young Witness Service (see paragraph 7.47). The purpose of preparation for court is to:

- provide the child with information about the legal process;
- address any particular concerns or fears which the child may have in relation to giving evidence; and
- reduce anxiety.

The timing of the preparation for court is important. If it is carried out too soon before evidence is given, the child's anxieties may be increased. On the other hand, if it is carried out at the last minute the child may feel rushed and be unable to assimilate the information given. There can be benefits from a break in therapy in the lead up to trial when support from the NSPCC Young Witness Service is in place, on the understanding that the child can see the therapist if required. Close liaison between the NSPCC Young Witness Service and the therapist is important to ensure that support in the lead up to a trial is tailored to the needs of the individual child.

7.16 Appendix T includes materials which will assist with the preparation of the child witness for giving evidence in court. The NSPCC Young Witness Pack (2011), which is aimed at both children and young people, provides booklets for specific age groups. There is a video addition to the Pack entitled 'Giving Evidence - What's It Really Like?' (NSPCC 2000) which is suitable for older children. The Barnardo's video 'So, You're Going to be a Witness' (1996) is suitable for younger children.

What are the consequences of therapeutic help being given to a child witness prior to a criminal trial?

7.17 A criminal court can only convict a defendant of an offence if it is satisfied, on the basis of the evidence brought by the prosecution, that the defendant is guilty. Evidence is something that tends to prove or to disprove any fact or conclusion.

7.18 Each witness will give their evidence which is then cross-examined, to test its accuracy and truthfulness. The jury (in a Crown Court trial) decides the weight to be attached to the evidence when assessing whether guilt is proved.

7.19 Discussions prior to a criminal trial with or between all types of witness have been held by the courts in a number of cases to give rise to the potential for:

- witnesses giving inconsistent accounts of the events in issue in the trial; and
- fabrication, whether deliberate or inadvertent. For example, a witness may:
    - become aware of gaps or inconsistencies in his or her evidence, perhaps when compared with that of others; and
    - become more convinced (or convincing) in his or her evidence but no less mistaken.

7.20 Therapy is one kind of discussion which may take place prior to a trial. Other examples of discussions which may give rise to the evidence of adults and children being challenged include:

- informal contacts (for example, with friends and family);
- operational de-briefing by police officers (for example, after a large public disorder incident); and
- training.

At court, witnesses other than experts are not permitted to sit in court before giving evidence (so that they do not hear the accounts of other witnesses) and they are not permitted to discuss their evidence until the case is concluded.

7.21 Children may derive therapeutic benefit from simply talking about their experiences. To an extent they will determine when they are ready to do this but the professionals concerned should be aware of the possible consequences of allowing this to happen. These may include allegations of coaching and, ultimately, the failure of the criminal case. It should also be borne in mind that the professionals concerned may themselves be called to court as witnesses in relation to any therapy undertaken prior to the criminal trial.

7.22 The issue raised by all discussions undertaken prior to the criminal trial, including therapy, is whether the process can affect - that is to say undermine - the actual or perceived reliability of that witness's evidence and the weight the jury will attach to it. This will depend on a number of factors, such as the circumstances in which the discussions take place. Some of these factors are explored in paragraphs 7.40 to 7.64 below, which set out guidelines on the use of therapy.

Records of therapy and confidentiality

7.23 The administration of justice and the need to ensure a fair trial demand that any information and evidence which could have an impact on the decision to prosecute, the conduct of the case, or the outcome of proceedings is made available to the police and the PPS.

7.24 The rules of disclosure place certain responsibilities on the investigator, prosecutor and also third parties, that is to say individuals or bodies who are not part of the prosecution. Therapists will generally be third parties for this purpose. Those responsibilities mean that all material that may be relevant to the issues disputed in the case must be preserved.

7.25 The PPS must provide the defence with copies of, or access to, any material which might reasonably be considered capable of undermining the prosecution case or of assisting the defence case. This is a continuing duty throughout the trial process. Where a prosecutor believes that a third party has material or information which might be relevant to the prosecution case, prosecutors should take what steps they regard as appropriate in the particular case to obtain it. Similarly, there is a duty for the police to pursue all reasonable lines of enquiry, whether these point towards or away from the suspect. A third party has no obligation to reveal material to the police or prosecutor, nor is there any duty on the third party to retain material, which may be relevant to a future investigation. Organisations and independent practitioners will have policies for the retention and destruction of client records, which are compatible with data protection legislation and good practice. Therefore, particularly in the case of historic inquiries, it is conceivable that records may no longer be available. However, therapeutic records should be maintained in line with the advice in paragraph 7.68. Organisations and independent practitioners will have policies for the retention and destruction of client records, which are compatible with data protection legislation and good practice. Therefore, particularly in the case of historic inquiries, it is conceivable that records may no longer be available. However, therapeutic records should be maintained in line with the advice in paragraph 7.68. If the police, namely the Disclosure Officer, alerts the prosecutor to the possibility that the third party has material that has a bearing on the case, the prosecutor should consider whether it is appropriate to advise the police to

seek access to the material as part of their duties to explore all reasonable lines of enquiry. Where a third party refuses to provide material voluntarily, consideration may be given to making application for a witness summons. If the prosecutor decides that it is not necessary to take steps to obtain third party material, the defence may likewise seek a witness summons. The witness is not obliged to agree to the release of material but the Investigating Officer must explain to the witness that, if the court concludes that it is necessary that the defence should have access to the material in order to ensure a fair trial, its release will be ordered. The witness should be informed that the court will only order the disclosure of such material as is necessary to enable a fair trial, to take place and that in deciding whether to order the release of the material the court will take into account the witness's rights under Article 8 of the European Convention of Human Rights and Fundamental Freedoms (the right to respect for private and family life).

7.26 Disclosure should not be viewed as a tool to enable the prosecution or defence to satisfy their curiosity. It is a principle designed to ensure that information that is of genuine relevance to a criminal case is available to the parties and the court.

7.27 This guidance does not set out the detailed provisions relating to disclosure but aims to highlight some of the issues that may affect the handling of those cases. The Crown Court Judicial Committee protocol on third party disclosure can be found in Appendix N.

7.28 Requests for information to be obtained from third parties may be made at various stages in a criminal case by:

- the police;
- the prosecutor;
- the defence; or
- the court.

7.29 The requests should explain the issues in the case, so far as they are known, and be reasonably precise. Speculative inquiries are discouraged. The purpose should be to elicit a genuine and focused search for relevant documents or information. Careful maintenance of records of therapy will facilitate this focused approach. Where a therapist receives a request for information or documents, legal advice should be obtained before complying with the request. If, for example, the therapist is employed by a Health and Social Care Trust the legal department of the Trust will provide advice.

7.30 In addition to informal requests for information, if there are real grounds to believe that material which could affect the outcome of the prosecution is being withheld, an application may be made to the court for a witness summons to obtain the material. If, as will usually be the case, a therapist, having taken appropriate legal advice, believes that the material should not be disclosed, he or she may oppose the witness summons application. In that case the court may hold a hearing at which the therapist's employer may be legally represented. The court, having heard representations from the advocate representing the applicant for the witness summons and the advocate for the therapist's employer, will decide whether or not to issue a summons requiring the disclosure of the material.

7.31 Due to the recognition that maintaining a child's trust is central to the provision of therapy, it will usually only be appropriate to breach confidentiality in compliance with a court order, as outlined in the paragraph above. Those aspects of the therapy that have no material relevance to criminal proceedings should not have to be disclosed. However, the issue of relevance may need to be reviewed at different stages of the criminal case, as more becomes known about the prosecution and defence cases. Confidentiality cannot therefore be guaranteed in advance. Bearing this in mind, it is important that an understanding is reached with the child and carers at the outset of therapy, of the circumstances under which material obtained during treatment may be required to be disclosed. The limits of confidentiality in relation to information that identifies child care concerns or a risk of harm to self or others must be borne in mind and all work should be carried out in accordance with the Regional Area Child Protection Committee (ACPC) Policy and Procedures and, where appropriate, Safeguarding Vulnerable Adults: Regional Adult Protection Policy and Procedural Guidelines.

Decision making

Who makes the decisions about the provision of therapy where there are criminal proceedings?

7.32 The PPS is responsible for reviewing and conducting the majority of criminal cases involving child victims and witnesses. Once a prosecutor considers that there is a realistic prospect of conviction, the public interest must be considered. A primary consideration for prosecutors when taking decisions in these circumstances is the best interests of the child.

7.33 The prosecution in these criminal cases must do what it can to:

- identify cases in which the provision of therapy before the criminal trial might be thought to have some material impact on the evidence;
- assess the likely consequences for the criminal trial in these cases;
- ensure that these cases are dealt with as quickly as possible; and
- safeguard the confidentiality of therapy sessions wherever possible whilst ensuring that the defence and the court are aware of the existence of information which might undermine the prosecution case or assist the defence.

These questions are not unique to therapy which takes place before the criminal trial, but the ethical, medical, welfare and legal issues are of particular importance in these cases.

7.34 Whether a child should receive therapy before the criminal trial is not a decision alone for the police or the PPS. Such decisions can only be taken by professionals from all of the agencies responsible for the welfare of the child, in consultation with the carers of the child and the child him or herself, if the child is of sufficient age and understanding.

7.35 The best interests of the child are the paramount consideration in decisions about the provision of therapy before the criminal trial. In determining what is in the best interests of the child, due consideration should be given to ascertaining the wishes and feelings of the child, in a manner which is appropriate to the child's age and understanding. When working with the child, either for assessment or therapeutic purposes, account should be taken of the child's gender, race, culture, religion, language and (if appropriate) disability.

7.36 If there is a demonstrable need for the provision of therapy and it is possible that the therapy will prejudice the criminal proceedings, consideration may need to be given to abandoning those proceedings in the interests of the child's wellbeing. In order that such consideration can be given, it is essential that information regarding therapy is communicated to the prosecutor.

7.37 Alternatively, there may be some children for whom it will be preferable to delay therapy until after the criminal case has been heard, to avoid the benefits of the therapy being undone.

7.38 While some forms of therapy may undermine the evidence given by the witness, this will not automatically be the case. The PPS will offer advice, as requested in individual cases, on the likely impact on the evidence of the child receiving therapy.

Communication

7.39 Clear lines of communication are required to ensure that everyone involved in the process is fully and reliably informed. Named contact points should be established in each agency for each child. Information should be routed through the police contact point although direct consultation between the professionals involved may be advisable in certain circumstances. This should be arranged using the same named contact points.

Guidelines on the use of therapy

7.40 Set out below are guidelines on the use of appropriate therapy with child witnesses. The stated principles mark the distinction between the use of psychotherapy and counselling by qualified practitioners and formal preparation of the witness for the giving of evidence in court. Where such preparation takes place, the witness should not discuss or be encouraged to discuss the evidence which s/he is to give in the criminal proceedings but may receive general support to help them through the process of appearing in court.

7.41 All people who work with children before a criminal trial should be aware of the possible impact of their work on subsequent evidence in the trial. Some types of therapeutic work are more likely to be seen as prejudicial and therefore undermine the perception of a child's credibility and reliability, or to influence a child's memory of events or the account they give. Preparation for court and carefully planned preventive work, which does not focus on past abuse, presents less of a problem than interpretive psychodynamic psychotherapy. Therefore, there is a spectrum of evidential risk to the criminal trial which should be considered.

7.42 The least problematic aspect of therapy will focus on improving self-esteem and self-confidence, often using cognitive/behavioural techniques. Other issues which might be addressed include:

- the reduction of distress about the impending legal proceedings; and
- the treatment of associated emotional and behavioural disturbance that does not require the rehearsal of abusive events.

7.43 Careful recording is essential and, prior to therapy beginning, the child's need for such therapy should be clearly stated.

Who are the therapists?

7.44 Professionals offering therapy may be working within Health and Social Care Trusts, other statutory agencies, the voluntary sector or privately.

7.45 There are a number of factors relating to qualifications, training and experience which can guide the relevant professionals about the competence of any single individual to undertake psychotherapy or counselling with a child who is to be a witness in a criminal trial.

7.46 Providers and purchasers of therapy for children in this situation must ensure that any therapist or counsellor has appropriate training according to the level of work to be undertaken, as well as a thorough understanding of the effects of abuse. Membership of an appropriate professional body or other recognised competence would be expected in these circumstances. They must also have a good understanding of how the rules of evidence for witnesses in criminal proceedings may require modification of techniques.

7.47 Children may receive preparation for the experience of giving evidence in court. This must be given by suitably trained individuals, who will need to be aware of the clear distinction between the preparation of a child for the experience of giving evidence in court and the provision of therapy or counselling to address trauma. See Appendix L.

Assessment of the need for therapy

7.48 Assessment of the need for therapy of any child during the pre-trial period (when that child may become a witness in the subsequent trial), should only be undertaken following consultation with the relevant other professionals involved. This may be appropriate in the context of a strategy discussion or child protection conference convened under child protection procedures. If the child is not the subject of child protection processes, and it is judged desirable, a meeting of all relevant professionals might be convened for the purpose of discussing an assessment and treatment strategy.

7.49 The function of any such discussion should be to discuss the needs and best interests of the particular child. The discussion should include the logistics of setting up a specialist assessment of the child, with agreement on who will undertake this assessment and which professional agencies will support it, for example by bringing the child to appointments and working with the family.

7.50 Although it would be inappropriate to pre-empt the outcome of a subsequent specialist assessment for therapy of whichever kind proposed, it is nonetheless important that priority be given to the best interests of the child. The impact of any therapy on the conduct of the criminal case should also be fully discussed. The PPS will advise, as requested, on the likely effect of a particular type of therapy on the evidence of witnesses in individual cases and will need to be informed about any planned or ongoing therapy. Where a criminal case is at an advanced stage, it may be possible to consult the judge in chambers as to the potential consequences of a proposed course of action.

7.51 It is vital that a trained professional person with a recognised competence in such assessments should see the child and any relevant family members. One or more careful assessment interviews should be conducted in order to determine whether and in what way the child is emotionally disturbed and also whether further treatment is needed. This could be as part of an assessment undertaken according to the UNOCINI assessment framework.

7.52 It is important to note that not all children who are assessed in this way will need therapy. Final recommendations from the assessment will indicate the type of therapy or intervention, if any, required by the particular child. It will be important for such findings to be made available to other relevant agencies involved as soon as possible after the assessment is completed.

Important issues regarding an assessment

7.53 A whole range of issues may arise in the course of any assessment, but for those undertaking an assessment of child witnesses to determine whether they require therapy, it is important to address the following areas.

7.54 Developmental factors must be taken into account during the assessment of each child. Children of the same age may have different levels of understanding. An assessment should therefore address the child's development in both emotional and cognitive terms, as well as any relevant physical illnesses or developmental problems which might affect a child's performance as a witness in court, and which could be worked with in the course of therapy provided prior to the criminal trial.

7.55 A child with specific needs may, with the appropriate assistance, be a competent witness. An assessment of children with specific needs, including physical and learning disabilities, and hearing and speech impairments, should be conducted in conjunction with specialist workers who are trained in these areas of work. This is an area where the use of an intermediary should be considered.

7.56 The issue of possible suggestibility in an interview situation, or during cross-examination in court, should also be addressed during an assessment. It should be remembered that some children including young children, learning disabled children, very severely abused children who have been intimidated or physically beaten, or severely emotionally disturbed children are more likely to produce erroneous or ambiguous responses to leading questions from interviewers, than less vulnerable or older children. Particular care, therefore, should be taken in the assessment of such vulnerable children to use short, plain, words, to ask open questions where possible and to avoid convoluted, hypothetical or other leading questions.

7.57 The assessor should use a limited range of selected assessment tools such as drawing materials and appropriate toys (for example, non-anatomical dolls) to supplement questioning within a session. The use of anatomical dolls in assessment for therapy is unlikely to be necessary, since specific investigative work about alleged abuse (which may or may not involve anatomical dolls) will already have been undertaken in the joint investigative interview. The use of any materials which suggest or presume that abuse has taken place should be avoided.

7.58 If deemed clinically appropriate, children should also have a separate psychological and/or developmental assessment to obtain baseline data on their cognitive and emotional functioning. Such a psychological assessment will indicate whether the child has specific needs which may require assistance in court, for example an intermediary or interpreter, as well as contributing to an understanding of the child's emotional needs.

7.59 Some children are so severely traumatised that the short term provision of, for example, once or twice weekly therapeutic sessions may be either inadequate for their needs or positively disturbing for them, particularly if their home or alternative care situation has not been fully resolved. With certain children, therefore, it may be better to delay long-term therapeutic work until a placement is made within a containing environment and then commence more intensive therapeutic work.

7.60 This may, in some cases, mean delaying therapy until the criminal proceedings are at an end (though in such cases prosecutors will wish to do all that they can to expedite the proceedings). This does not, however, preclude the important provision of general support for the child and family or briefer forms of more focused therapy.

Potential problem areas

7.61 Problems may arise when the therapist attempts to distinguish fantasy from reality. In this kind of situation, the therapist should be as open to the idea that material presented as factual truth may be a distortion, as they are to a fantasy being a representation of reality.

7.62 Interpretative psychotherapy may therefore present evidential problems even if carefully conducted. The professional background and training of the therapist, the provision of adequate supervision arrangements, the appropriateness and robustness of the policies of the agency providing therapy will all help to obviate problems.

7.63 There are therapeutic approaches that would very definitely present problems as far as evidential reliability is concerned. These would include hypnotherapy, psychodrama, regression techniques and unstructured groups.

7.64 As the courts become more familiar with the provision of therapy prior to the criminal trial and more confident in the standards and knowledge of the agencies providing it, anxieties will become less. Training for professionals providing therapy, and for the judiciary and legal profession will be of value.

Conclusion

7.65 It should be understood that those involved in the prosecution of an alleged offender have no authority to prevent a child from receiving therapy.

7.66 The police and the PPS should be made aware that therapy is proposed, is being undertaken, or has been undertaken.

7.67 The nature of the therapy should be explained so that consideration can be given to whether or not the provision of such therapy is likely to impact on the criminal case. There should be a locally agreed mechanism for communicating this information and enabling it to be routed through the police to the PPS using named contact points assigned to each individual child. Direct consultation between the professionals involved may be desirable in some circumstances and should be arranged in the same way.

7.68 Records of therapy (which includes videos and tapes as well as notes) and other contacts with the witness must be maintained so that they can be produced if required by the court. They should include, in the case of therapy, details of those persons present and the content and length of the therapy sessions. It is not expected, for practical reasons, that verbatim written records will be kept.

7.69 At the outset of therapy an understanding should be reached with the child and the carers, of the circumstances under which material obtained during therapy might be required to be disclosed. Maintaining a child's trust will remain important and it can be confirmed that those aspects of the therapy that have no material relevance to criminal proceedings will not have to be disclosed. However, what is "relevant" may change as the case progresses and so confidentiality cannot be guaranteed.

7.70 In newly arising allegations, therapy should not usually take place before a witness has provided a statement or, if appropriate, before a video recorded interview has taken place. However, in existing cases where therapy is already under way, a decision about how to proceed may be best made after discussion at a multi-disciplinary meeting which includes the child's therapist. Clearly, when therapeutic work is in progress, disruption of therapy should be avoided even if new investigations must be conducted. If it is decided that leading questions or interpretations must be used to help a child in psychotherapy then the evidential implications of this should be understood and made clear.

7.71 If the prosecutor advises that the proposed therapy may prejudice the criminal case, those responsible for the child's welfare should take this into account when deciding whether to agree to the therapy. It may still be in the best interests of the child to proceed with the therapy.

7.72 The therapist should be made aware of any pending criminal proceedings before commencing the therapy and should also be aware of the implications of using techniques which may result in the child's evidence being discredited.

7.73 Therapists or counsellors should avoid using leading questions or discussing the evidence which the individual or any other witness will give, including exploring in detail the substance of specific allegations made.

7.74 Prior to the criminal trial, group therapy where the specific recounting of abuse takes place is best avoided. The particular danger of this kind of group therapy is that the witness may adopt the experiences of others taking part in the therapy. Structured group therapy approaches, which help in a neutral way to improve the child's self esteem, are less likely to cause difficulties. As a general principle, group therapy should not be offered to the child witness prior to the trial.

7.75 Children may derive therapeutic benefits from talking about their experiences, but any detailed recounting or re-enactment of the abuse may be perceived as coaching. Therapists should recognise that the criminal case is almost certain to fail as a consequence of this type of therapeutic work. This should be differentiated from the accepted practice of allowing witnesses, prior to giving evidence, to refresh their memory by reading their statements or viewing their video recorded interview.

7.76 Professionals should avoid the use of jargon and take care to use language that will not be perceived, if repeated by a child witness, as evidence of the witness being instructed. The language content of the therapy and counselling sessions is guided by the child but equally it must be recognised that children do use different forms of language in differing situations and contexts.

7.77 During therapy, witnesses should never be encouraged to extend their account of the abuse which they have suffered. However, it is acceptable to offer general reassurance and support to a child during this difficult process.

7.78 Any disclosure of materially new allegations by the witness undergoing therapy, including possible disclosures of their own abusive behaviour, should be reported to the police, the relevant Health and Social Care Trust and any other statutory agency in accordance with the Regional Area Child Protection Committee (ACPC) Policy and Procedures and where appropriate Safeguarding Vulnerable Adults: Regional Adult Protection Policy and Procedural Guidelines. Because therapists will avoid discussion of evidence in pre-trial therapy it will be difficult for them to know if a witness introduces any material, departure from or inconsistency with the original allegations in the context of the therapeutic work. Should the therapist suspect that this may have occurred they should seek supervisory support and discuss their concerns with the police. Decisions about further therapy should be made with reference to paragraphs 7.70 and 7.71. It may be appropriate to halt any further work until a multi-disciplinary discussion has taken place which includes input from the police and the PPS. Risks to the criminal trial must be weighed in any decision making process about continuing therapy but the welfare of the child will be the paramount consideration in any decision.

7.79 Prosecutors must be informed that the witness has received therapy. Prosecutors must then obtain an assurance that the witness did not, in the therapy session(s), say anything inconsistent with the statements made by the witness to the police. Prosecutors may need to be made aware of the contents of the therapy sessions, as well as other details specified in the above paragraph, when considering whether or not to prosecute and their duties of disclosure.

7.80 Discussions at local level between the agencies concerned, exploring practical ways to facilitate good practice, will be helpful in handling the issues outlined in this guidance. A local protocol setting out the approach to be followed may be helpful.

Provision of therapy for vulnerable or intimidated adult witnesses prior to a criminal trial - practice guidance

8

Background

Witnesses are fundamental to the success of the criminal justice system. Vulnerable or intimidated adult witnesses should not be denied the emotional support and counselling they may need both before and after the trial.

This guidance is based on guidance for England and Wales produced by the Department of Health, the Crown Prosecution Service and the Home Office.

The guidance is primarily for the assistance of therapists, those who commission or arrange therapy, and legal representatives involved in making decisions about the provision of therapeutic help for vulnerable or intimidated adult witnesses prior to a criminal trial. The guidance makes it clear that the best interests of the witness are paramount when deciding whether, and in what form, therapeutic help is given. It is intended to be helpful for all practitioners, especially those in the criminal justice system, health and social care agencies, education services, other statutory agencies, voluntary organisations and those in private practice. The guidance complements the good practice guidance for child witnesses which is contained in Chapter 7.

The guidance has been produced following consultation within the criminal justice system and with many professionals from a range of different disciplines. Its use will enable vulnerable or intimidated adult witnesses to receive the therapeutic help necessary both to assist their recovery and to give their best evidence in criminal proceedings.

Introduction

8.1 Concern has been expressed that witnesses, including vulnerable or intimidated adult witnesses, have been denied therapy pending the outcome of a criminal trial for fear that their evidence could be tainted and the prosecution lost. This fear may conflict with the need to ensure that vulnerable or intimidated adult victims are able to receive, as soon as possible, immediate and effective treatment to assist their recovery. In the context of this potential conflict, the following matters are relevant:

- many victims express the wish to see the alleged offender convicted and punished;
- there is a wider public interest in ensuring that offenders are brought to justice to prevent further offences; and
- all defendants are entitled to a fair trial.

8.2 It follows therefore that victims, service provision professionals and forensic investigators have a mutual interest in ensuring, wherever possible, that those who receive therapy prior to a criminal trial are regarded as witnesses who are able to give reliable testimony.

8.3 In June 1998, the Report "Speaking Up For Justice" ("the Report") was published in England and Wales. The Report was produced by an interdepartmental working group that considered the treatment of vulnerable or intimidated witnesses in the criminal justice system. Recommendation 28 of the Report said that vulnerable or intimidated witnesses should not be denied the emotional support and counselling they may need both before and after the trial. In the subsequently issued implementation programme document "Action for Justice" (England and Wales), it was said that good practice guidance on the provision of therapy prior to trial for vulnerable or intimidated adult witnesses would be issued.

8.4 The Report also recommended that there should be special measures to enable vulnerable or intimidated witnesses in a criminal trial to give their best evidence. That recommendation was enacted by Articles 4 – 21 of the Criminal Evidence (NI) Order 1999 in this jurisdiction. These Articles provide for a range of special measures, for example the giving of evidence by means of a live TV link (Article 12) and the giving of evidence by way of pre-recorded video interview (Article 15), to enable a vulnerable or intimidated witness to give their best evidence. However, it will be for the court to decide which, if any, of the special measures will be made available to the particular witness.

8.5 As mentioned in the paragraph above, one of the special measures introduced by the 1999 Order is the possibility of admitting, as evidence, a video recorded interview with a vulnerable or intimidated adult witness. Wherever possible, pre-trial therapy should not take place before such a video recorded interview is completed.

8.6 Article 4 of the 1999 Order states that adult witnesses may be deemed to be vulnerable if the court considers that the quality of evidence given by the witness is likely to be diminished because:

(a) the witness suffers from mental disorder within the meaning of the Mental Health (NI) Order 1986 or otherwise has a significant impairment of intelligence and social functioning; or
(b) the witness has a physical disability or is suffering from a physical disorder.

8.7 Article 5 of the 1999 Order states that a witness may be deemed to be intimidated if the court is satisfied that the quality of evidence given by the witness is likely to be diminished by reason of fear or distress in connection with testifying.

Purpose and use of this guidance

8.8 This guidance is primarily aimed at those who arrange or commission therapy, therapists and lawyers involved in making decisions in cases where pre-trial therapy is a consideration. However, it is hoped that the guidance will be helpful for everyone involved in these cases.

8.9 It is recognised that decisions made in individual cases will depend on the particular considerations which apply to those cases. The guidance is intended to be practical in nature and to avoid assumptions based on perceptions which may be unfounded. It is also acknowledged that practice will continue to evolve. The guidance simply aims to support this process by providing information based on current thinking about these issues.

8.10 In particular the guidance which follows seeks to:

- improve understanding of the difficulties for criminal prosecutions associated with the provision of therapy for vulnerable or intimidated adult witnesses prior to a criminal trial;
- clarify the roles of those involved in making decisions about the provision of therapy prior to a criminal trial;
- explain the use of terminology, and provide advice on the appropriateness of different therapeutic techniques; and
- set out a framework for good practice which highlights the important issues.

8.11 Until now, this guidance has not been issued in a Northern Ireland format although the England and Wales version has been widely used to guide good practice.

What is therapy?

8.12 The term "therapy" covers a range of treatment approaches, including counselling, but in this context it does not include any physical treatments.

8.13 A precise definition of psychotherapy is not straightforward but the definition used in the guidance for child witnesses came from Kazdin (Psychotherapy for child and adolescent (1990) Annual Review of Psychology 41, 21-5) and is set out below: "Psychotherapy includes interventions designed to decrease distress, psychological symptoms and maladaptive behaviour, or to improve adaptive and personal functioning through the use of interpersonal interaction, counselling or activities following a specific treatment plan. Treatment focuses on some facet of how clients feel (affect), think (cognition) and act (behaviour)".

8.14 Psychotherapies and counselling can be grouped in a number of ways; for example, psychodynamic, cognitive behavioural, systemic, experiential. They are underpinned by different models of understanding and techniques, and vary in the context in which they are given (individual, family, group, etc.) and frequency of session.

Types of therapeutic work undertaken prior to a criminal trial

8.15 Two broad categories of therapeutic work with vulnerable or intimidated adults prior to a criminal trial can be identified:

(i) Counselling

This will address a number of issues, including:

- the impact of the incident on the adult;
- improving the self-esteem and confidence of the adult; and
- providing the vulnerable or intimidated adult with information with regard to dealing with and avoiding abusive situations. The purpose of this is to help the adult to protect him herself and to access appropriate help.

(ii) Psychotherapy

This will address a number of issues, including:

- treatment of emotional and behavioural disturbance, for example post-traumatic stress disorder; and
- treatment of an adult who has been highly traumatised and shows symptoms which give rise to concern for his/her mental health.

Both counselling and psychotherapy may require long term involvement with the vulnerable or intimidated adult.

Preparation for court

8.16 A vulnerable or intimidated adult witness may have no previous experience of giving evidence in court and some preparation work prior to the criminal trial is likely to be of considerable value. This should be done by someone who does not have detailed knowledge of the case to avoid the risk of contamination or a perception of coaching. For this reason it is advisable that counsellors and therapists do not engage in structured preparation for court and leave this work to the Victim Support NI (VSNI) Witness Service (see Chapter 5).

8.17 The purpose of this work will be to:

- provide information about the legal process, for example the respective roles of judge, legal representatives, jury;
- address any particular concerns or fears which the adult may have in relation to giving evidence; and
- reduce anxiety.

The timing of the preparation for court is important. If it is carried out too soon before evidence is given, the witness's anxieties may be increased. On the other hand, if it is carried out at the last minute, the witness may feel rushed and be unable to assimilate the information given. There can be benefits from a break in therapy in the lead up to trial when support from the VSNI Witness Service is in place, on the understanding that the witness can see the therapist if required. Close liaison between the VSNI Witness Service and the therapist is important to ensure that support in the lead up to a trial is tailored to the needs of the individual witness.

8.18 Any information provided will need to be available in forms accessible for the particular witness taking account of such issues as language, literacy, communication (including British Sign Language, use of Braille etc.), cultural understanding and disability.

8.19 Guidance on pre-trial preparation can be found in Chapters 5 and 6. What are the consequences of therapeutic help being given to a vulnerable or intimidated adult witness prior to a criminal trial?

8.20 A criminal court can only convict a defendant of an offence if it is satisfied, on the basis of the evidence brought by the prosecution, that the defendant is guilty. Evidence is something that tends to prove or to disprove any fact or conclusion.

8.21 Each witness will give their evidence which is then cross-examined to test its accuracy and truthfulness.

8.22 Discussions prior to a criminal trial with or between all types of witnesses have been held by the courts in a number of cases to give rise to the potential for:

- witnesses giving inconsistent accounts of the events at issue in the trial; and
- fabrication, whether deliberate or inadvertent. For example, a witness may:
  - become aware of gaps or inconsistencies in his or her evidence, perhaps when compared with that of others; or
  - become more convinced, or convincing, in his or her evidence, but no less mistaken.

8.23 Therapy is one kind of discussion which may take place prior to a trial. Other examples of discussions which may give rise to the evidence of adults (and children) being challenged include:

- informal contacts, for example with friends and family;
- operational de-briefing by police officers (for example, after a large public disorder incident); and
- training.

At court, witnesses other than experts are not permitted to sit in court before giving evidence (so that they do not hear the accounts of other witnesses) and they are not permitted to discuss their evidence until the case in concluded.

8.24 The key issue with regard to pre-trial discussions of any kind is the potential effect on the reliability, actual or perceived, of the evidence of the witness and the weight which will be given to in court. Pre-trial discussions may lead to allegations of coaching and, ultimately, the failure of the criminal case. It should also be borne in mind that the professionals concerned may themselves be called to court as witnesses in relation to any therapy undertaken prior to the criminal trial.

Records of therapy and confidentiality

8.25 The administration of justice and the need to ensure a fair trial demand that any information and evidence, which could have an impact on the decision to prosecute, the conduct of the case, or the outcome of proceedings, is made available to the police and the Public Prosecution Service (PPS).

8.26 The rules of disclosure place certain responsibilities on the investigator, prosecutor and also third parties, that is to say individuals or bodies who are not part of the prosecution. Therapists will generally be third parties for this purpose. Those responsibilities mean that all material that may be relevant to the issues disputed in the case must be preserved.

8.27 The PPS must provide the defence with copies of, or access to, any material which might reasonably be considered capable of undermining the prosecution case or of assisting the defence case. This is a continuing duty throughout the trial process. Where a prosecutor believes that a third party has material or information which might be relevant to the prosecution case, prosecutors should take what steps they regard as appropriate in the particular case to obtain it. Similarly, there is a duty for the police to pursue all reasonable lines of enquiry, whether these point towards or away from the suspect. A third party has no obligation to reveal material to the police or prosecutor, nor is there any duty on the third party to retain material which might be relevant to a future investigation. Organisations and independent practitioners will have policies for the retention and destruction of client records, which are compatible with data protection legislation and good practice, so, particularly in the case of historic inquiries, it is conceivable that records may no longer be available. However, therapeutic records should be maintained in line with the advice in paragraph 8.76. If the police, namely the Disclosure Officer, alerts the prosecutor to the possibility that the third party has material that has a bearing on the case , the prosecutor should consider whether it is appropriate to advise the police to seek access to the material as part of their duties to explore all reasonable lines of enquiry. Where a third party refuses to provide material voluntarily, consideration may be given to making an application for a witness summons. If the prosecutor decides that it is not necessary to take steps to obtain third party material, the defence may likewise seek a witness summons. The witness is not obliged to agree to the release of material but the Investigating Officer must explain to the witness that if the court concludes that it is necessary that the defence should have access to the material in order to ensure a fair trial its release will be ordered. The witness should be informed that the court will only order the disclosure of such material as is necessary to enable a fair trial to take place and that, in deciding whether to order the release of the material the court will take into account the witness's rights under Article 8 of the European Convention of Human Rights and Fundamental Freedoms (the right to respect for private and family life).

8.28 Disclosure should not be viewed as a tool to enable the prosecution or defence to satisfy their curiosity. It is a principle designed to ensure that information that is of genuine relevance to a criminal case is available to the parties and the court.

8.29 This guidance does not set out the detailed provisions relating to disclosure but aims to highlight some of the issues that may affect the handling of those cases. The Crown Court Judicial Committee protocol on third party disclosure can be found in Appendix N.

8.30 Requests for information to be obtained from third parties may be made at various stages in a criminal case by:

- the police;
- the prosecutor;
- the defence; and
- the court.

8.31 The requests should explain the issues in the case, so far as they are known, and be reasonably precise. Speculative inquiries are discouraged. The purpose should be to elicit a genuine and focused search for relevant documents or information. Careful maintenance of records of therapy will facilitate this focused approach. Where a therapist receives a request for information or documents, legal advice should be obtained before complying with the request. If, for example, the therapist is employed by a Health and Social Care Trust, the legal department of the Trust will provide advice.

8.32 In addition to informal requests for information, if there are real grounds to believe that material which could affect the outcome of the prosecution is being withheld, an application may be made to the court for a witness summons to obtain the material. If, as will usually be the case, a therapist, having taken appropriate legal advice, believes that the material should not be disclosed, he or she may oppose the witness summons application. In that case the court may hold a hearing at which the therapist's employer may be legally represented. The court, having heard representations from the advocate representing the applicant for the witness summons and the advocate for the therapist's employer, will decide whether or not to issue a summons requiring the disclosure of the material.

8.33 Due to the recognition that maintaining trust is central to the provision of therapy, it will usually only be appropriate to breach confidentiality in compliance with a court order, as outlined in the paragraph above. Those aspects of the therapy that have no material relevance to criminal proceedings should not have to be disclosed. However, the issue of relevance may need to be reviewed at different stages of the criminal case, as more becomes known about the prosecution and defence cases.

8.34 Confidentiality cannot therefore be guaranteed in advance. Bearing this in mind, it is important that an understanding is reached with the vulnerable or intimidated adult witness (and, where appropriate, any other emotionally significant person) at the outset of any therapy undertaken of the circumstances under which material obtained during treatment may be required to be disclosed. The limits of confidentiality in relation to information that identifies or a risk of harm to self or others must be borne in mind and all work should be carried out in accordance with, where appropriate, Safeguarding Vulnerable Adults: Regional Adult Protection Policy and Procedural Guidelines.

Decision making

Who makes the decisions about the provision of therapy where there are criminal proceedings?

8.35 The PPS is responsible for reviewing and conducting the majority of criminal cases involving vulnerable or intimidated adult witnesses. Once a prosecutor considers that there is a realistic prospect of conviction, the public interest must be considered.

8.36 The prosecution in these criminal cases must do what it can to:

- identify cases in which the provision of therapy before the criminal trial might be thought to have some material impact on the evidence;
- assess the likely consequences for the criminal trial in these cases;
- ensure that these cases are dealt with as quickly as possible; and
- safeguard the confidentiality of therapy sessions wherever possible whilst ensuring that the defence and the court are aware of the existence of information which might undermine the prosecution case or assist the defence.

These questions are not unique to therapy which takes place before the criminal trial but the ethical, medical, welfare and legal issues are of particular importance in these cases.

8.37 Whether a vulnerable or intimidated adult witness should receive therapy before the criminal trial is not a decision for the police or the PPS. Such decisions can only be taken by the witness, in conjunction with the professionals from the agencies providing service to that witness.

8.38 The best interests of the vulnerable or intimidated adult witness are the paramount consideration in decisions about the provision of therapy before the criminal trial. In determining what is in the best interests of the witness, will be essential to consider the wishes and feelings of the witness and, where appropriate, their carers or those who are emotionally significant to the witness. The witness will need to be given information on the nature of the therapy proposed in a form which is accessible. Account should be taken of issues associated with gender, race, culture, religion, language, disability and any communication difficulties both in initial discussions about the proposed therapy and in the provision of the therapy itself.

8.39 While some forms of therapy may undermine the evidence given by the witness, this will not automatically be the case. The PPS will offer advice, as requested in individual cases, on the likely impact on the evidence of the witness receiving therapy.

8.40 If there is a demonstrable need for the provision of therapy and it is possible that the therapy will prejudice the criminal proceedings, consideration may need to be given to abandoning those proceedings in the interests of the wellbeing of the vulnerable or intimidated adult witness. In order that such consideration can be given, it is essential that information regarding therapy is communicated to the prosecutor.

Communication

8.41 Clear lines of communication are required to ensure that everyone involved in the process is fully and reliably informed. Named contact points should be established in each agency involved in a particular case.

8.42 Information should be routed through the police contact point, although direct consultation between the professionals involved may be advisable in certain circumstances. This should be arranged using the same named contact points.

8.43 Inter-agency information exchange will need to comply with Human Rights Act 1998 and the Data Protection Act 1998. Decisions on exchange of information will need to be made on a case by case basis and carefully documented.

Guidelines on the use of therapy

8.44 Set out below are guidelines on the use of appropriate therapy with vulnerable or intimidated adult witnesses. The stated principles mark the distinction between the use of psychotherapy and counselling by qualified practitioners and formal preparation of the witness for the giving of evidence in court. Where such preparation takes place, the witness should not discuss or be encouraged to discuss the evidence which s/he is to give in the criminal proceedings but may receive general support to help them through the process of appearing in court.

8.45 All people who work with vulnerable or intimidated adult witnesses before a criminal trial should be aware of the possible impact of their work on subsequent evidence in the trial. Some types of therapeutic work are more likely to be seen as prejudicial and thereby undermine the perception of the credibility and reliability of a witness, or to influence memory of the witness as to events or the account they give.

8.46 Preparation for court and carefully planned preventive work which does not focus on past abuse presents less of a problem than interpretive psychodynamic psychotherapy. Therefore, there is a spectrum of evidential risk to the criminal trial which should be considered.

8.47 The least problematic aspect of therapy will focus on improving self-esteem and self-confidence, often using cognitive/behavioural techniques. Other issues which might be addressed include:

- the reduction of distress about the impending legal proceedings; and
- the treatment of associated emotional and behavioural disturbance that does not require the rehearsal of abusive events.

8.48 The need for therapy should be clearly stated before it begins, and both therapist and vulnerable or intimidated adult witness should be aware of the related criminal case, which may or may not have already been commenced. Careful recording is essential.

Who are the therapists?

8.49 Professionals offering therapy may be working within Health and Social Care Trusts, other statutory agencies, the voluntary sector or privately. Therapists may specialise in work with particular groups, for example people with learning disabilities or with victims of particular offences, for example rape.

8.50 There is, at the moment, no centrally available register of those qualified to provide therapy to vulnerable or intimidated adult witnesses. Vulnerable or intimidated adult witnesses are not a homogeneous group and may have a wide range of needs. Professionals qualified to work with one group of witnesses may not be qualified to work with other witnesses who have different disabilities or problems. Treatment responses will need to draw on both general therapeutic skills and specialised knowledge of the particular cause of vulnerability. Skills in communication with the particular witness will always be important.

8.51 Providers and purchasers of therapy for vulnerable or intimidated adult witnesses must ensure that any therapist or counsellor has appropriate training and supervision, according to the level of work undertaken. Membership of an appropriate professional body or other recognised competence would be expected. The therapist or counsellor must also have a good understanding of how the rules of evidence for witnesses in criminal proceedings may require modification of techniques. Agencies involved in the provision of therapy should consider the need for the training for therapists and counsellors who work with vulnerable or intimidated adult witnesses prior to the criminal trial.

8.52 Vulnerable or intimidated adult witnesses may receive preparation for the experience of giving evidence in court. This must be done by suitably trained individuals, who will need to be aware of the clear distinction between the preparation of the witness for the experience of giving evidence in court and the provision of therapy or counselling to address trauma (see Chapters 5 and 6).

Assessment of the need for therapy

8.53 Assessment of the need for therapy during the pre-trial period (when the vulnerable or intimidated adult witness may become a witness in the subsequent trial) should only be undertaken following consultation with:

- the witness;
- where appropriate, carers or those who are emotionally significant to the witness; and
- the relevant professionals.

The police and the PPS should be informed about any planned or ongoing therapy at the assessment stage.

8.54 If it is judged desirable, a meeting of all relevant professionals might be convened for the purpose of discussing an assessment and treatment strategy. This assessment and treatment strategy should take into account the special measures which might be available under the 1999 Order, so that an early application to the court can be made. However, it is important to remember that it will be for the court to decide which, if any, special measures will be made available to the witness. Accordingly, it is essential that unrealistic expectations on the part of the witness are not raised.

8.55 The function of any such discussion should be to discuss the needs and best interests of the particular witness. The discussion should include the logistics of setting up a specialist assessment of the witness, with agreement on who will undertake this assessment and the nature of the support necessary from other agencies, professional or voluntary. Issues to be considered will include:

- who is to fund the therapy;
- who will, if necessary, transport the witness to appointments; and
- who will work with the family. Mechanisms for communication between all those involved should be agreed and recorded at this stage.

8.56 The views and wishes of the witness and their carers and those who are emotionally significant to the witness must be taken into account. If not present at the decision-making meeting, there should be a means of ensuring that the informed views of the witness, and those who are emotionally significant, are sought and used as part of the decision-making process. Communication should take account of any special needs of the witness and how to meet these.

8.57 Priority must be given to the best interests of the vulnerable or intimidated witness. The impact of any therapy on the conduct of the criminal case should also be fully discussed and this discussion should include the witness, if not previously consulted on this issue.

8.58 The PPS will advise, if requested, on the likely effect of a particular type of therapy on the evidence of witnesses in individual cases. Where a criminal case is at an advanced stage, it may be possible to consult the judge in chambers as to the potential consequences of a proposed course of action.

8.59 It is important that anyone involved in an assessment, or in subsequent therapy, should be a trained professional person with a recognised competence, such as a social worker, psychiatrist, psychologist, psychotherapist, nurse or other relevant qualified person. On occasions, an assessment may be carried out by a different professional from the one who will undertake the therapy. It is for the agency funding or commissioning assessment and therapy to satisfy itself of the relevant competence of those undertaking either assessment or therapy.

8.60 Assessment for possible therapy may require more than one interview to determine whether, and in what way, the witness is emotionally disturbed and whether this problem can best be helped by the provision of therapy. Not all witnesses who are assessed in this way will need therapy.

8.61 Final recommendations from the assessment will indicate the type of therapy or intervention, if any, required by the particular witness. Decisions should be documented and findings made available to the agencies that need to know, as soon as possible after the assessment is completed.

Important issues regarding an assessment

8.62 A whole range of issues may arise in the course of any assessment but for those undertaking pre-trial assessment of vulnerable or intimidated adult witnesses, who may require therapy, some issues are particularly important to address.

8.63 Assessment of witnesses with special needs requires particular consideration. Special needs include:

- physical or learning disabilities;
- hearing or speech difficulties; and
- the need for an interpreter, where the first language of the witness is not English.

8.64 It is important that an accurate picture of the needs and wishes of the witness is obtained. This is likely to require input from professionals skilled and trained in work with the particular special need. For some witnesses, there may be a need for a particular method of communication, for example sign language. Attention should be given to the patterns of communication and use of language and expression by the witness, so that misunderstanding is avoided.

8.65 For a witness whose first language is not English, it will be important to identify an interpreter who is not only competent in the relevant language and dialect but who is also aware of the vocabulary used in the criminal justice system and the need to ensure that no coaching of the witness takes place.

8.66 There is some evidence that some people who have been intimidated or physically beaten, and some severely emotionally disturbed people, are more likely to produce erroneous or ambiguous responses to leading questions from interviewers, than are less vulnerable people. Particular care therefore should be taken to ensure that any assessment:

- uses short, plain words;
- does not ask convoluted, hypothetical or leading questions;
- uses open-ended questions wherever possible; and
- checks that the witness has understood the questions.

8.67 Some victims or witnesses may be so seriously traumatised that their needs can only be met by a placement within a containing environment, based on therapeutic principles as well as the provision of any necessary specific treatment. If the assessment identified this to be the case and it is considered that a less intense short-term provision of outpatient treatment will not be adequate, or may be unsatisfactory, it may be better, after considering the views of the witness and professionals involved, to delay therapy until after the criminal proceedings have been completed. However, such a witness can be offered general support as well as information and support about the court process. In such cases, prosecutors will wish to do all that they can to expedite the proceedings. It is important to restate again that in all such decision making the welfare of the witness must be the paramount consideration.

Potential problem areas

8.68 Problems may arise during therapy when the therapist attempts to distinguish fantasy from reality in the responses made by the witness. In this kind of situation, the therapist should be as open to the idea that the material presented as factual truth may be a distortion (even though real and meaningful to the witness), as they are to a fantasy being a representation of reality.

8.69 Some of the concerns in this area have been clarified by the report 'Recovered Memories' published by the British Psychological Society (BPS). More recently, recommendations for good practice were published, with the approval of the Royal College of Psychiatrists, in the October 1997 edition of Psychiatric Bulletin under the title "Reported recovered memories of child sexual abuse – Recommendations for good practice and implications for training, continuing professional development and research". See also guidelines issued by the BPS in The Psychologist May 2000 under the title "Guidelines for Psychologists working with clients in contexts in which issues related to recovered memories may arise".

8.70 Interpretative psychotherapy may present evidential problems even if carefully conducted. The professional background and training of the therapist, the provision of adequate supervision arrangements, the appropriateness and robustness of the policies of the agency providing therapy will all help to obviate problems.

8.71 There are therapeutic approaches that would very definitely present problems as far as evidential reliability is concerned. These would include hypnotherapy, psychodrama, regression techniques and unstructured groups.

8.72 As the courts become more familiar with the provision of therapy prior to the criminal trial, and more confident in the standards and knowledge of the agencies providing it, anxieties will become less. Training for professionals providing therapy, and for the judiciary and legal profession will be of value.

Conclusion

8.73 It should be understood that those involved in the prosecution of an alleged offender have no authority to prevent a vulnerable or intimidated adult witness from receiving therapy.

8.74 The police and the PPS must be made aware that therapy is proposed, is being undertaken, or has been undertaken.

8.75 The nature of the therapy should be explained so that consideration can be given to whether or not the provision of such therapy is likely to impact on the criminal case. There should be an agreed mechanism for communicating this information and enabling it to be routed through the police to the PPS, using named contact points assigned to each individual witness. Direct consultation between the professionals involved may be desirable in some circumstances and should be arranged in the same way.

8.76 Records of therapy (which includes videos and tapes as well as notes) and other contacts with the witness must be maintained so that they can be produced if required by the court. They should include, in the case of therapy, details of those persons present, and the content and length of the therapy sessions. It is not expected, for practical reasons, that verbatim written records will be kept.

8.77 At the outset of therapy an understanding should be reached with the witness and, where appropriate, their carers or those who are emotionally significant to the witness, of the circumstances under which material obtained during therapy might be required to be disclosed. Maintaining trust will remain important and it can be confirmed that those aspects of the therapy that have no material relevance to criminal proceedings will not have to be disclosed. However, what is "relevant" may change as the case progresses and so confidentiality cannot be guaranteed.

8.78 In newly arising allegations, therapy should not usually take place before a witness has provided a statement or, if appropriate, before a video recorded interview has taken place. However, in existing cases where therapy is already under way, a decision about how to proceed may be best made after discussion at a multidisciplinary meeting which includes the therapist. Clearly, when therapeutic work is in progress, disruption of therapy should be avoided even if new investigations must be conducted. If it is decided that leading questions or interpretations must be used to help a witness in psychotherapy, then the evidential implications of this should be understood and made clear.

8.79 If the prosecutor advises that the proposed therapy may prejudice the criminal case, this should be taken into account when deciding whether to agree to the therapy. It may still be in the best interests of the witness to proceed with the therapy.

8.80 The therapist should be made aware of any pending criminal proceedings before commencing the therapy and should also be aware of the implications of using techniques which may result in the evidence of the witness being discredited.

8.81 Therapists or counsellors should avoid using leading questions or discussing the evidence, which the individual or any other witness will give, including exploring in detail the substance of specific allegations made.

8.82 Prior to the criminal trial, group therapy where the specific recounting of abuse takes place is best avoided. The particular danger of this kind of group therapy is that the witness may adopt the experiences of others taking part in the therapy. Structured group therapy approaches which help in a neutral way to improve the witness's self esteem are less likely to cause difficulties. As a general principle, group therapy should not be offered to the vulnerable or intimidated witness prior to the trial.

8.83 Witnesses may derive therapeutic benefits from talking about their experiences, but any detailed recounting or re-nactment of the offending behaviour may be perceived as coaching. Therapists should recognise that the criminal case is almost certain to fail as a consequence of this type of therapeutic work. This should be differentiated from the accepted practice of allowing witnesses, prior to giving evidence, to refresh their memory by reading the statement or viewing the video recorded interview.

8.84 Professionals should avoid the use of jargon and take care to use language that will not be perceived, if repeated by a witness, as evidence of the witness being instructed. The language content of the therapy and counselling sessions is guided by the witness but equally it must be recognised that witnesses do use different forms of language in differing situations and contexts.

8.85 During therapy, witnesses should never be encouraged to extend their account of the offending behaviour which they have suffered. However, it is acceptable to offer general reassurance and support to a witness during this difficult process.

8.86 Prosecutors must be informed that the witness has received therapy. Prosecutors must then obtain an assurance that the witness did not, in the therapy session(s), say anything inconsistent with the statements made by the witness to the police. Prosecutors may need to be made aware of the content of the therapy sessions as well as other details specified in the paragraph above, when considering whether or not to prosecute and their duties of disclosure.

8.87 Discussions at local level between the agencies concerned and exploring practical ways to facilitate good practice will be helpful in handling the issues outlined in this guidance. A local protocol setting out the approach to be followed may be helpful.

Glossary

Child witness – For the purposes of special measures directions made under the Criminal Evidence (NI) Order 1999, as amended by the Justice Act (NI) 2011, to assist eligible witnesses to give evidence, a child witness is a witness who is eligible because they are under 18 when the direction is made.

Civil proceedings – A case at civil law can either be one of private law between people and/or organisations when it is typically about defining the rights and relations between individuals (e.g. matrimonial proceedings and disputes about where the child of separated parents should live) or it can be one of public law, where proceedings are brought, for example in order to remove a child from the care of its parents.

Compellability (of a witness) – The general rule is that, if a witness is competent to give evidence, they are also compellable. This means that the court can insist on them giving evidence.

Competence or **competent** (of a witness) – In criminal proceedings, a person who is not competent may not give evidence. Article 31 of the Criminal Evidence (NI) Order 1999 provides that 'all persons are (whatever their age) competent to give evidence'. An exception applies where a person is not able to understand questions put to them as a witness and to give answers which can be understood. If the question of competence is raised, it is for the judge to decide whether a particular witness falls within the exception and the party who wishes to call the witness to give evidence must prove that they do not. A person over 14 years, who is competent but who does not appreciate the significance of an oath, gives evidence unsworn, as do children under the age of 14.

Complainant – According to Article 2(2) of the Criminal Evidence (NI) Order 1999, 'complainant', in relation to any offence or alleged offence, means a person against or in relation to whom the offence was (or is alleged to have been) committed. Therefore, a person may be a complainant even where they did not actually make the initial complaint. The 1999 Order makes special provision for complainants in sexual cases in relation to their status as eligible witnesses and in relation to the prohibition on the defendant from cross-examination in person.

Cross-examination – The procedure in the trial after examination in chief where the legal representative for the side that did not call the witness seeks to establish its own case by questioning the other side's witnesses. The Criminal Evidence (NI) Order 1999 allows eligible witnesses to be cross-examined by means of a live link or (where examination in chief is so conducted) by means of a video recording. The making of such a recording normally precludes any further cross-examination. Articles 22 and 23 of the 1999 Order prevent the defendant from cross-examining in person a witness who is the complainant in a case involving sexual offences or a child witness where the offence is of a violent or sexual nature. Article 24 gives the court power to prevent the defendant from cross-examining a witness in person in any other criminal case where to do so is justified in the circumstances of the case.

Crown Court – The criminal court that tries those charged with offences which are generally too serious for the magistrates' court to deal with. This includes the most serious offences which are triable only on indictment, such as rape. Trial at the Crown Court is by judge and jury.

Defendant – A person who is on trial in criminal proceedings. Under the Criminal Evidence (NI) Order 1999, a defendant is not normally eligible for special measures, even though they would be so eligible if they gave evidence as a witness at the trial of another person.

Eligible (of a witness) – The term used in the Criminal Evidence (NI) Order 1999, as amended, to describe a witness in respect of whom a special measures direction may be made. A witness may be eligible (i) on the grounds of age if under 18 when the direction is made; (ii) on the grounds of incapacity if they have a physical or mental condition specified by Article 4 and the quality of the witness's evidence is likely to be diminished as a result; and (iii) on the grounds that the quality of the witness's evidence is likely to be diminished by reason of fear or distress on their part in connection with testifying in the proceedings. In deciding eligibility, the court must take account of the views expressed by any witness who is said to have an incapacity or to be likely to suffer fear or distress. A witness who is a complainant in relation to a sexual offence is automatically eligible unless they tell the court that they wish not to be. The defendant is not an eligible witness.

Evidence in chief – The evidence that a witness gives in response to examination on behalf of the party who has brought the person forward as a witness. Once evidence in chief has been completed, the witness is normally made available for cross-examination by the other party or parties to the proceedings. Under the Criminal Evidence (NI) Order 1999, it is possible for a video recording to be used as a witness's evidence in chief even where they are not available for cross-examination, provided that the parties to the proceedings have agreed that cross-examination is not necessary or where a special measures direction provides for the witness's evidence on cross-examination to be given other than by means of testimony in court.

Examination in chief – The procedure in the trial where, normally, the legal representative for the side that has called the witness takes that person through their evidence. The Criminal Evidence (NI) Order 1999 allows a video recording of an interview with an eligible witness to be played as the witness's evidence in chief. When such a recording is admitted, the witness is not normally examined in chief by the legal representative at the trial. Depending on the matters raised in cross-examination, the party who called the witness in the first place may choose to conduct a further examination in chief, or re-examination, as it is called. For example, where the prosecution calls a woman to give evidence that she has been raped by two men, she will give evidence in chief on behalf of the prosecution and will be open to cross-examination on behalf of both defendants, with the prosecution having the option to re-examine. Where cross-examination is pre-recorded, re-examination will take place at the same time.

Interests of justice – Those interests which, according to Article 15 of the Criminal Evidence (NI) Order 1999, may preclude a court from making a special measures direction for a video recording to be admitted as a witness's evidence in chief. The 1999 Order does not define 'interests of justice': it is for the court to determine in the light of all the circumstances. The court is unlikely to reject the recording on these grounds unless it considers that to use it would be in some way unfairly prejudicial to the defendant (or, if there is more than one, to any of the defendants). Another example of a case where it might not be in the interests of justice to admit a recording is where the witness has subsequently retracted the statement and it is known that they intend to give evidence that contradicts it. In relation to adult witnesses who are eligible for special measures, the court has a wide discretion as to whether to make a special measures direction in favour of video recording, which is limited only in the circumstances stated above. Where a child witness is involved, the strong preference that the 1999 Order expresses for evidence in chief to be video recorded is still subject to the 'interests of justice' test. If only part of the recording is objected to, the 1999 Order expressly states that the court must weigh any prejudice to a defendant which might result from showing that part of the recording against the desirability of showing the whole, or substantially the whole, of it.

Intermediary – One of the special measures which the Criminal Evidence (NI) Order 1999 (Article 17) allows for certain eligible witnesses is that they may give evidence (both examination in chief and cross-examination) through an intermediary. An intermediary must be approved by the court. They assist by communicating to the witness the questions which are put to them, and to anyone asking such questions, the answer given by the witness in reply to them. The intermediary may explain the questions or answers to the extent necessary to enable them to be understood. An intermediary may also be called on to assist in the making of a video recording with a view to making it the witness's evidence in chief. In such a case, the court will decide whether it was appropriate to use the intermediary when deciding whether to admit the recording in evidence. Only witnesses eligible on grounds of age or incapacity may receive the assistance of an intermediary under the Order, although the court also has inherent powers to call on an intermediary in other cases.

Intimidated witness – 'Intimidated' witnesses are defined by Article 5 of the Criminal Evidence (NI) Order 1999 as those whose quality of testimony is likely to be diminished by reason of fear or distress. In determining whether or not a witness falls into this category, the court will take account of a number of factors, including the nature and circumstances of the offence, the age and circumstances of the witness and the behaviour of the defendant or their family/associates. Intimidated witnesses are sometimes included under the umbrella term 'vulnerable' witness and are sometimes excluded from it, depending on whether a narrow or broad definition of 'vulnerability' is applied.

Legal representative – In this guidance, the term 'legal representative' is used both generally, to cover all legal advisers to any party to the proceedings, and more specifically, to refer to advocates appearing in court on their behalf. A legal representative will normally be a qualified solicitor or barrister.

Live link – One of the special measures that the Criminal Evidence (NI) Order 1999 allows for eligible witnesses is that they may give evidence (both examination in chief and cross-examination) by means of a live link. According to Article 12(6) of the Criminal Evidence (NI) Order 1999, 'live link' means a live television link or other arrangement whereby a witness, while absent from the courtroom or other place where the proceedings are being held, is able to see and hear a person there, and to be seen and heard by the judge, the jury (if there is one), legal representatives acting in the proceedings and any interpreter appointed to assist the witness. The link enables the witness to give evidence from another room, without appearing in open court in the presence of the defendant, the jury and the public. The witness sits in front of a television monitor and can see the faces of those who put questions to them. The witness's demeanour can be observed in court and all proper questions can be put, so that the use of the live link does not detract from the right to cross-examine. The judge is also able to monitor the conduct of any other person who is in the room with the witness in the role of supporter. Child witnesses are normally cross-examined using live link.

Magistrates' court – The criminal court that tries most offences, specifically non-serious cases that are triable summarily only, and offences triable either on indictment or summarily (either-way offences) which are judged to be suitable for summary trial. District Judges try cases alone in the magistrates' court, while a youth court consists of one District Judge and two lay magistrates.

Newton hearing – Where a defendant pleads guilty to a charge, it may still be necessary to hold a hearing to establish the facts that are relevant to sentencing, particularly where there is a conflict between the prosecution and the defence as to what actually occurred. The hearing at which evidence is called to establish a factual basis for sentencing is called a 'Newton' hearing after the case in which the procedure was established.

Pre-trial hearing (or review) – Hearings before a trial in the Crown Court or a contest in the magistrates' or youth court are focused on resolving pre-trial issues and managing the case. In the Crown Court such hearings are called 'pre-trial hearings'; in the magistrates' or youth court they are called 'pre-trial review'. This guidance emphasises the importance of an early pre-trial hearing/review to make decisions in relation to special measures and ensure that the needs of victims and witnesses have been properly considered.

Quality (of an eligible witness's evidence) – According to Article 4(5) of the Criminal Evidence (NI) Order 1999, 'quality' means quality in terms of completeness, coherence and accuracy, and 'coherence' for this purpose refers to a witness's ability when giving evidence to give answers that address the questions put to them and can be understood both individually and collectively.

Special measures – The measures specified in the Criminal Evidence (NI) Order 1999, as amended, which may be ordered in respect of some or all categories of eligible witnesses by means of a special measures direction. The special measures are the use of screens; the giving of evidence by live link; the giving of evidence in private; the removal of wigs and gowns; the showing of video recorded evidence in chief, and aids to communication.

Special measures direction – The order by which the court states which, if any, of the measures specified in the Criminal Evidence (NI) Order 1999 will be used to assist a particular eligible witness. Directions may be discharged or varied during the proceedings but normally continue in effect until the proceedings are concluded, therefore enabling the witness to know what assistance to expect. In deciding which measures to employ, the court is aiming to maximise the quality of the witness's evidence so far as practicable, while still allowing the party challenging the evidence to test it effectively. The witness's own views are also considered.

Trial – Unless the defendant pleads guilty the prosecution must establish their guilt by calling evidence, the truth of which is then assessed (tried). In the Crown Court, the body that decides the disputed issue of guilt or innocence is the jury. In the magistrates' court it is the District Judge.

UNOCINI (Understanding the Needs of Children in Northern Ireland) – The multidisciplinary assessment of need framework for use in Northern Ireland, used primarily by Health and Social Care agencies but suitable for use by other agencies working with children.

Video recording – According to Article 2(2) of the Criminal Evidence (NI) Order 1999, 'video recording' means 'any recording, on any medium, from which a moving image may by any means be produced, and includes the accompanying sound-track'.

Vulnerable witness – The Criminal Evidence (NI) Order 1999, as amended, provides for the making of special measures directions to assist certain vulnerable witnesses in giving evidence. Vulnerability is effectively defined in two ways. In the narrow sense it can be confined to witnesses defined as 'vulnerable' under Article 4 of the 1999 Order because they are under 18 or have a mental disorder, significant impairment of intelligence and social functioning, or a physical disorder/disability; when the term 'vulnerable witness' is used in this way, 'intimidated' witnesses (see above) tend to form a separate category.

Youth court – The youth court deals with most young people aged between 10 and 17 who are prosecuted for criminal offences. However, young people who are accused of homicide are heard in the Crown Court. The youth court can also send young people accused of very serious crimes, such as sexual assault or cases where an adult could be sent to prison for 14 years or more, to the Crown Court if it thinks its own powers are not sufficient. Magistrates who sit in the youth court receive specialised training.

Applying the use of intermediaries pending commencement and implementation of Article 17 of the Criminal Evidence (NI) Order 1999

In an unreported judgment in Northern Ireland involving an adult victim who suffered from Cerebral Palsy and who also had learning difficulties, the prosecution successfully sought leave to adduce the victim's video interviews and her social worker's interpretation of her speech as the victim's evidence in chief and also that the social worker was permitted to act as interpreter during cross-examination.

The defendant was charged with a number of sexual offences which had been committed over a number of years. The victim had been video interviewed and, by reason of her disability, she had been accompanied by her social worker who, by reason of her occupation and experience, was able to interpret for the victim. The prosecution submitted that, in the absence of the social worker's interpretation, the evidence would be unintelligible.

Article 7(2) of the 1999 Order provides "Where the court determines that the witness is eligible for assistance by virtue of Article 4 or 5, the court must then

> (a) determine whether any of the special measures available in relation to the witness (or any combination of them) would, in its opinion, be likely to improve the quality of evidence given by the witness; and etc."

Quality is defined in Article 4(5) as "in terms of completeness, coherence and accuracy; and for this purpose coherence refers to a witness's ability in giving evidence to give answers which address the questions put to the witness and can be understood both individually and collectively".

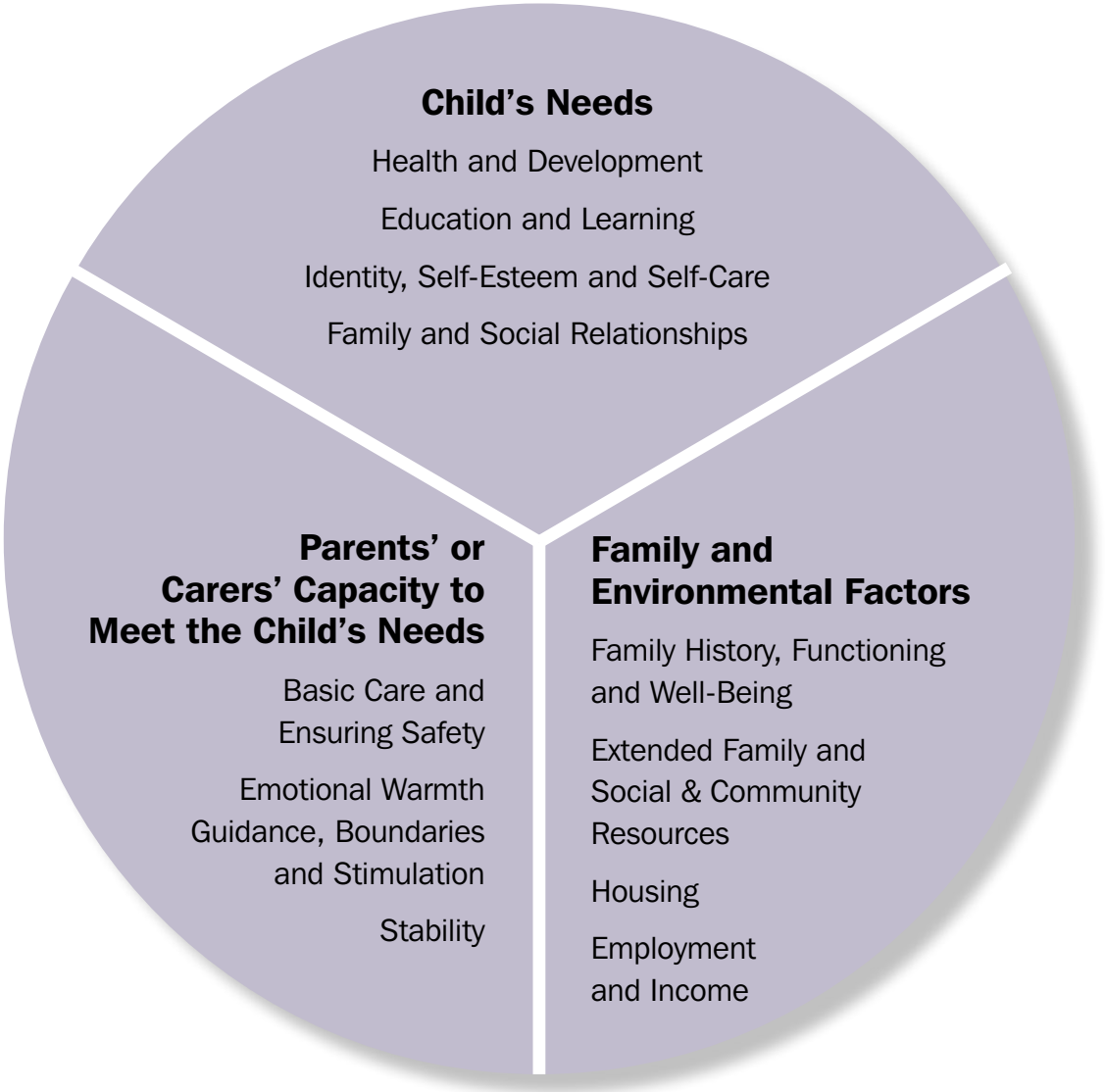
It was submitted by the prosecution that the case in question was directly analogous with R-v-Duffy [1998] Crim LR 650, although, in this case, the victim and the social worker would be available for cross-examination. It was further submitted that permitting the social worker to interpret would not offend the rule in R –v- Mitchell [1970] Crim LR.

The prosecution submitted that the social worker's ability to interpret the victim's speech was based on both her professional competence and her experience of working with the victim, and, as a result, it would not be possible to obtain an interpreter who had not worked with the victim. It was further submitted that it would be in the interests of justice that the social worker's interpretation be adduced in evidence, otherwise it would not be possible for the victim to give any comprehensible evidence.

C

Understanding the Needs of Children in Northern Ireland (UNOCINI)

Assessment Framework



Levels of Need

Level 1: Base Population

Children 0-10 living in Northern Ireland, including children and families who may require occasional advice, support and/or information

Level 2: Children with additional needs

Vulnerable children who may be at risk of social exclusion

Level 3: Children in need

Children with complex needs that may be chronic and enduring

Level 4: Children with complex and/ or acute needs

Children in need of rehabilitation; children with critical and/or high risk needs; children in need of safeguarding (inc LAC); children with complex and enduring needs.

Case Law regarding witness training, coaching and preparation

Relevant extracts from R v Momodou & Limani [2005] EWCA Crim 177; [2005] 2 All ER 571; [2005] 2 Cr App R 6 are set out below. This is an important judgement which is worth studying in full.

45 It was an agreed fact between the prosecution and the defence at trial that, the training offered by Bond Solon was "wholly inappropriate and improper". The judge took a particularly robust view of what had happened and unusually directed that he should there and then be expressly associated with that agreed fact. In the case of one defendant against whom the evidence largely consisted of witnesses who had been so trained, he withdrew the case from the jury. In relation to the present appellants, and other defendants, his directions to the jury were uncompromising. In a broad ranging, stinging, criticism, he ended this part of his directions to the jury:

"There is no place for witness training in our country, we do not do it. It is unlawful."

56 We have however further examined whether the information about witness treatment or training which, with the assistance of the prosecution, became available by the end of the trial, should lead us to doubt the safety of the conviction. Again, no criticism can be directed at the way the judge summed up these issues. To the contrary he was at the greatest pains to give lengthy, unequivocal and robust support to every aspect of the conduct of Group 4 which was rightly criticised before the jury by the prosecution and the defendants. We have no reason to doubt that the jury would have been fully alert to those directions and the judicial concern which led to their expression.

Witness Care

ICAS

57 The ICAS [Independent Counselling and Advisory Service] arrangements were not improperly motivated. As employers, Group 4 provided this facility for members of their staff who wished to have it, or thought they needed it. Two potential dangers were identified. First, discussions between those who had been grouped together during specific parts of the incident might influence individual recollections, and second, there would be no means of checking whether this had happened.

58 We understand the submission, but we are unimpressed with it as a matter of complaint. It was not unreasonable for employers to do everything they could to alleviate the pressures and stresses endured by those members of their staff who were involved in or witnessed this incident. In its immediate aftermath, we can well understand why little, if any, thought was given to the position of potential witnesses who might become involved in any subsequent prosecutions of any detainees. At that time there was no process to be abused. Litigation, civil or criminal, would have been far from the mind of any of these potential witnesses. Many of them had endured a ghastly experience. Provided that no attempt was made to conceal what had happened from the jury (and none was), it was not abused. Each relevant witness for the prosecution was cross-examined about his or her involvement in the ICAS arrangements, and the jury was properly informed of the relevant facts.

McGurk

59 The later cognitive therapy is more troublesome because, by then, the employees who needed such treatment included witnesses in the forthcoming prosecution. The potential conflict between necessary pre-trial treatment for a witness or victim of crime and the possible contamination of that evidence by constant out of- court reiteration or aspects of treatment which consciously or unconsciously involved the prodding of memory is well-recognised. Without treatment, some victims and witnesses may suffer serious continuing psychological ill-health. On the other hand, treatment which involves discussion and analysis of the incident which is the subject of the prosecution may affect the clarity and accuracy of the witnesses' memory. The dilemma is most frequently observed in cases where the victim has endured serious, sometimes prolonged, sexual crimes. Early treatment would help the victim to come to terms with what she (as it usually is) has suffered. The treatment process however does sometimes lead to a reduced possibility of conviction. In some cases therefore the conundrum resolves itself into a decision about priorities. The correspondence encapsulates this dilemma. Where, as here,

the court was not involved in the decision about priorities, the critical requirement is that the court should be properly informed of any witness who has received pre-trial treatment of any kind. That enables its possible impact on the evidence to be investigated at trial, as appropriate. The trial then proceeds on the basis of the known facts, which can be properly assessed.

60 In the present case, by the time the jury retired, it was fully informed of precisely which prosecution witnesses had attended for the McGurk cognitive therapy, and when it happened, and the identity of others who received treatment at the same time. With the judge's directions, and in the context of very modest levels of therapy which actually took place, and the very limited possibility of cross-contamination of evidence which related to the participation of either appellant in the violent disorder, a proper evaluation of their evidence could be made.

Witness training (coaching)

Bond Solon

61 There is a dramatic distinction between witness training or coaching, and witness familiarisation. Training or coaching for witnesses in criminal proceedings (whether for prosecution or defence) is not permitted. This is the logical consequence of well-known principle that discussions between witnesses should not take place, and that the statements and proofs of one witness should not be disclosed to any other witness. (See Richardson [1971] CAR 244; Arif, unreported, 22nd June 1993; Skinner [1994] 99 CAR 212; and Shaw [2002] EWCA Crim 3004.) The witness should give his or her own evidence, so far as practicable uninfluenced by what anyone else has said, whether in formal discussions or informal conversations. The rule reduces, indeed hopefully avoids any possibility, that one witness may tailor his evidence in the light of what anyone else said, and equally, avoids any unfounded perception that he may have done so. These risks are inherent in witness training. Even if the training takes place one-to-one with someone completely remote from the facts of the case itself, the witness may come, even unconsciously, to appreciate which aspects of his evidence are perhaps not quite consistent with what others are saying, or indeed not quite what is required of him. An honest witness may alter the emphasis of his evidence to accommodate what he thinks may be a different, more accurate, or simply better remembered perception of events. A dishonest witness will very rapidly calculate how his testimony may be "improved". These dangers are present in one-to-one witness training. Where however the witness is jointly trained with other witnesses to the same events, the dangers dramatically increase. Recollections change. Memories are contaminated. Witnesses may bring their respective accounts into what they believe to be better alignment with others. They may be encouraged to do so, consciously

or unconsciously. They may collude deliberately. They may be inadvertently contaminated. Whether deliberately or inadvertently, the evidence may no longer be their own. Although none of this is inevitable, the risk that training or coaching may adversely affect the accuracy of the evidence of the individual witness is constant. So we repeat, witness training for criminal trials is prohibited.

62 This principle does not preclude pre-trial arrangements to familiarise witness with the layout of the court, the likely sequence of events when the witness is giving evidence, and a balanced appraisal of the different responsibilities of the various participants. Indeed such arrangements, usually in the form of a pre-trial visit to the court, are generally to be welcomed. Witnesses should not be disadvantaged by ignorance of the process, nor when they come to give evidence, taken by surprise at the way it works. None of this however involves discussions about proposed or intended evidence. Sensible preparation for the experience of giving evidence, which assists the witness to give of his or her best at the forthcoming trial is permissible. Such experience can also be provided by out of court familiarisation techniques. The process may improve the manner in which the witness gives evidence by, for example, reducing the nervous tension arising from inexperience of the process. Nevertheless the evidence remains the witness's own uncontaminated evidence. Equally, the principle does not prohibit training of expert and similar witnesses in, for example, the technique of giving comprehensive evidence of a specialist kind to a jury, both during evidence-in-chief and in cross-examination, and, another example, developing the ability to resist the inevitable pressure of going further in evidence than matters covered by the witnesses' specific expertise. The critical feature of training of this kind is that it should not be arranged in the context of nor related to any forthcoming trial, and it can therefore have no impact whatever on it.

63 In the context of an anticipated criminal trial, if arrangements are made for witness familiarisation by outside agencies, not, for example, that routinely performed by or through the Witness Service, the following broad guidance should be followed. In relation to prosecution witnesses, the Crown Prosecution Service should be informed in advance of any proposal for familiarisation. If appropriate after obtaining police input, the Crown Prosecution Service should be invited to comment in advance on the proposals. If relevant information comes to the police, the police should inform the Crown Prosecution Service. The proposals for the intended familiarisation programme should be reduced into writing, rather than left to informal conversations. If, having examined them, the Crown Prosecution Service suggests that the programme may be breaching the permitted limits, it should be amended. If the defence engages in the process, it would in our judgment be extremely wise for counsel's advice to be sought, again in advance, and again with written information about the nature and extent of the training. In any event, it is in our judgment a

matter of professional duty on counsel and solicitors to ensure that the trial judge is informed of any familiarisation process organised by the defence using outside agencies, and it will follow that the Crown Prosecution Service will be made aware of what has happened.

64 This familiarisation process should normally be supervised or conducted by a solicitor or barrister, or someone who is responsible to a solicitor or barrister with experience of the criminal justice process, and preferably by an organisation accredited for the purpose by the Bar Council and Law Society. None of those involved should have any personal knowledge of the matters in issue. Records should be maintained of all those present and the identity of those responsible for the familiarisation process, whenever it takes place. The programme should be retained, together with all the written material (or appropriate copies) used during the familiarisation sessions. None of the material should bear any similarity whatever to the issues in the criminal proceedings to be attended by the witnesses, and nothing in it should play on or trigger the witness's recollection of events. As already indicated, the document quoted in paragraph 41, if used, would have been utterly flawed. If discussion of the instant criminal proceedings begins, as it almost inevitably will, it must be stopped. And advice given about precisely why it is impermissible, with a warning against the danger of evidence contamination and the risk that the course of justice may be perverted. Note should be made if and when any such warning is given.

65 All documents used in the process should be retained, and if relevant to prosecution witnesses, handed to the Crown Prosecution Service as a matter of course, and in relation to defence witnesses, produced to the court. None should be destroyed. It should be a matter of professional obligation for barristers and solicitors involved in these processes, or indeed the trial itself, to see that this guidance is followed.

66 On the facts apparently established, alternatively on the factual assumptions made at trial, so far as these appellants were concerned this guidance was not complied with in relation to two witnesses, Wakefield and Burns. As already indicated, their names were among those provided to the defence as having attended for training.

67 We have closely examined the relevant material. We have already noted the facts agreed by the Crown at trial and the judge's directions. The fact of and the arrangements for the training programme organised by Group 4 with Bond Solon reflected adversely not on the defence but on the Crown. Legitimate and powerful forensic criticism of the facts was made by the defence: the Crown conceded its justification: the judge unequivocally endorsed it. In Wakefield's case, his contemporaneous notes of the incident were made on the following day. If his evidence drifted away from those notes, there was ample scope for cross-

examination. In Burns' case, her evidence was not wholly critical of Limani. In any event, the way in which the "training" issue was left to the jury meant that it was damaging to the creditworthiness of every witnesses who received it. In the result, looking at the evidence overall, the arrangements for training for Burns and Wakefield do not undermine the safety of the conviction.

Technical Guidance

Preliminaries

E1 The following guidance sets out the basic recommendations about the equipment that should be used to achieve a standard of recording that is adequate for use in court and is likely to meet the requirements of court rules. The general specifications for equipment purchased before September 2010 can be found in *Visual Recording of Evidence within the Criminal Justice System – Equipment Specification Private Standard* (2004). The specifications for new equipment purchased after September 2010 fall within the scope of the Information Systems Improvement Strategy (ISIS). A list of approved suppliers of this equipment is available from ISIS at ISIS@npia.pnn.police.uk. Basic hand-held equipment should not be used and more reliable tripod-mounted portable equipment should only be used in exceptional circumstances, for example when the witness has severely limited mobility and is in hospital or residential care. Preference should always be given to the use of a fixed interview suite over the use of portable equipment. It should also be noted that, if the use of portable recording equipment is decided on, then the rationale for such deployment must be clearly recorded by the investigating officer. When this equipment has to be used, follow the guidance in paragraphs E17 to 20.

E2 For the purposes of this guidance, video recorded interviews may be carried out using either analogue (VHS tape) or digital (currently DVD disk; however, this may change with the development of digital technology) recording equipment. This is permissible by virtue of the meaning ascribed to 'video recording' in Article 2 of the Criminal Evidence (NI) Order 1999. The use of two cameras is recommended: one pan, tilt, zoom (PTZ) camera to record the picture of the witness, and one wide-angle lens camera to capture the view of the whole room.

E3 Whatever equipment is chosen, it must only be operated by properly trained staff (equipment operators). The equipment operator has the overall responsibility for the quality of the captured image, and for the smooth and effective running of the recording equipment. The recording equipment should be properly maintained and regularly tested. Such testing should involve making a short recording using sound and vision, and replaying the recording on another machine to confirm that the quality is adequate. Testing should be the responsibility of a local technician or other suitably trained person, and should be governed by local procedures.

E4 Interviews should not normally be conducted in an operational police station, but in a specifically equipped interview room. However, where it is impractical to locate the interview room in a building other than a police station, consideration should be given to having a separate entrance for witnesses attending the interview suite. If this is not possible, then care should be taken to avoid operational areas such as custody suites and suspect interview rooms, and the interviewing officer should arrange to meet the witness so that they can be escorted straight to the interview suite without any undue delay, or any need to explain themselves to station reception officers or other police staff. The room should be selected to ensure a reasonably quiet location away from traffic or other sources of noise such as offices, toilets and banging doors. It should have a carpeted floor and curtains on the windows. Ideally, the room should be rectangular (not square) and no larger than necessary (less than 5m by 4m). When furnishing the room for the interview, consideration should be given to simplicity in order to avoid a cluttered image on the screen. The furniture should be set out in advance in relation to camera angles and the light source, and to obtain the best view possible.

E5 It is very important that the furniture, cushions and, in the case of children, any toys or props do not provide a source of noise or distraction. Furniture filled with polystyrene chips (such as beanbags) should not be used and care should be taken to avoid intrusive noise from other sources, such as rustling papers.

Equipment operator

E6 The equipment operator must remain in control of the recording equipment at all times during the interview process until the final recorded media (DVD or VHS) is ejected. It is their responsibility to ensure that the quality of the recorded media is acceptable. Guidance for this can be found in paragraphs E7 to 16. The equipment operator's role may also include the completion of evidential statements as to the reliability and function of the equipment, and the preparation of any 'Index to video recorded interview'. The equipment operator's role should, therefore, be independent from that of the interviewer.

Vision

E7 For the purposes of this guidance, video recorded interviews may be carried out using one or two cameras. However, while the use of a single fixed camera need not produce a recording of inferior quality, it will provide less assurance to the courts as to who was present in the room throughout the interview. This requirement can most easily be satisfied by the use of two cameras: one PTZ camera that is focused on the witness, and one wide-angle lens camera giving a general view of the room. If only one camera is to be used, the requirement of the rules may need to be satisfied by evidence from those who were present at the interview. A single-camera system is unlikely to be suitable for very young witnesses who are more likely to move around the room.

E8 If a two-camera system is adopted, each camera should record to independent tapes, disks, or video streams: this option has the advantage of producing an unobscured recording of the witness. Alternatively, a vision-mixing unit can be used to allow the image from the camera that is recording the whole room to be inset within a corner of the screen that is relaying the image from the camera focused on the witness (picture-in-picture (PIP)). When operating with a PIP system, mounting the cameras close together may avoid a disorientating effect when the images are displayed on the screen. The exact placement of the cameras can best be determined by factors such as the location of doors and windows.

E9 As far as it is technically feasible, the first camera (PTZ) should aim to show the witness's head, face and upper body clearly. If this camera is fixed, care should be taken to ensure that is not set too high or so low that the view of the witness is obstructed. A good, clear picture of the witness's face may help the court to determine what is being said and to assess the emotional state of the witness. Every reasonable effort should be made to ensure the definition and quality of the image of the witness's face throughout the interview. The second camera (wide-angle lens) should provide as full a picture as possible of the whole room. The court may need to be reassured that any part of the interview room that was not recorded by this camera was unoccupied: the placing of fixed furniture in any blind spot could provide that reassurance and should prevent the witness from straying into the 'blind' area.

E10 Some younger child witnesses may want to wander around the room. By careful placement of the furniture in a small room, it may be found that the child can be encouraged to settle in one spot and not move far from it during the interview. However, some children might find it more difficult to remain in one place. This problem might be overcome by the first camera having PTZ facilities, although using these features requires considerable skill. Although the equipment operator has no editorial function with regard to what the witness is saying or doing, care should

be taken to ensure, for instance, that particular parts of the witness's statement are not highlighted by the use of close-up. Close-ups using the first camera (PTZ), however, can be useful if the child is drawing a plan or picture, or is demonstrating with dolls or other props where the information being conveyed would otherwise be obscured. The second camera should maintain the overall view of the room.

E11 A different two-camera system to that described above has been found useful in clinical applications dealing with young and psychologically disturbed children. This system comprises two colour cameras mounted on the wall diagonally opposite each other, at eye level. The effective use of such a system is likely to require specialised, skilled resources; and, for criminal proceedings, particular care will be needed to ensure that any decisions about the editing or selection of the camera images are fully consistent with evidential objectives, and do not distort or detract from the testimony in any way.

E12 Modern video equipment does not normally require special additional lighting. Natural daylight may be perfectly adequate, particularly if enhanced by pale-coloured walls and a white ceiling. However, shafts of light, or sudden changes in natural light, can present problems for the automatic iris of the camera and should be avoided if possible. If natural daylight proves insufficient or unsuitable, normal fluorescent light can be used effectively. Ideally, the main sources of light should be either side of the camera. A mixture of natural, tungsten and fluorescent light should be avoided. This can cause unnatural effects when colour equipment is used.

Acoustics

E13 The evidential value of the video recorded interview will depend very much on the court being able to discern clearly what was said, both by the interviewer and the witness. Provided that a room of the dimensions and furnishings recommended above (see paragraphs E4 and 5) has been selected, acoustics should not present a problem. However, the selection and placing of microphones will require very careful attention if a satisfactory recording is to be made.

E14 The video recorder should preferably be capable of two-track sound recording. Ideally there should be manual recording-level controls for each sound channel so that these can be set at an appropriate level for the facilities and there should be a sound-level meter.

E15 Microphones of the type normally used for recording interviews with suspects (i.e. boundary layer microphones) will also be suitable for the purpose of this guidance, provided that the system is correctly installed. Preferably, a minimum of two microphones should be used, with the aim of locating one close to the conversation (within two metres) to provide the main sound recording. The use of ceiling-mounted microphones is inappropriate and must be avoided. A small pre-amplifier should be used with each microphone to bring the signals up to normal audio line input levels.

E16 Care is also needed in the placing of remote microphones if they are not to obtrude, distract or otherwise impede the witness's communication. Witnesses may find them inhibiting and some children may be drawn to them as playthings. A further problem is that some witnesses (e.g. children) might move around the room and away from the intended location for which the equipment has been installed. A recommended solution is to mount further microphones unobtrusively on the wall to provide better recording. The use of multiple microphones will also ensure that some sound is recorded if one microphone should fail.

Portable equipment

E17 In the event that exceptional circumstances dictate that the recording is made with a portable system, a good-quality recording may still be possible if sufficient care is taken. VHS and digital portable units with hi-fi sound are available, and 8mm VHS recorders have digital sound recording that allows for high-quality sound reproduction.

E18 Some portable cameras will have built-in microphones and normally these will have to be used, although separate microphones should be used if they are available. The composition of the visual image that is recorded might not be ideal where the built-in microphone is used because the camera will probably need to be located near the witness to get a clear sound recording. In these circumstances, some compromise on picture content may be necessary to meet the paramount aim of obtaining a clear recording of the witness's speech. This problem can be eliminated with the use of separate microphones on long leads so that the camera(s) can be placed in an optimum recording position.

E19 Where the recording is made in locations other than the interview room, there may be particular problems with poor lighting or extraneous sounds which should be resolved, if possible.

E20 Portable equipment may be less reliable than fixed systems due to damage in transit, careless handling or storage in poor conditions (e.g. exposure to heat and humidity). Where the equipment is brought in from the cold into a warm environment, condensation will form. The equipment should therefore be allowed time to warm up before it is used. Another cause of difficulty can be lack of familiarity with the controls. Again, only a properly trained equipment operator should operate this equipment. Batteries should not be relied on, but care must be taken with trailing cables to ensure that they do not present a hazard.

Recorders and tapes

E21 The format of the equipment should be such as to produce recordings of suitable quality which can be played in court.

E22 Use of a generator to insert the time and date into the picture should avoid the need to demonstrate to the court for each video recording both when the recording was made and the continuity of the interview. Such devices are therefore strongly recommended. Nevertheless, oral statements of the time and date should still be made at the beginning and at the close of the interview to confirm that the device is accurate.

E23 The equipment should ideally be capable of making two simultaneous recordings during the interview: the master copy, that should be sealed after the interview, and the working copy. The master copy should be played only once to check its quality before its submission for criminal proceedings. If two recordings are not made during the interview, all copies required must be made in a secure and verifiable way, with a statement of where and by whom the copy was made and confirming that no further copies were made.

E24 Where two recorders are used, the video and audio should not be looped through one recorder to the other in case of failure of one of the recorders.

E25 Only good quality video tapes and digital disks from a reputable manufacturer, which are consistent with the specifications issued by the supplier of the recording equipment, should be used. No more than one interview should be recorded on a new, unused, sealed tape/disk. Ideally, the working copy should also be recorded on a blank tape/disk.

Conducting a video recorded interview - the legal constraints

F1 Introduction

F1.1 A video recorded interview may replace the first stage of a vulnerable or intimidated witness's evidence in court in a criminal case. The video recording will count as evidence of any fact stated by the witness which could have been given in evidence in court. This means that, in principle, the rules that govern procedure in court may be applied to the video recorded interview.

F1.2 There are rules that can render certain matters inadmissible irrespective of their truth, so that they cannot form part of the case. A criminal court has no power to depart from such rules. However, there are also conventions of the court which the court may relax where the need arises. The most obvious example of such a convention is the avoidance of leading questions.

F1.3 The court will not expect video recorded interviews exactly to mimic examination of a witness by counsel in court. But rules of evidence have been created in order to ensure a fair trial for the defendant, and they cannot be ignored. Where the recording that is being made is likely to form part of the prosecution's case, early consultation with the Public Prosecution Service (PPS) should assist in identifying potential areas of difficulty. If the recording may be tendered in evidence for the defence, the defendant's legal representative should be consulted.

F1.4 It is good practice to conduct an interview as far as possible in accordance with the rules that would apply in court. Interviewers who ignore these rules are likely to produce video recordings that are unacceptable to a criminal court. They will therefore fail to spare the witness from having to give the first stage of their evidence in person. As the provisions for video recording cross-examination and re-examination under the Criminal Evidence (NI) Order 1999 will apply only to cases in which a video recording has been given in evidence as the witness's evidence in chief, the rejection by the court of a video recording as evidence in chief means that these further provisions will also be unavailable at trial.

F1.5 This appendix explains the rationale behind those rules most likely to affect a video recorded interview – leading questions, previous statements showing consistency or truth, and statements about the bad character of the defendant. As with most rules, there are circumstances in which they need not be applied. This is easier to determine when a child is being questioned in court and the legal representatives can agree at the time with the judge what is acceptable. The interviewer has no such opportunity and should therefore err on the side of caution but, as this appendix goes on to describe, there are circumstances when the rules can properly be disregarded.

F2 Leading questions

F2.1 It is not generally permissible to put leading questions to a witness. A leading question is one which either suggests the required answer, or which is based on an assumption of facts that have yet to be proved. Therefore, 'Daddy hurt you, didn't he?' is an example of the first type of leading question, and 'When did you first tell anyone about what Daddy did?', put to a child who has not yet alleged that Daddy did anything, is an example of the second type.

F2.2 Where a leading question is improperly put to a witness in court, the answer is not inadmissible but may be accorded little or no weight because of the manner in which it was obtained. When witnesses testify live in court, a leading question can be objected to before a witness replies. The party objecting to such a question in a video recorded interview has no such opportunity and so may ask for part of the video recording to be edited out.

F2.3 However, there are circumstances where leading questions are permissible:

- A witness is often led into their testimony by being asked to confirm their name and address or some other introductory matter, because these matters are unlikely to be in dispute. More central issues may also be the subject of leading questions if there is no dispute about them. For example, where it is common ground that a person, X, has been killed at a particular time, it is not inappropriate to ask a witness 'What were you doing when X was killed?' However, at the interview phase it may not be known what facts will be in dispute at the trial, and so it will be safer to assume that most matters are still in dispute.
- The courts also accept that in certain cases other than the above it is impractical to ban leading questions. This may be because the subject matter of the question is such that it cannot be put to the witness without leading, as for example when the witness is to be asked to identify the person who

hurt them. Or it may be because the witness does not understand what they are expected to tell the court without some prompting, as in the case of a very young child or a person with a learning difficulty.

F2.4 An interviewer who follows the provisions in the guidance as to the conduct of an interview will avoid leading questions. As the courts become more aware of the difficulties of obtaining evidence in an interview with a vulnerable or intimidated witness, particularly from witnesses who are very young or who have a learning difficulty, and of counteracting the pressure on some witnesses to keep silent, a sympathetic attitude may develop towards necessary leading questions. A leading question that succeeds in prompting a witness into providing information spontaneously beyond that led by the question will normally be acceptable. However, unless there is absolutely no alternative, the interviewer should never be the first to suggest to a witness that a particular offence was committed or that a particular person was responsible. Once this step has been taken, it will be extremely difficult to counter the argument that the interviewer put the idea into a suggestible witness's head and that the witness's account is therefore false.

F2.5 If leading questions are judged by the court to have been improperly used during the interview, it may well be decided not to show the whole or that part of the recording to the court, so that the witness's answers will be lost. Alternatively, the whole interview may be played, leaving the judge to comment to the jury, where appropriate, on the weight to be given to that part of the evidence that was led. Neither outcome is desirable, and both can be avoided if interviewers avoid leading questions.

F3 Previous statements

F3.1 A witness in court is likely to be prevented by the court from giving evidence of what they have previously said or what was said to them by another person. If allowed in evidence, previous statements might have two functions. First, in the case of the witness's own statement, the court might be asked to take account of the fact that the witness has consistently said the same thing in deciding whether they are to be trusted. Secondly, in the case both of the witness's own statements and of statements made to them by others, the court might be asked to take the further step of deciding that what was said out of court was true. In a criminal trial, both functions are frowned on: the first because, in law, it says little for the reliability of a witness to show that they have been consistent; and the second because courts are reluctant to accept statements as true unless made in court and subject to the test of cross-examination.

F3.1 Previous statements showing consistency

F3.1.1 Although consistency adds little to the credibility of the witness, it will always be proper for the interviewer to ask the witness if they have told anyone about the alleged incident(s), who they told, when they told them and why. But the interviewer must not ask the witness details of what was said except in certain circumstances. These circumstances are as follows:

- when a witness has voluntarily given details of an alleged sexual offence soon after that offence took place; and
- when a witness has previously made a positive identification of the defendant. Identification may be formal (in the course of an identification parade) or informal, for example where a child points out the defendant to a teacher and says 'This man tried to push me into his car'. Where such a prior identification has been made, it may be referred to in the video recorded interview.

F3.1.2 A case that may give rise to difficulty is where there is some doubt as to the fairness of admitting the identification. If, for example, a child tells her father that she has just been sexually assaulted by a man in a leather jacket, and the father apprehends the first leather-clad man he sees and demands 'Is this him?', a court might be understandably reluctant to admit the child's positive answer as a positive identification, and therefore it should not be mentioned in the video recorded interview. The interviewer must be aware of the circumstances of any identification made by the child before the interview.

F3.2 Previous statements showing truth

F3.2.1 The technical name for an out-of-court statement that is used in court to prove that what was said is true is 'hearsay'. The admissibility of hearsay is now governed by the Criminal Justice (Evidence) (NI) Order 2004. Article 18 of the 2004 Order provides that hearsay statements are generally inadmissible, unless:

- it can be brought under a statutory provision;
- it is admissible under common law – which is set out in Article 22;
- the parties agree; or
- the interests of justice require it to be admitted.

F3.2.2 The statutory grounds of admissible hearsay statements in Article 21 cover business or professional documents, where it is a specific previous statement of a witness or where the witness is unavailable.

F3.2.3 Words (and conduct – e.g. nodding in agreement) are only hearsay if used to prove their truth. There may be other reasons for proving that words were spoken, in which case the hearsay rule is not broken. For example, a witness's report of a child's statement 'Dad taught me to fuck' would be admissible to demonstrate a child's use of age-inappropriate language but inadmissible as evidence that the child's father had had intercourse with her.

F3.2.4 The use of a video recording of an interview with a witness as part of the witness's evidence is itself an example of a statutory exception to the rule against admitting hearsay evidence. Without a detailed appreciation of the scope of the provisions, it will be difficult for an interviewer to gauge the chances of a hearsay statement being regarded as admissible in court, and it is best to aim to avoid the inclusion of previous statements in the interview so far as possible. There are a couple of rules of thumb which should assist:

- With the exception of inconsistent statements, or statements of identification or complaint that are respectively referred to in Articles 23 and 24 of the Criminal Justice (Evidence) (NI) Order 2004, most statements made by the witness about the alleged offence prior to the interview are likely to be hearsay and should not be deliberately elicited from the witness during a video recorded interview. If the witness spontaneously begins an account of what has been said to them, the interviewer may decide that it is best not to interrupt. If so, it should be remembered that this section of the recording is likely to be edited so it will be necessary to go over any relevant non-hearsay information gleaned at this point at a later stage of the interview.
- The video recording should capture the witness's responses directly, as the interviewer's description of the witness's response is itself hearsay. For example, if a child is asked where she was touched by an abuser and in response she points to her genitals, that action should be captured by the camera. It will not be enough for the interviewer to say 'She is pointing to her genitals', as this is a statement of the interviewer, not the child. Once this is understood, it should be relatively easy to ensure that the relevant evidence comes from the witness.

F4 Character of the defendant

F4.1 An important rule of evidence concerns the previous bad character of the defendant. The Criminal Justice (Evidence) (NI) Order 2004 significantly expanded the circumstances in which the bad character of the defendant may be admissible at trial. 'Bad character' is defined as evidence of or of a disposition towards misconduct. 'Misconduct' means the commission of an offence or 'other reprehensible conduct' and includes previous convictions, previous charges and other trials pending and may include evidence of bullying or racism.

F4.2 A basic understanding of the expanded circumstances should assist interviewers in deciding what evidence may be admissible at trial. Article 6 of the 2004 Order sets out the circumstances in which bad character evidence that is relevant to the issues in the case may be admissible. There are seven 'gateways' to admissibility. These include evidence that is 'important explanatory' evidence (e.g. evidence about motive) and evidence relevant to an important matter in issue (for Article 6 purposes, whether the defendant have a propensity to commit offences of the type with which they are charged or to be untruthful).

F4.3 Despite the change in the law, the interviewer should be cautious when witnesses mention such discreditable facts. It is important to remember that the admission of evidence of bad character in these circumstances is very much a matter for the court and should not be taken for granted at the time of the interview. The court will not, in particular, admit bad character evidence relevant to an important matter in issue if it thinks it would have an adverse effect on the fairness of the proceedings.

F4.4 In many cases, the line between admissibility and inadmissibility is a difficult one to draw. Complex legal considerations are involved. All that can be done before the trial when making a video recording that may be put in evidence by the prosecution is to estimate the chances that the court will be prepared, say, to hear that a schoolteacher has been accused of buggery by four of his pupils, or a father of incest by two daughters. This presents no difficulty for the interviewer if the evidence of one witness is quite separate from that of another. However, it may be that the victim of one offence claims to have witnessed the occurrence of another offence against a different victim. In such cases it might be advisable, following consultation with the PPS, to record separately the witness's account of (i) offences allegedly committed against them; and (ii) what they know about offences involving other victims.

F5 The court's discretion to exclude evidence

F5.1 A court trying a criminal case has a general power to exclude evidence tendered on behalf of the prosecution, even if the evidence complies with the strict rules of admissibility. Under Article 76 of the Police and Criminal Evidence (NI) Order 1989, the court may exclude evidence on the grounds that, because of the way in which it was obtained or for any other reason, the admission of the evidence would have such an adverse effect on the fairness of the proceedings that the court ought not to admit it. Courts may also exercise a common law power (i.e. one supported by previous decisions of the courts) to exclude evidence, the prejudicial effect of which outweighs its probative value. The definition of these powers is deliberately broad in order to preserve their flexibility.

F5.2 Specifically in relation to out-of-court statements (hearsay), Article 30 of the Criminal Justice (Evidence) (NI) Order 2004 provides the courts with a discretion to exclude 'superfluous' statements if they are satisfied that the value of the evidence is substantially outweighed by the undue waste of time that its admission would cause. Where the prosecution wishes to adduce evidence of the defendant's bad character either under the gateways relating to an important matter in issue or when the defendant attacks another's character, and the defendant applies to exclude it, the court must exclude that evidence if it would have an unfair effect on the proceedings.

F5.3 It is unlikely that the powers described above will be invoked with regard to video recorded evidence, as the court has the duty, under Article 15(2) of the Criminal Evidence (NI) Order 1999, to exclude a recording that in the interests of justice ought not to be admitted. This duty applies equally to video recordings tendered in evidence by the prosecution and those tendered by the defence. It also empowers a court to exclude part of a recording only. The court is likely to refer to Article 15(2) first when ruling on whether a video recording should be received in evidence, and it is unlikely that a recording that the court decided to admit under Article 15(2) would be found to be objectionable by applying either the common law power or the power in Article 76 of the Police and Criminal Evidence (NI) Order 1989 described above. A court might, however, invoke its discretion under Article 76 or common law to exclude other evidence, for example the evidence of what occurred when a witness attended an identification parade that was adjudged to have been unfair.

Guidance on the completion of an Index to Video Recorded Interview (IVRI)

G1 Introduction

G1.1 The purpose of this guidance is to identify the functions served by the compilation of an Index to Video Recorded Interview (IVRI) with a vulnerable or intimidated witness, and to assist those completing IVRIs to include all the relevant points and details.

G1.2 An IVRI is distinct from a ROTI, which is a Record of Taped Interview with a suspect. It is not:

- a statement;
- a transcript;
- a replacement for the video; or
- an exhibit.

G1.3 An IVRI should not be confused with any notes that might be taken by an interview monitor during an interview for the purpose of determining any immediate investigative action that might be necessary.

G1.4 The functions served by an IVRI are such that one should be compiled in every case where a vulnerable or intimidated witness is interviewed on video, irrespective of whether or not a transcript is subsequently created.

G2 Functions of an IVRI

G2.1 The overall function of an IVRI is to contribute towards the effective investigation and management of a case, by guiding investigating officers and prosecutors through their viewing of the interview.

G2.2 During the pre-charge investigation, an IVRI should assist informed decision-making as to:

- whether the witness should be re-interviewed;
- what further enquiries should be conducted;
- planning interviews with alleged offender(s); and
- pre-charge advice/charging decisions.

G2.3 Following a decision to charge, an IVRI should assist:

- prosecutors to make decisions about editing;
- prosecutors to prepare for a pre-trial interview with the witness;
- prosecutors at bail applications and guilty pleas;
- transcribers at the PPS Video Transcription Unit (VTU); and
- prosecuting and defence advocates in the preparation of their case.

G3 Content of a IVRI

G3.1 General content

G3.1.1 IVRIs must always be recorded on the appropriate form, typed where possible, and should meet the following specifications:

- all fields at the top of the form should be completed or deleted as appropriate (e.g. the exhibit box should be deleted or marked 'not applicable');
- all time entries should be recorded in hours, minutes and seconds using the clock shown on the video; and
- speakers should be identified against the relevant time entry and text.

G3.2 Descriptive content

G3.2.1 Although each interview is unique, as a general rule an IVRI should be as succinct as possible. Most of what is reported should be in indirect speech, but direct speech should be used where local, idiosyncratic or potentially ambiguous language is reported.

G3.2.2 The finished IVRI should, as far as possible, give a chronological account of the conduct of the interview and include the following:

- rapport (engage and explain), including ground rules and, where appropriate, truth and lies. Simply identifying that a rapport phase took place will usually be all that is required in an IVRI. However, there may be occasions when further information needs to be included, for example where the witness's appreciation of distance, colour, number and times are relevant;

- identification issues, such as detailed descriptions or identifying features of suspects. This should include the identification points raised in the R v Turnbull and Camelo (1976) case;
- details of the location of the event witnessed;
- points to prove the offences;
- details of the time, frequency, dates, locations and those present when the offence(s) occurred;
- the extent of any injuries;
- any threats and admissions made;
- key statements made by the witness, the suspect or other witnesses;
- anything that negates a potential defence (e.g. consent);
- any aggravating factors (including racial, homophobic, gender, etc.);
- any corroborative evidence identified (witnesses, CCTV, forensic, etc.); and
- any issue that undermines the prosecution case or supports the defence case.

G3.2.3 Where a Victim Impact Statement has been made on the same tape/disk, reference to that fact should be made on the IVRI, and a short summary included.

G3.2.4 Background material of no apparent relevance should be summarised in general terms as far as possible.

G4 Distribution of an IVRI

G4.1 Copies of the IVRI should be provided to all parties in the proceedings, including prosecution and defence counsel, and the judge.

Storage, custody and destruction of video recordings

H1 Introduction

H1.1 A video recording made in accordance with this guidance can be a highly valuable piece of evidence in any investigation. It is also a record of intimate and highly personal information and images, which, in the interest of the witness, should be held strictly in confidence and for its proper purpose. It is therefore essential that adequate arrangements are made to store the recording safely and securely in a steel cabinet, and that access to it or to any official copies is restricted to those authorised to view the recording.

H2 Ownership

H2.1 The video recording will be treated as a document for the purposes of criminal proceedings, and the statements in it will not belong to anybody except that in so far as they are the property of the person who made them. However, the medium on which they are made is likely to be the property of the police or social services and the fact of ownership of the recording itself conveys certain rights and responsibilities which, if properly exercised, will help to ensure that it is appropriately safeguarded.

H2.2 It is essential that all recordings (analogue tape or digital disk), whether master or working copies, containing interviews prepared under joint police/social services or NSPCC investigative arrangements, and conducted under this guidance, should be kept under optimal conditions. Decisions regarding access to any recording should be taken by the principal agency or agencies involved in their preparation. Once the case has passed to the Public Prosecution Service (PPS), decisions as to disclosure of information will be made by them. In taking such decisions, all agencies should have regard to the provisions in this appendix.

H3 Tape/disk registration, storage, management and disposal

H3.1 It is essential that local guidelines are developed by the police in conjunction with other relevant agencies covering the registration, storage and management, and disposal of recordings and any associated audio material. Such guidelines should cover all of the issues referred to in this appendix. Wherever practicable, one named person should be responsible for supervision of these functions. They must keep a movement log in which the details of all interviews are registered, as well as a record of the history of the recordings. The initial entry in the logbook should record the serial number of the recording, the names of the witness and the interviewer(s) and all others present, as well as the date and time of the interview. Any subsequent copying, transporting, viewing or editing of recordings must be registered against the relevant entry in the movement log. The movement log should be regularly supervised by a manager who has been specifically given responsibility for it.

H4 After the interview

H4.1 Once a recording is completed, in the case of VHS, the tape should be fully rewound and ejected from the recorder. The 'record protect' device fitted to cassettes should be activated to prevent the accidental erasure of the recording. The tape should be checked for the quality of the recording and the master copy should be sealed in the presence of the interviewee. The seal should then be signed by all those present.

H4.2 In the case of a digital recording, the disk should be removed from the recorder, the label completed and the disk checked for audio and visual quality. It should then be placed in a box to minimise the risk of damaging the recorded surface of the disk and the master copy or copies should be sealed in the presence of the interviewee. The seal should then be signed by all those present.

H4.3 It is recommended that during the course of the interview the equipment operator prepares a brief index of the recording so that the most relevant passages regarding the alleged offence can be readily located later. The index is not a précis of the tape, but it should serve a similar purpose, enhanced by the video recording itself. The index should be carefully preserved and safeguarded along with other papers on the case. If a summary of the interview has also been prepared, a copy should be kept with the index. Paper documents should never be placed within the recording box itself because of potential damage to the recorded media.

H4.4 The master tape of the recording and all copies should be individually labelled and identified in the logbook, so that copies can be distinguished one from another and the master copy readily identified. The seal should not be broken except with the authority of the court or the PPS, in the presence of a representative of the PPS

and for the purposes of copying or editing. The ownership of the master tape and any copies must be clearly indicated, with a warning that none must be copied or shown to unauthorised persons. A recommended form of words for the label is shown in Appendix R.

H5 Storage

H5.1 Video recordings will inevitably suffer deterioration and loss over time; video tape should not be considered a permanent archiving medium. New technologies, such as digital recording, may solve these problems. However, rates of deterioration can be greatly reduced by proper storage arrangements and periodic inspection.

H5.2 Tapes should be stored on edge, that is with the reels vertical, so that the tape is supported by the hub. They should be kept in rigid cases, which are clean and impervious to dust, but they should not be sealed in airtight containers, which may cause condensation damage. When taken out for viewing or copying, tapes should not be left in video recorders unnecessarily, particularly when switched off. Excessive use of the pause facility can damage or even rupture a tape. Digital disks must be kept in their box when not in use and should not be placed face-side-down on any surface, as this could inadvertently cause damage to the recorded surface by scratching. Recordings (tape or disk) must never be left lying about on desks or in players, where unauthorised persons can gain access to them.

H5.3 Before long-term storage, tapes should be first wound and then rewound, and checked for damage. All recordings must be kept in locked, secure containers. They should not be subjected to extremes of temperature or humidity, and should be stored away from any devices that cause a strong electrical or magnetic field, such as electric motors or loudspeakers.

H6 Copies and access

H6.1 Decisions about copying and access to recordings prepared under this guidance should be taken on an individual basis and with careful regard to the following principles:

- copying of and access to the recording of an interview should be confined to the absolute minimum consistent with the interests of the witness and justice;
- no one should have access to any recording unless they are able and willing to safeguard it to the standard set out in this guidance; and
- no persons accused or implicated in the alleged offences should have custody of, or unsupervised access to, any recording made in connection with the investigation.

H6.2 Production of copies should be minimised and carried out in a secure manner in accordance with locally agreed procedures. Particular attention should be paid to the quality of the audio track on any copy. It is recommended that, when making copies, the hi-fi track of the original recording be used as the sound source.

H6.3 In most criminal cases, access to a recording will be needed by the joint investigating team, the PPS and the court. A further copy will be required, for disclosure to the defendant's legal representative, either because it is part or all of the case against the defendant, or because it is unused material which is disclosable under the Criminal Procedure and Investigations Act 1996. When the defendant is unrepresented, access should be under strict police supervision. Applications from other individuals or agencies to view or borrow a recording must be scrutinised carefully. Any access should be authorised only in respect of named individuals. If such individuals wish to borrow a recording, they must sign a written undertaking concerning protection and safeguarding of the recording and confirm that it will be returned to the police or local authority at the end of the proceedings. A form of undertaking, based on a model developed by the Law Society, is reproduced in Appendix S of this guidance.

H6.4 Applications from other individuals or agencies to view or borrow a recording should be scrutinised carefully. Claims to be acting in the interests of the witness or justice should be validated and considered on their merits. Consideration should always be given to allowing supervised access in preference to lending a recording; and to a loan in preference to making a further copy.

H6.5 Any persons borrowing recordings must have their attention drawn to:

- the precise ownership of the recording;
- the likelihood that such recordings will form part of a criminal trial; and
- the fact that misuse or unauthorised retention of such recordings may constitute contempt of court or other criminal offence.

H6.6 An entry must be made in the police movement log every time a recording is borrowed. The entry should include the names of the borrower and any other persons permitted to view the recording, together with details of the specific authority granted to them. Similar logbooks should also be maintained by any other body authorised to have custody of copies of recordings, and such logbooks should be available for periodic inspection by management.

H7 Disposal of recordings

H7.1 The Code of Practice made under the Criminal Procedure and Investigations Act 1996 lays down that the minimum period for the retention of interview records should be six months from the date of any conviction or from the date on which a convicted person was released from custody, whichever is the longer. Material must also be retained for the full duration of any appeal. This ruling applies both to the master copy and to any edited version of the recording approved by the court for use in the trial.

H7.2 However, for video recorded interviews with witnesses, there are good reasons for extending the retention period well beyond the minimum laid down by the Code. In addition to their use in criminal investigations and applications to the Criminal Cases Review Commission, recordings of interviews with witnesses may be used in civil proceedings and for criminal injury compensation claims, where a considerable delay can ensue between the original investigation and any proceedings. In cases of alleged sexual or physical abuse, new allegations against an accused can emerge many years after the original investigation. It will be vital to both prosecution and defence to have access to as complete a record of the original interview(s) as possible. The need for the preservation of such material needs to be weighed against the understandable concern of many witnesses to close a particular chapter in their lives and to know that all recordings dealing with their allegations have been destroyed.

H7.3 Duplicate material may be destroyed early. Once any proceedings are completed or after five years have elapsed since the interview took place, working copies of interviews can be disposed of. However, for the reasons outlined above, it is recommended that the master copy of any analogue, digital or audio recording should be retained for a period of six years where the witness was an adult at the time of the interview, or six years after the witness has attained the age of 18 years where they were a child at the time of the interview. A witness who was a child at the time of the interview may request the destruction of a recording prior to this date, when they reach the age of 18 years.

H7.4 Where tapes need to be disposed of, this is best done by crushing or by burning. Strict controls must be in place to ensure that all tapes are destroyed and a certificate must be supplied to this effect by the organisation responsible. Tapes or disks must never be reused: there is a risk of incomplete erasure of the original recording and deterioration in tape quality and reliability.

H8 Recordings in legal proceedings

Recordings and transcripts

H8.1 Video recorded interviews are the primary medium by which vulnerable and, intimidated witnesses will give their evidence in chief in court. However, it can assist the court to have a typewritten transcript of what the witness has said in their interview. The timing of a request for a typewritten transcript is important. Too early a request may result in production of a transcript which is not then required. Too late a request may provide insufficient time for production and checking of the transcript against the recording. The preparation of transcripts of such interviews for use in criminal proceedings is the responsibility of the PPS, and should not be prepared by police officers as a matter course. Local guidelines should be established to effectively monitor and control the preparation of any transcripts initiated by the police. The checking of transcripts of interviews is an essential step in the production of the evidence and is best conducted by the person who conducted the interview.

Collection and delivery

H8.2 Care should be taken in the packaging, delivery and collection of recordings by court officials and legal representatives to ensure that the security of recordings is safeguarded at all times. Recordings should be sent in tamper-proof packaging, and must be signed for when collected and received to ensure an audit trail while in transit. Wherever possible, interviews containing sensitive information or relating to evidence from children should be delivered to the PPS by hand. However, other acceptable methods for delivery of recordings can include delivery by recognised security couriers that are governed by local policies and procedures.

Video recordings at court

H8.3 When a video recording is submitted to court as an exhibit in a Crown Court trial, it should be kept securely until the case is concluded.

H9 After the court hearing

H9.1 At the conclusion of the case, the court will retain the tapes for an eight week period to allow for any appeal, at which point the tapes will be returned to the PPS who will sign on receipt. The police officer-in-charge will be responsible for collection from the PPS of all master tapes/disks and copies that have been produced as a result of the criminal proceedings. The movement log must then be updated to reflect the return of such recordings.

H10 Use of recordings for training and other purposes

H10.1 Video recorded interviews may be used for training, or for other official purposes such as audit or research, provided that specific and informed consent has been secured, preferably from the witness themselves. Alternatively, if the witness is not in a position to provide informed consent, the adult who discharges the principal duty of care for the witness must be consulted. The witness should be reassured that granting consent does not mean that anyone who wishes to see the recording will be able to do so. Consent must not be sought before the interview, nor will it always be right to do so immediately afterwards. If consent is granted, this should be recorded in a logbook or by completing a form designated for this purpose, and should only be done at the conclusion of any criminal or civil proceedings, or when no proceedings are to be instigated.

H11 Lost or mislaid recordings

H11.1 Should any recording become lost or mislaid, an internal investigation must be instigated by the last recorded agency to have possession of the recording (this should be governed by local guidance and procedures). Further copies of the recording(s) must not be routinely made to replace any lost recording(s) until the whereabouts of the lost recording(s) have been established and steps taken to recover them.

Identification parades involving vulnerable and intimidated witnesses

J1 The attendance of a vulnerable or intimidated witness at an identification parade or video identification (in which the witness sees a series of video clips of different people, including the suspect) requires advance planning and liaison between the police officer responsible for the identification procedure and the officer with knowledge of the witness. A pre-trial supporter who is not, or is not likely to be, a witness in the investigation should accompany the witness. Officers responsible for identification procedures rely on investigators to keep them appraised of any particular issues relating to witnesses and will consider measures to accommodate the needs of the witness but must take care to ensure that the procedure remains fair to the accused.

J2 The assessment of the witness's ability is relevant. Explanations to the witness about the purpose of the identification procedure and the wording of instructions during the procedure itself should be considered ahead of time and tailored to the witness's level of understanding. If necessary, intermediaries can assist with this.

J3 If the witness has particular communication difficulties, or requires an interpreter, someone who can communicate with the witness must attend. If the witness does not recognise numbers, consideration should be given to the use of symbols to distinguish participants. The symbols must not have any special meaning for the witness. The best evidence is a verbal identification but if the witness is unable or is likely to be unable to speak, they should be advised that it is acceptable to point. If the witness wears spectacles or contact lenses, or uses a hearing aid, these can be worn or used at the identification procedure.

J4 At identification parades, a one-way screen should always be used and should be demonstrated to witnesses before the parade itself. They should be encouraged to say if they do not understand any part of the procedure. Arrangements should be made to escort vulnerable or intimidated witnesses to and from the location where the parade is held. They should be reassured that they will not encounter anyone who took part in the line-up on leaving the building.

J5 Code D of the Police and Criminal Evidence (NI) Order 1989 provides for the identification of persons by the police. Annex B of Code D sets out the procedures for identification parades and provides that either a colour photograph or a video film should be taken of the parade. Code D provides for other forms of identification procedure such as video identification (now the primary source of identification evidence), group identification and confrontation, which may be video recorded. The procedures are set out in Annex A. A witness giving video recorded evidence or testifying over a live link will be unable to point out the defendant in court. In the absence of a requirement in the code to video record the procedure, it is good practice to video any identification procedure where the witness subsequently may not be physically present in the courtroom. It is essential that investigating officers appraise identification staff of this requirement.

Standards for the Court Witness Supporter in the Live Link Room

(These standards are based on the 'National Standards for the Court Witness Supporter in the Live Link Room' set out in the England and Wales version of Achieving Best Evidence. This is an equivalent standard which has been amended to reflect Northern Ireland policy and practice.)

K1 Role of the court witness supporter

The role of the court witness supporter is, by their presence, to provide emotional support to the witness and to reduce their anxiety and stress when giving evidence, therefore ensuring that the witness has the opportunity to give their best evidence. It is normal practice that, where a court witness supporter is available, they will act as the 'accompanying officer' which in practice means that a member of Court Service staff will not need to be present in the live link room. However, it is for Court Service staff to ensure that the equipment in the live link room is working correctly.

K2 Identity of the court witness supporter

If the witness expresses a wish to be supported in the live link room, there can be benefits, both in reducing the stress suffered and in the quality of the witness's evidence, if this wish is granted. However, in each individual case, it is a matter for the judge to determine who should accompany a witness in a live link room. An application by the prosecution or defence for the witness to give evidence by means of live television link may be made in advance of the trial for determination at a pre-trial hearing/review. The key characteristics of anyone acting in this capacity should be as follows:

- someone not involved in the case, who has no knowledge of the evidence and who has not discussed the evidence with the witness;
- someone who has received suitable training in their role and conduct (depending on the court witness supporter's identity, consideration needs to be given to their training); and
- someone with whom the witness has a relationship of trust. Ideally, this should be the person preparing the witness for court, but others may be appropriate.

When the court has decided on the identity of the court witness supporter in any particular case, the prosecution, the defence, the police and the relevant witness service should be informed. The witness should be informed by either the police or the court witness supporter themselves.

K3 Skills required by the court witness supporter for a child or vulnerable or intimidated adult witness

Required skills include:

- impartiality;
- communication skills (including with parents/carers, professionals and young people), particularly listening skills;
- awareness of the needs of abused children and adults, the effects of crime and the effects of the court appearance on the witness;
- flexibility;
- knowledge of the criminal justice system;
- confidence of the police, the Public Prosecution Service (PPS), defence legal representatives, legal representatives and the court;
- ability to liaise and work with other agencies; and
- familiarity with the basic rules of evidence and awareness of the danger of contaminating or discrediting the evidence of the witness.

K4 The court witness supporter's conduct

The court witness supporter will need to act according to agreed standards of conduct, covering communication with the witness, both within and outside the live link room, ensuring the witness's comfort and alerting the judge to any problem arising while the witness is giving evidence. Court witness supporters should be familiar with the guidance for Accompanying Officers in Appendix Q. The suggested behaviour to be observed in this role is as follows.

K4.1 Before the witness gives evidence

- If required, liaise with the local court office or relevant witness service to arrange a pre-trial visit.
- Liaise with the relevant witness service (where the court witness supporter is not from one of the witness services).
- Accept and follow the instructions of the judge with regard to witnesses and procedures to be observed.

- Ensure that the live link room is available and ready for the witness.
- Take the witness (and any carer) to the waiting room and ensure that they are comfortable.
- Remain with the witness at all times while in non-public areas of the court building.
- Be present in court to take the oath as required.
- Escort the witness to the live link room.

K4.2 In the courtroom

It may be necessary for the court witness supporter to be in the courtroom in which case the following would apply.

- Do not attend the trial prior to the witness giving evidence.
- Dress appropriately whilst in court.
- Enter the courtroom quietly during proceedings ensuring that there is no prohibiting noise.
- If supporting more than one witness, ensure that confidentiality is maintained and that evidence is not discussed.
- Do not make any notes whilst in court.

K4.3 In the live link room

- Sit the witness in the chair.
- Place the warning notice in the corridor and close the door.*
- As directed by the judge, swear in the witness by enabling them to repeat the oath or promise, as appropriate.*
- Communicate relevant concerns (through the agreed procedure) to the court.
- Be present throughout the time that the witness is in the room.
- Communicate if the witness cannot clearly see and hear the transmission.
- Sit beside the witness and in view of the camera, remaining visible to the judge.
- Ensure that the witness can be clearly seen by the courtroom at all times.
- Hand any exhibits to the witness without comment.
- Where requested remain with the witness during any breaks, ensuring that evidence is not discussed.
- Remain with the witness in the event of failure of the equipment.
- Prevent any unauthorised person entering the room.
- Communicate any interruption in the live link room to the court.

NB - Court Service staff performing the role of Accompanying Officer should refer to Circular 17/1996 for further guidance (see Appendix Q).

K4.4 Contact with the witness

- Do not speak to the witness about the case, or about their evidence, before or during the proceedings or in any interruption to the proceedings.
- Do not explain, interpret, guide or make comments about the evidence in the case.
- Do not interrupt or intervene while court proceedings are taking place, unless it is to alert the judge to a problem.
- Do not prompt or seek to influence the witness in any way.
- Ensure that any other person in the room observes these prohibitions.
- Maintain a neutral but sympathetic manner, in order to provide comfort and reassurance, and help the witness to give their evidence clearly, with a minimum of stress.
- If the witness becomes distressed and the proceedings are interrupted, the court witness supporter may listen if the witness talks about the case, and may make comforting gestures to ease the witness's distress.
- When requested by the judge, direct the attention of the witness to the questioner.

K4.5 In case of difficulties

- In the event of a problem, contact the court through the agreed procedure.
- If necessary, speak to the judge via the live link (according to the procedure previously agreed with the court).

K4.6 After the evidence has been given

- After completion of the evidence, return with the witness to a safe place.

** Tasks which could be carried out by the court witness supporter, but which would be more appropriate for a member of the court staff, if one is present.*

K5 Key steps, responsibilities and considerations for the court witness supporter in the live link room

The six steps below set out some of the key roles and responsibilities involved for agencies and organisations responsible for assisting witnesses to make an informed decision about the court witness supporter where there is a likelihood that a live link special measures application will be made - supporters in the live link room. This should be seen as good practice.

K5.1 Police investigation

The role of the witness supporter in court and views of the witness should be discussed initially with them (and, where appropriate, their parent or carer) during the explanation of special measures during the police investigation. The police should ensure that their explanation covers the following key points:

- that the role of the court witness supporter is to provide emotional support and not to discuss the evidence with the witness;
- the supporter cannot be a party to the case and must not have a detailed knowledge of the case;
- the supporter should have a relationship of trust with the witness; and
- it is a matter for the court to make the decision on the supporter after taking into account the views of the witness and the presence of a preferred supporter cannot be guaranteed.

Where possible and in appropriate circumstances, the police should provide examples about who the witness may consider might act as their supporter. The police should also provide the witness with information about pre-trial support and appropriate local support organisations.

It is acknowledged that in view of the early stage of the case, some witnesses may not be able to express a view about the identity of a court witness supporter in court during the police investigation. Nevertheless, the police should endeavour to provide the witness with basic information about the role of the supporter so that the issue can be pursued at a later time.

K5.2 Communicating the information

Once the views of the witness have been obtained by the police, this information should be recorded as part of any information to be passed to the PPS for the purposes of a special measures application. This information should include the name of any individual nominated by the witness, together with their contact details.

If necessary, the police should have a meeting with the PPS to discuss the views of the witness in further detail.

If the witness' views have not been obtained at the interview or statement taking stage, the police should discuss the issue with the witness (and, where applicable, their carer) at a suitable time afterwards and pass the information to the PPS. **Where there is an organisation offering pre-trial support, the court witness supporter should be discussed as part of the pre-trial preparation or at the pre-trial court familiarisation visit.**

If the views of the witness change about special measures or the court witness supporter after initial discussions during the police investigation, the PPS should be informed by the police as soon as practicable, ideally before submission of a special measures application.

K5.3 Special measures application

The PPS or defence submit a special measures application to the court. In the event that the witness is unable to provide the name of an individual or does not have a view on the matter, with prior agreement, the name of the relevant witness service should be submitted on the special measures application form.

K5.4 Court determination of application

The Court considers the special measure application, taking into account the views of the witness and determines who will accompany the witness as a supporter in the live link room.

In the event that the special measures application is not determined at an early stage, the investigating police officer or pre-trial supporter should continue to review and ascertain the views of the witness about the supporter in the live link in case they have changed by the time the special measures application is determined.

K5.5 Communicating the Court's decision

The Court notifies the PPS or defence practitioner of the decision. This information is then passed on to the witness.

If the court decides that the witness supporter should be a member of one of the witness services, necessary pre-trial arrangements should follow.

If the court directs that the witness supporter should be the individual submitted on the special measures application form, that individual should be informed by the witness, their parent/carers, support organisation or defence practitioner, as applicable.

If the supporter is not from one of the witness services, they should be given relevant guidance by the relevant witness service on the role of a supporter, which should cover the court process in the Crown Court, magistrates' courts or youth court, as applicable.

There should be a continuation of pre-trial support/witness preparation for giving evidence in court.

K5.6 Informing the court witness supporter of the trial date and arrangements on the day

The witness, their parents/carers or defence practitioner, as applicable, will notify their court witness supporter of trial dates and any arrangements on the day. Supporters should ensure they have a basic knowledge of any local protocols.

Standards for Young Witness Preparation

(These are based on the 'National Standards' in Achieving Best Evidence for England and Wales, and have been amended to be compatible with Northern Ireland policy and practice.)

L1 Purpose of preparation

- To help the young witness feel more confident and better equipped to give evidence at court.
- To help the young witness understand the legal process and their role within it.
- To encourage the young witness to share their fears and apprehensions about the court process and therefore assist the young person in giving their best evidence in court.

Preparation must not involve rehearsing the evidence or coaching the witness.

L2 Key characteristics required by person undertaking witness preparation

- Have experience and training in child development.
- Have experience of direct work with children.
- Ability to communicate with young children and young people in age-appropriate language.
- Ability to demonstrate a caring, mature and supporting attitude to both the young person and their parent or carer.
- Ability to deal with difficult feelings and emotions.
- Willingness and ability to offer continuity of support throughout the trial.
- Willingness and ability to work within a framework of equal opportunities.
- Willingness and ability to work within a framework of confidentiality.

In addition to the above, the person undertaking witness preparation must:

- be seen to be independent and focusing entirely on the young person's welfare in preparing for the experience of giving evidence;
- not have been involved in the preparation of the case;
- not discuss the details of the case or the evidence that the young person has given or is to give; and
- have received basic training from local agencies.

L3 Key tasks

- Obtaining information on which special measures have been ordered by the court at a pre-trial hearing to assist the young witness, including whether consideration has been given as to who accompanies the young witness while they give evidence.
- Liaising with the police and the Public Prosecution Service (PPS) if there are any changes in circumstances which might require a variation in the special measures to be provided.
- Liaising with any other agencies that may be involved with the young witness and/or the family.
- Undertaking an assessment of the young person's needs in general in relation to a court appearance, taking account of their developmental status.
- Deciding when the witness preparation should begin, bearing in mind the trial date and who the young person wishes to be present when this takes place.
- Ensuring that the young person and parent or carer has the Young Witness Pack (NSPCC (NI), 2011) and, if appropriate, viewing the Young Witness video 'Giving Evidence – What's it Like?' with the young witness and their parent or carer.
- Helping the young witness to understand the court process and their role in it. This will include discussion of the roles of the participants in the case, the importance of telling the truth and the nature of cross-examination. Question and answer role play on non-evidential subjects is likely to help young witnesses to understand the rules for answering questions in court.
- Preparing the young person for any possible outcomes of the trial such as a late change of plea, adjournments or acquittal.
- Liaising with the NSPCC Young Witness Service to arrange a familiarisation visit to the court before the trial and ensuring that the young witness, and their parent or carer, if appropriate, are shown whatever special measures have been granted by the court in their case.
- Providing the young person with stress reduction and anxiety management techniques.

- Involving the young person's parent or carer, if appropriate.
- Checking with the young witness that they have had the opportunity to refresh their memory by viewing the video recorded police interview and, if not, bringing this to the attention of the police or the PPS or the defence representative (if called by the defence).
- If special measures have not previously been identified and the young witness may benefit from them, bringing this to the attention of the person who has called the young witness, for example the prosecution or defence representative.
- Checking the young witness's preferred special measures and discussing if these are most appropriate (e.g. giving evidence in court but screened from the defendant rather than by live link, or giving evidence in private, where applicable).
- Informing the officer-in-charge if the need for an intermediary is identified (where this need has not already been identified).
- Communicating information (including the young person's wishes) to and from the police, the PPS (or defence) and the courts, keeping the young person, parent or carer informed and ensuring that practical arrangements are made for the young person.
- Co-ordinating arrangements with the court to ensure that the waiting time at the court is kept to a minimum.
- De-briefing the young witness and parent or carer and arranging for any follow-up support, including the need for specialist help.
- Ensuring that the work with the young person is fully documented.

First Day of Trial Guidance

Guidance issued to Northern Ireland Judiciary by the Lord Chief Justice on 12 May 2009 in relation to young witnesses and victims.

- Young witnesses and victims should not attend court on the first day of trial.
- If the Crown is opening the case on the first day of the trial, the young witness or victim should begin their evidence on the second day. He or she should be in the TV link room at 10.30 am. If the Crown intends to open the case on the second day, the judge should address the issue of the timetable on the first day. If it is likely that the opening will take some time and could result in the child's evidence being disrupted by lunch, then the child should be asked to come to the TV link room (or the court) at a time when it is likely that he or she will start their evidence (this may be after lunch).
- It is recognised that this approach may not be possible in every case but the Lord Chief Justice would like to see the practice applied as widely as possible.
- The practice of introducing a child or young person to the environs of the court and of Crown counsel consulting with him or her prior to the hearing is strongly encouraged. This should preferably occur in both instances well before the date fixed for hearing.
- The judge should ask the court staff to test the equipment prior to the trial starting and also to check each morning well in advance of the court starting. There can sometimes be difficulties with the TV link equipment and a daily test will avoid the young witness or victim being disrupted in giving their evidence due to technology problems.
- The above approach might also be adopted for other vulnerable witnesses or victims.

Crown Court Judicial Committee protocol on third party disclosure

The purpose of this protocol is to ensure that third party disclosure applications are made promptly, well in advance of scheduled trial dates and that trial dates are not vacated by reason of late applications. Defendants' legal representatives must address the issues of third party disclosure early and obtain the relevant information from the prosecution to enable them to draft applications. The procedure provided for in this protocol is designed to ensure that the necessary information is available at an early stage.

The officer in charge of the case should, at an appropriate time, (which in any event should be no later than the service of the committal papers) inform the complainant of the matters outlined in the paragraphs that follow. In cases involving young children this information should be provided to their parents. However, in the case of children over the age of 14 the officer should provide the information to the young person as well as to his/her parents.

1. The officer should explain to the complainant that the defendant's legal advisers may make an application to the court to see their medical notes, and any records from any counsellor they are attending as a result of the incident(s) that are the subject of the charge(s). The complainant should be asked to provide their date of birth (so that the correct medical notes and records can be obtained); the name of their doctor; the hospital (if any) they attended; the name of the counsellor and the name and address of the counselling organisation they have attended. The officer should ascertain whether the injured party has made a criminal injury application and whether there has been any social services intervention with the complainant. It should be explained that the purpose of obtaining this information at this stage is to identify the persons or bodies who might have such material. If the complainant is unwilling to provide the information sought at this stage it should be explained that this information may be obtained by other means.

2. Having obtained the names and addresses of those persons or agencies that may hold material which might be the subject of an application, the officer in charge should proceed as follows:

(i) The officer should explain to the complainant that he or she is not obliged to agree to the release of material from these sources but that if the court concludes that it is necessary that the defence should have access to that material in order to ensure a fair trial its release will be ordered.

(ii) The complainant should be informed that the court will only order the disclosure of such material as is necessary to enable a fair trial to take place and that, in deciding whether to order the release of the material, the court will take into account the complainant's rights under Article 8 of the European Convention on Human Rights and Fundamental Freedoms (the right to respect for private and family life).

(iii) The complainant should then be asked whether he or she is agreeable to the release of the material to the legal representatives of the defendant(s). He or she should be informed that if they are not agreeable to the disclosure of this material an application might be made by the defendants' legal advisers for an order of third party disclosure. The complainant should be told that they are entitled to make representations to the court on such an application. These representations can be made in writing or in person at the time that the application to the court is made.

3. The prosecution should then inform the magistrate and the defendant's solicitor (in writing) at the committal stage (or the judge at first hearing in the Crown Court) of the complainant's date of birth, name of GP, and the name of any psychiatrist, counsellor or counselling organisation that the complainant has attended. The court should also be informed if the complainant has made a criminal injury application at this stage.

4. The solicitor seeking a third party disclosure order on behalf of a defendant should, in the first instance, write to the third party indicating clearly the category of documents sought and the reasons why disclosure is being sought. He or she should ask for confirmation that the proposed third party holds such documents. The letter should then state that an application will be made to the judge, who if he or she makes an order will direct the production of the documents to the court, and not to the solicitor for the defendant, and that only documents which are relevant to the trial will be disclosed by the judge. The third party against whom the order is sought should be informed that they are entitled to appear and object to any disclosure being made.

5. The defence should lodge and serve their application 7 days after the committal, or after direction of the court, so that any party objecting to disclosure has 7 clear days notice of the application and the opportunity to be hear on the issue.

6. Third parties should be informed of the time and date of the third party application by the applicant. The applicant should send a copy of the notice and supporting affidavit to the Public Prosecution Service for transmission to the complainant(s).

7. Third party disclosure applications shall be heard at the initial arraignment application or as soon thereafter as the court directs.

8. The order, if made, will then issue with a court return date, which will be at least 7 clear days after the making of the third party disclosure order.

9. The third party disclosure order should be drawn up by the court. The party applying for the order should then obtain a copy of the order and serve it on the third party. Each court office should have and maintain a register recording the date that third party documents are lodged with the court and the date when they are returned to the third parties.

Admissibility of video recordings under other provisions of the Criminal Justice (Evidence) (Northern Ireland) Order 2004

P1 Even in circumstances where it is thought that a vulnerable or intimidated witness may not give evidence at trial, there may still be value in video recording their interview. Under Article 20 of the Criminal Justice (Evidence) (NI) Order 2004 (the 2004 Order) a video recorded statement will be admissible provided that the witness is unavailable to testify for a specified reason.

P2 The hearsay provisions set out in the 2004 Order (which came into operation on 18 April 2005) allow for certain assertions made by a person outside the courtroom to prove the facts alleged in those assertions. A statement (whether written or oral) can be put in evidence provided that it was made by an identifiable person and that the evidence would have been admissible if they had been available to give evidence. Certain further conditions must be met. Firstly, the witness cannot simply be unwilling to give oral evidence. They would have to be unavailable owing to:

- death;
- 'unfitness' because of a bodily or mental condition (the availability of special measures under the Criminal Evidence (NI) Order 1999, as amended by the Justice Act (NI) 2011, will be considered in determining this);
- being outside the UK and it not being reasonably practicable to secure their attendance; or
- not being found despite taking such steps as are reasonably practicable to locate them.

P3 Another ground of admissibility is where the witness does not give or (once proceedings have commenced) does not continue to give oral evidence through fear. The court must give leave and can only do so if it is in the interests of justice. Fear is to be construed widely and includes fear of the death or injury of another person or of financial loss.

P4 If the above conditions are met, the evidence will not be allowed if a party (or someone acting on their behalf) is the cause of that person not being available to give evidence.

P5 Article 6 of the European Convention on Human Rights provides that, as part of a fair trial, a defendant has a right to cross-examine all witnesses called against them, and that includes the right to obtain the attendance of witnesses. Article 28 of the 2004 Order preserves the right of a defendant to challenge the credibility of the maker of a statement who does not give oral evidence in the proceedings. Furthermore, Article 30 provides a discretion for the court to exclude 'superfluous' statements that may waste time and substantially outweigh the case for admitting them. The court can also exclude evidence that is otherwise unfair under Article 76 of the Police and Criminal Evidence (NI) Order 1989.

Court Service staff performing the role of Accompanying Officer

ACCOMPANYING a child in a TV Link case

Notes for guidance

1 You must abide by any instructions given to you by the Judge/Resident Magistrate [District Judge] at the Briefing before the commencement of the case.

2 If a pre-trial visit to the courthouse is arranged for the child, you should meet the child so that you are familiar to the child on the day of the trial.

3 Before the proceedings commence you must satisfy yourself that the TV link equipment is fully operational and that the child can see and hear the transmission and can be seen and heard in the courtroom.

4 You must be present in the remote witness room with the child throughout the time that he/she is required to be there. It is your duty to ensure that no other person enters the room or makes any attempt to interrupt, intervene or intimidate the child. You must not yourself interrupt or intervene during the giving of evidence or cross-examination via the TV link, unless to report to the Judge/Resident Magistrate [District Judge] that an attempt at interruption, intervention or intimidation is taking place, in which case you must do so immediately you suspect anything untoward.

5 You must refrain from prompting the child in any way, offering him/her any explanations, interpretations or guidance and from making comments or signals to the child, except to direct his/her attention to the questioner if the child appears not to be concentrating. Any exhibits should be handed to the child without comment. You must sit in such a position in relation to the child so that the transmission to the courtroom shows you both clearly.

6 In the event of interruption in transmission from the courtroom or failure of the equipment you must remain with the child. You must on no account speak to him/her about the case or his/her evidence during any interruption in the proceedings. This also applies to any interruption due to the child becoming distressed or unable to continue to give evidence.

7 On termination of the child's evidence and cross-examination you must ensure that he/she is safely delivered into the care of a responsible person.

Extract from NI Court Service Circular 17/1996

BW/141

Warning label for video recordings

This video recording is the property of PSNI [PRINT NAME AND ADDRESS OF DISTRICT COMMAND UNIT].
It has been prepared pursuant to the Criminal Evidence (NI) Order 1999 and must **NOT be copied or shown to unauthorised persons.**

UNAUTHORISED USE OR RETENTION MAY LEAD TO A FINE OR A PERIOD OF IMPRISONMENT OR BOTH.

Specimen form of receipt and undertaking for video recorded evidence

Form of undertaking recommended when receiving recorded evidence of witnesses prepared to be admitted in evidence at criminal trials in accordance with Article 15 of the Criminal Evidence (NI) Order 1999.

Name of person(s) who it is proposed should have access to recording .....

Position in organisation .....

Organisation .....

Address .....

Telephone email .....

I/We acknowledge receipt of the recording marked "evidence of" .....

.....

I/We undertake that, whilst the recording is in my/our possession, I/we shall:

a) not make, or permit any other person to make, a copy of the recording;
b) not release the recording to [name of the defendant];
c) not make or permit any disclosure of the recording or its contents to any person except when in my/our opinion it is strictly necessary in the interests of the witness and/or the interests of justice;
d) ensure that the recording is always kept in a locked, secure container and not left unattended in vehicles or otherwise unprotected;
e) return the recording to [name of person receiving recording] when I am/we are no longer professionally involved in the matter; and
f) record details of the name of any person allowed access to a recording together with details of the source of the authorisation granted to him or her.

Signed .....

For and on behalf of .....

Date .....

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The NSPCC (NI) (2011) Young Witness Pack series includes:

For young witnesses:

Let's Get Ready for Court: an activity booklet for child witnesses aged 5–9

Tell Me More about Court: a book for young witnesses aged 10–15

Inside a Courtroom: a card model of a courtroom with slot-in characters, for use with younger witnesses

Going to Court: information and advice for Crown Court witnesses aged 13–18

Young Witnesses at the Magistrates' Court and the Youth Court: for 9–18-year-olds

Screens in Court: an information sheet for 9–18-year-olds

For parents and carers:

Your Child is a Witness

For child witness supporters:

Preparing Young Witnesses for Court

For witnesses with learning difficulties:

Picture books without words published by St George's Hospital Mental Health Library in association with Voice UK, available from the Royal College of Psychiatrists' publication department:

Going to Court

I Can Get Through It

Videos:

Giving Evidence – What's it Really Like?: a video addition to the Young Witness Pack for 11–15-year-olds

Barnardo's, So You're Going to Be a Witness: for younger witnesses

Relevant government publications

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The Children (Northern Ireland) Order 1995

Children's Evidence (Northern Ireland) Order 1995

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Criminal Justice (Evidence) (Northern Ireland) Order 2004

Criminal Justice (Miscellaneous Provisions) Act (Northern Ireland) 1968

Criminal Justice (Northern Ireland) Order 2008

Data Protection Act 1998

Disability Discrimination (Northern Ireland) Order 2006

Human Rights Act 1998 (see also United Nations Convention on the Rights of the Child and the Rights of Persons with Disabilities)

Justice Act (Northern Ireland) 2011

Mental Health (Northern Ireland) Order 1986

Police and Criminal Evidence (Northern Ireland) Order 1989

Useful websites

Northern Ireland

The Bar of Northern Ireland: www.barlibrary.com

Compensation Agency: www.compensationni.gov.uk

Department of Justice: www.dojni.gov.uk

Health and Social Care in Northern Ireland: www.hscni.net

Judicial Studies Board for Northern Ireland: www.jsbni.com

Law Society of Northern Ireland: www.lawsoc-ni.org

Northern Ireland Courts and Tribunals Service: www.courtsni.gov.uk

NI Direct (government services): www.nidirect.gov.uk

Northern Ireland Prison Service: www.niprisonservice.gov.uk

Police Service of Northern Ireland: www.psni.police.uk

Probation Board for Northern Ireland: www.pbni.org.uk

Public Prosecution Service: www.ppsni.gov.uk

Victim Support NI: www.victimsupportni.co.uk (Note: VSNI has a database of organisations offering support services)

Youth Justice Agency: www.youthjusticeagencyni.gov.uk

Other UK

British Association for Counseling & Psychotherapy: www.bacp.co.uk

ChildLine: www.childline.org.uk

NSPCC: www.nspcc.org.uk

Royal College of Speech and Language Therapists: www.rcslt.org

United Kingdom Council for Psychotherapy: www.ukcp.org.uk

NSPCC: www.nspcc.org.uk

Royal College of Speech and Language Therapists: www.rcslt.org

Scottish Government: www.scotland.gov.uk

Victim Support: www.victimsupport.org.uk

Voice UK: www.voiceuk.org.uk

Adult Protection Board for Northern Ireland (APBNI)
Terms of Reference

Terms of Reference

1.0 BACKGROUND

The Health Minister has undertaken to bring forward a new Adult Protection Bill for Northern Ireland, to help protect care home residents and other vulnerable members of society. This is in response to the first report from an independent review commissioned to examine the health and social care system's response to care failings at Dunmurry Manor Care Home. This review, by CPEA, was commissioned by the Department of Health (DoH) following the Commissioner for Older People's 2018 'Home Truths' report on Dunmurry Manor. CPEA concluded that adult safeguarding practice 'did not actively contribute' to keeping residents safe at Dunmurry Manor and that families voices were repeatedly unheard. It also found divergent safeguarding practices across the HSC Trusts.

The report proposes establishing an Adult Safeguarding/Adult Protection Change programme and an Adult Safeguarding/Protection Bill. The DoH will consult on a range of legislative options. The Chief Social Worker will chair a new Adult Safeguarding Transformation Board to oversee this work and to strengthen the governance around adult safeguarding to achieve a more accountable, regional approach.

In line with the Review's recommendations, the Minister confirmed that plans include standing down the Northern Ireland Adult Safeguarding Partnership (NIASP) in a move towards the establishment of an Independent Adult Safeguarding/Protection Board at arms-length from the DoH. In the interim the HSCB has been requested to establish an Adult Protection Board. The terms of reference for this interim Board set out below are based on the following planning assumptions:

- The move to an independent structure will require a statutory footing. The development and commencement of legislation (primary and secondary) and the establishment of the Board is likely to take at least 2 years.
- The Interim APBNI arrangements will remain in place until the necessary legislation has been passed and commenced.
- The interim APBNI arrangements will enable the Board to test new ways of working, underpinned by Human Rights considerations, which will inform the new legislation and adult protection arrangements.
- The interim APBNI will be hosted by the HSCB and Chaired by the Director of Social Care and Children.

2.0 KEY RESPONSIBILITIES

The Adult Protection Board for Northern Ireland will:

1. Develop a strategic plan to protect adults at risk of harm from abuse, neglect or exploitation.

2. Produce an Annual Report for the DoH Adult Safeguarding Transformation Board on how it has discharged its strategic plan, the impact that this has made in contributing to

people's safety and also information and data regarding the range of activities taken across the region to support and progress the overarching Adult Safeguarding and Protection agenda.

3. Establish arrangements and take responsibility for Serious Case Reviews.

4. Establish how the Board will hold partner agencies to account and have a stronger focus on quality of practice on the ground, to achieve a more standardised approach across the HSC Trusts in terms of best practice and procedures. This will include developing arrangements to monitor and review activity data.

5. Review current Adult Protection arrangements and develop new Multi-Agency Adult Protection Procedures

6. Support DoH in the implementation of the adult safeguarding recommendations in the COPNI 'Home Truths' report and CPEA's Independent Review into Safeguarding and Care at Dunmurry Manor (as summarised at **Annex A**) and consider best practice from elsewhere.

7. Develop the workforce of the APBNI member agencies so that the Adult Protection arrangements can be implemented.

8. Put in place a substructure to support the broader prevention and awareness raising agenda.

9. Oversee and facilitate a change management process in relation to Adult Protection.

10. Ensure mechanisms for collaborative engagement with users and carers, the Independent Sector, former NIASP members, workforce regulators and other relevant stakeholders are established.

3.0 FREQUENCY OF MEETINGS

Over a 12 month period there will be no less than 8 meetings.

4.0 QUORUM

The Quorum should be at least one third of members available to attend a meeting in person or by video conference. Members should not routinely delegate attendance to a deputy. In the event of their absence a substitute at the same organisational position to attend.

5.0 REPORTING ARRANGEMENTS

The Adult Protection Board for Northern Ireland will report to the DoH Adult Safeguarding Transformation Board chaired by the Chief Social Worker.

6.0 SUBGROUPS

The Adult Protection Board for Northern Ireland will establish the following subgroups:

- Performance and Data subgroup
- Training and development Subgroup
- Procedures Subgroup
- User Involvement Subgroup
- Serious Case Review Subgroup
- Any other subgroup required to achieve its strategic plan

Current Local Adult Safeguarding Partnership arrangements will continue until such time as alternative arrangements are established

Each subgroup will be chaired by a member of the Adult Protection Board for Northern Ireland. The membership of subgroups will include the community, voluntary and charitable sector.

7.0 MEMBERSHIP

Membership and terms of reference will be reviewed annually and approved by the DoH Adult Safeguarding Transformation Board.

Secretariat

A secretariat will be required to include:

- Administrative support (Band 3 or 4)
- Adult Protection Lead (Band 8b)
- Social Work Advisor (Band 8a)
- Reviewing officers (HSC Leadership centre Associate list)

Members

- HSCB Director of Social Care and Children (Chair)
- PSNI Chief Superintendent
- RQIA Chief Executive
- NISCC Chief Executive
- HSC Trust x5 Executive Directors of Social Work
- HSC Trust Directors of MHLD Services x2
- HSC Trust Directors of Older Services x2
- PHA Director of Nursing
- Trust Director of Nursing representative x 1
- PCC Chief Executive and Service User Reference Group representatives x2

It is expected that Adult Safeguarding leads in the HSC Trusts will brief their Directors in advance of meetings.

Annex A

COPNI and CPEA recommendations

COPNI Home Truths **https://www.copni.org/media/1478/copni-home-truths-report-web-version.pdf**	**Lead***
R1: An Adult Safeguarding Bill for NI should be introduced without delay.	**DoH**
R2: The Safeguarding Bill should clearly define the duties and powers on all statutory, community, voluntary and independent sector representatives working with older people. There should be a clear duty to report to the HSC Trust when there is reasonable cause to suspect that there is an adult in need of protection. The HSC Trust should then have a statutory duty to make enquiries.	**DoH**
R4: Practitioners must be trained to report concerns about care and treatment in a human rights context.	**HSCB**

CPEA, Independent Review **(headlines only, see full text at para 221 of report)** **https://www.health-ni.gov.uk/sites/default/files/publications/health/Adult-Safeguarding-Briefing-%20Dunmurry-Manor-Review-Team-Sept-2020.pdf**	**Lead**
(a) Establish an Adult Safeguarding Change Programme	**DoH**
(b) Assert adult safeguarding/adult protection principles	**DoH**
(c) Set out a Human Rights Based Framework	**DoH**
(d) Draft and consult on an Adult Safeguarding/Protection Bill	**DoH**
(e) Identify and publicise what organisations have the legal powers to do.	**DoH**
(f) Practice collective and pragmatic leadership. To include consideration of the roles of Adult Safeguarding Champions, Designated Adult Protection Officers etc.	**HSCB**
(g) Introduce action learning, research and training renewal	**HSCB**
(h) Detect what matters and use data and information to make a difference.	**DoH/HSCB**

**Where DoH lead, HSCB input may be required.*

Safer Management of Controlled Drugs

Guidance on Standard Operating Procedures for Northern Ireland

Department of Health, Social Services and Public Safety

October 2009

Guidance on Standard Operating Procedures (SOPs) for Controlled Drugs

Introduction

1. The purpose of this guidance is to promote the safe, secure and effective use of all controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. Strengthened measures have been introduced to make sure controlled drugs are managed safely. These governance arrangements need to be implemented in a way that supports professionals, and encourages good practice around the management and use of these important medicines when clinically required by patients.

2. This Department has introduced new monitoring and inspection arrangements for controlled drugs in the Health Act 2006[1]. These will work within and alongside existing governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009[2] ("Regulations") made under the Health Act 2006 will require each Designated Body to appoint an Accountable Officer, responsible for the safe and effective use of controlled drugs in their organisation. The Regulations also introduce Standard Operating Procedures (SOPs) for the use and management of controlled drugs, as one of the practical measures that will help to ensure good practice throughout the health and social care system.

3. The Regulations require Accountable Officers to ensure that his or her organisation, or a body or person acting on behalf of, or providing services under contract with his or her organisation, has adequate and up to date SOPs in relation to the use of controlled drugs.

4. The Standard Operating Procedures must in particular cover the following matters as stated in the Regulations:

    - who has access to the controlled drugs
    - where the controlled drugs are stored
    - security in relation to the storage and transportation of controlled drugs as required by Misuse of Drugs legislation
    - disposal and destruction of controlled drugs
    - who is to be alerted if complications arise
    - record keeping, including maintaining controlled drugs registers under Misuse of Drugs legislation and maintaining a record of Schedule 2 controlled drugs that have been returned by patients.

[1] Health Act 2006
[2] The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

Definition

5 A SOP is an unambiguous document, describing the responsibilities and the procedures necessary to safely and accountably manage any set of processes, in this case around the total management of controlled drugs. A SOP is a working document detailing the current agreed working practice that takes account of all the areas that are applicable to the management of controlled drugs in an individual setting. The responsibilities should be assigned to individuals where possible to ensure accountability.

6 This guidance is intended to provide base line advice on the areas that might be considered for inclusion in the SOP. Different health and social care settings may have practice areas in addition to those outlined below.

Principles

7 Why are SOPs needed for controlled drugs?

- To improve governance of controlled drugs within the organisation
- To ensure practice is in line with the regulatory frameworks
- To improve clarity and consistency for all staff handling controlled drugs
- To define accountability and responsibilities and clarify where responsibility can be delegated
- As a training tool for new and existing staff.

Validation within the organisation

8 A large organisation will require an overarching policy for SOPs, and smaller organisations such as GP practices will need to have an appropriate process in place to agree, adopt and review SOPs for use.

9 SOPs will need to be agreed at a senior level on behalf of the organisation, usually through the Accountable Officer for designated organisations (as defined in the Health Act Regulations and will include the HSC Board, Trusts, Northern Ireland Ambulance Service and Independent Hospitals) and/or involving other relevant stakeholders such as senior practitioners, senior partners, senior pharmacists, prescribing advisers, medical advisers, superintendent pharmacists, and Clinical Governance Leads as appropriate to the organisation.

10 A common template needs to consider inclusion of the following:

- Organisation/Area/Service to which the SOP applies
- Objective/purpose
- Scope
- Stages of the process for example other committees that need to agree such a document
- Responsibilities
- Other useful information such as interaction with other SOPs, what to do if circumstances change
- Validation by organisation and date
- Review period. e.g. one, two or three years
- Lead author and named people contributing to SOP

11 The SOP policy should take account of:

- Training considerations for new and existing staff including ownership and awareness training
- The review criteria, for example:
  - After a given time period
  - Following a critical incident, to include the learning from such incidents
  - Significant change in legislation or best practice
  - Where a specified named person is included in a SOP then the SOP will need to be changed if personnel circumstances change.
- Cascade mechanism of changes to all staff
- Staff responsibilities – requirement to notify variation/inability to follow SOP
- Opportunity to comment and be part of review process.

Scope of SOPs

12 SOPs are needed for every stage of the controlled drug's journey from procurement (ordering, receipt, and transport), safe storage, supply, administration, destruction and guidance for dealing with an incident. Most will require multi-disciplinary collaboration.

13 The organisation will need to decide how much to include in a single SOP and may need specific SOPs for specific areas.

14 The following is to assist in identifying the steps in handling controlled drugs that need to be considered in the SOP and what is appropriate for each organisation.

15 SOPs need to be accessible to staff at all times.

Areas to consider

Receiving into organisation/unit/individual practitioner

Activity	Detail	Comment
Ordering	Assessment of necessity for a licence/authority to produce, supply or possess the stock of controlled drugs.	Refer to Home Office web-site Refer to DHSSPS web-site Refer to "A guide to good practice in secondary care" Refer to "A guide to good practice in primary care"
	Format of requisitions including descriptions of other forms and stationery to be used	See Reg 14 of Misuse of Drugs (Northern Ireland) 2002 [MDR (NI) 2002]
	Named person(s) (consider deputy/locum) with authority to order	See Reg 14 of MDR (NI) 2002
	Organisational tendering processes	
Transport and secure transfer of stock	Ensure secure arrangement in place, particularly if not from wholesaler/manufacturer	To be risk assessed depending upon the drugs, amounts, frequency and distance of movement
Receipt	Personnel authorised within organisation to receive	
	Physical check of order for accuracy and completeness	Who is responsible for this and what happens if a deficiency is identified?
	Record keeping of receipt	Is a Proof of Delivery provided? How is the invoice stored and for how long? Refer to DHSS guidance – Good management, good records.
	Security on receipt	Who, where and when is responsible for this once the consignment is accepted?

Activity	Detail	Comment
Storage	Security and key/code security Personnel with access	Refer to Safe Custody Regulations. Does the storage meet the legislative requirements? Is key storage secure and is access limited to nominated individuals? Is there an updated list of those with authority to access?
	Appropriateness for product e.g. temperature	
	Out of Hours access	Can the person lawfully supply a controlled drug under the legislation? Refer to Guidance on Out of Hours procedures.
	Contingency for extended closure	Where are the drugs stored? Who has responsibility?
Register entry	Ensure entries are made in accordance with legislation and best practice guidance.	Who makes entries? When are entries made?
Stationery	Arrangements for controlled stationery including ordering and disposal	Who is responsible? Is a list of who holds what stationery maintained?
Audit	Regular(need to specify when) checks/audits Personnel involved.	To be risk assessed on drugs, amounts held and frequency of transactions. Is there a standard report format
Discrepancies	Action to take if any discrepancies noted	Cross check register entries and physical stocks. Formal investigation to be undertaken by whom and within what time scale.
	Identify chain of interested parties.	Who is to be informed and timescale for reporting. Who is accountable within the organisation? Do the police or other regulatory bodies need to be informed? Role of Accountable Officer.
Process for reconciliation when necessary	Standard format of report. Retention period of report.	Does the organisation have this? Where and how long is it stored?

Transfer within organisation/to practitioners

Activity	Detail	Comment
Request	Prescription	See Regs 15 and 16 of MDR (NI) 2002
	Signed order (correct stationery) by known signatory	See Reg 14 of MDR (NI) 2002
	Checking authority to order	Supplier able to check against specimen signature
Assembly and supply	Authorised personnel (responsible person)	Training/competency/qualifications
	Labelling issues	
	Register entry	
Hand over	Record keeping	To whom
Transport	Authorised personnel	Some organisations may require specific SOPs relating to transport.
	Audit trail on leaving department	To be risk, assessed depending on drugs, amounts held and frequency of transactions.
	Security	
Audit trail by receiving unit	Personnel authorised to receive	To be risk, assessed depending on drugs, amounts held and frequency of transactions.
	Record keeping of receipt	
	Security on receipt	

Prescribing

Activity	Detail	Comment
Prescribing	Authority to prescribe	Refer to legal position of who can prescribe which controlled drugs. Supplementary prescriber status, existing and new independent prescribers, private or NHS.
	Prescription stationery	Hospital charts
		HS21 types including SP1 and SP2
	Private prescribing	Prescriber Identification Number – PCD1
	Local restrictions	

Administration

Administration	Authority to prescribe	Consider supplementary prescriber status, existing and new independent prescribers
	Authority to administer	PGD considerations, legal and clinical check
	Assembly	Removal from cupboard/store
		Reconstitution/assembly
		Trained personnel
	Patient	Verification of patient/treatment. Use of clinical notes.
	Register Entry	Entry in patient's notes
	Special precautions	IV, calculations
	Patient specific documentation	
	Disposal/recording arrangements for any unused portion	Refer to "A guide to good practice in secondary care" Refer to "A guide to good practice in primary care" Refer to NMC Standards and Professional Guidance.

Records and Register

Record keeping	Record document management	Refer to DHSS guidance – Good management, good records.
	Retention of hard copies/back-up of records	Time period/location/responsible person
	Supplier of register	Contact details of supplier of register
	Record keeping (legal)	Requirements under Misuse of Drugs(Northern Ireland) Regulations 2002
	Record keeping	Patient returned controlled drugs – PDRCs Where is information recorded? By who? Storage of records?

Individual patient supplies

Supply to patient	Authority to supply	Legal and clinical check of prescription
	Assembly and supply	Removal from cupboard
		Training, competency/qualifications
		Standards of equipment used
		Authorised personnel (responsible person)
		Labelling
	Patient/representative	Verification of patient/treatment. Use of clinical notes.
		ID arrangements
	Delivery service	Transfer to delivery driver. Procedures on delivery to patient, consider if patient not at home, counselling.
	Register entry	
	Prescription forms	Arrangements for sending to the Business Services Organisation

Disposal

To include agreed record keeping requirements

Disposal	Unused portions (e.g. ampoules, syringe driver)	How is this undertaken and by whom?
	Out of date stock (ward and pharmacy)	How is this undertaken and by whom?
	Excess stock	Disposal
		Legal return to stock
	Patient Own	
	Denaturing	What is the process for this and what happens to clinical waste?
	Record keeping	
	Authorised witnesses if required	
	Disposal	Carrier and destination? Contact name, address and telephone number.

Illicit substances

Illicit substances	Removal	Who may lawfully undertake this activity?
	Storage	Where are drugs held until removal?
	Recording	How are they recorded?
	Reporting	Relevant contact numbers

Incidents

Incidents	Reporting mechanisms	Who has investigative responsibility? How is this documented?
	Review procedures	On-going reviews held when? Need to review in light of experience.

Audit of SOP

Audit	By whom	
	Format	
	Frequency	
	Reporting route	
	Record management	

Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

Safer Management of Controlled Drugs

A guide to good practice in secondary care (Northern Ireland)

Updated August 2012 mainly in respect of Misuse of Drugs Regulations amendments (Original version published 2009)

MAHI - STM - 097 - 9314

Safer Management of Controlled Drugs
A guide to good practice in secondary care (Northern Ireland)

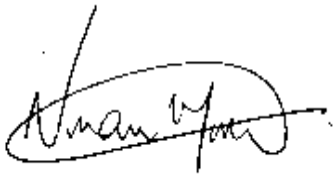
Foreword

There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care. However, as a result of the actions of Harold Shipman, and the recommendations arising from the Shipman Inquiry, significant changes have been made in both governance and legislation surrounding the use and management of controlled drugs.

In implementing better controls which support professionals and encourage good practice we must ensure that patients have appropriate and convenient access to controlled drugs to meet their clinical needs.

This document has been developed for secondary care in Northern Ireland and is designed to provide guidance on good practice for the management of controlled drugs. It seeks to take account of the important legislative changes and developments in professional practice and accountability.

In commending this guidance to secondary care organisations I wish to acknowledge the multidisciplinary input and the extent and quality of the responses to the consultative draft. The application of this guidance will, I believe, make a significant contribution to improving governance and patient safety.



Norman C Morrow

Contents

Changes to text in the August 2012 updated version include

Section 2.1: Table 1: BNF style of indication of CD schedule included
Section 2.2: Inclusion of Pharmacist Independent Prescribers
Section 2.2.1: Updating of PGD information
Section 2.2.2 and 5.8: Updating regarding Midwives
Section 4.10.5: Updating regarding Nurse Independent Prescribers; deletion of Table specifying Controlled Drugs and indications
Section 4.10.6: Updating regarding Pharmacist Independent Prescribers
Section 5 Index: Correction – omit “PGDs” include “Illicit Substances”
Section 6.1.1: Removal of word “doctor” to reflect lawful responsibility for controlled drugs in operating theatres
Section 7.9: Updating retention periods as in *Good Management Good Records*
Section 7.11: Implications of repeal of section 10(7) of the Medicines Act 1968
Glossary: Definitions -“Relevant Persons” changed; “Prescribe” updated
Appendix 1: Updating of description of legal provisions
Throughout document: Consequential page renumbering. Hyperlinks updated. Obsolete references to RPSGB removed.

1 Executive summary

The purpose of this guidance is to promote the safe and effective use of controlled drugs in healthcare organisations providing secondary care. The new strengthened governance arrangements for controlled drugs and legislative changes that flow from the Government response to the fourth report of the Shipman Inquiry impose significant new responsibilities on healthcare organisations. This guidance sets out how these changes apply to the use and management of controlled drugs in secondary care settings and will support healthcare professionals and organisations in implementing the new arrangements. It has been developed from an original document published by the Department of Health. [*Safer Management of Controlled Drugs A guide to good practice in secondary care*, 17th October 2007, www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079618]. That document emerged following widespread consultation with key stakeholders, including representation from Northern Ireland, chaired by the Royal Pharmaceutical Society of Great Britain. The work of the Royal Pharmaceutical Society is acknowledged and appreciation is expressed to the Department of Health for permission to use the original document as the basis for the Northern Ireland version. The document, as revised for Northern Ireland, has been reviewed by professionals here. A list of those who contributed to the design and content of the guidance appears at Appendix 6.

The Northern Ireland response to the Shipman Inquiry's Fourth Report was set out in *Improving Patient Safety – Building Public Confidence.* [27th Nov 2006, www.dhsspsni.gov.uk/improving_patient_safety_-_building_public_confidence.pdf] The response identified ways for strengthening the current systems for managing controlled drugs to minimise the risks to patient safety of the inappropriate use of controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. However, as the Inquiry recognised, there have been major advances in the therapeutic use of controlled drugs in the last few years. Controlled drugs are now an essential part of modern clinical care. Strengthened controls must be implemented in a way that supports professionals and encourages good practice in the use of these important medicines when clinically required by patients.

Improving Patient Safety – Building Public Confidence set out a substantial programme of work to improve the management of controlled drugs. As a result, a number of changes affecting the prescribing, record keeping and destruction of controlled drugs were introduced through amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 (SR 2002 No. 1) (MDR). The Health Act 2006 provided for regulations to be made relating to strengthened governance and monitoring arrangements for controlled drugs. The Health Act 2006 is primary legislation and applies to the whole of the UK. The Regulations developed under the Health Act differ to some extent in the different administrations. The Northern Ireland legislation, The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, came into operation on 1st October 2009.

This document is intended to provide guidance on good practice for the management of controlled drugs in secondary care in Northern Ireland. It aims to set out robust

systems for procuring, storing, supplying, transporting, prescribing, administering, recording, and disposing safely of controlled drugs, whilst at the same time helping to ensure appropriate and convenient access for those patients that require them. It is not designed to provide advice on the clinical choice or use of controlled drugs. However, individual professional organisations provide a range of advisory services to their members (see Appendix 4). Although this guidance is focussed on the safe use and management of controlled drugs in secondary care settings, patients and healthcare professionals will move and work across care sectors. The DHSSPS has published a guide to good practice in the management of controlled drugs in primary care which is available on its website.

This guidance recognises developments that have taken place to modernise working practices in recent years: the changing roles of healthcare professionals, the need to ensure optimal use of skill mix and the key contribution of pharmacy technicians and other healthcare professionals, for example, Operating Department Practitioners, and seeks to clarify how these fit within the existing legal framework for controlled drugs.

Controlled Drugs are those listed in Schedule 2 to the Misuse of Drugs Act 1971. For practical purposes they are classified in Schedules 1 to 5 to the Misuse of Drugs Regulations (Northern Ireland) 2002 according to the controls necessary for their governance. Within this document the emphasis is placed on those contained in Schedule 2 to the MDR, as these are subject to the highest levels of control. On occasions, healthcare organisations choose to manage non-controlled drugs and controlled drugs in other Schedules in the same way as Schedule 2 controlled drugs to ensure a higher level of governance. This is a matter for local decision and does not form part of this guidance.

This guidance is intended to build on and augment the advice provided in two previous documents: *Use and Control of Medicines - Guidelines for safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services* (April 2004, www.dhsspsni.gov.uk/use_control_of_medicines.pdf) and *The Safe and secure handling of medicines: A team approach* (the Revised Duthie Report), (March 2005, www.rpharms.com/support-pdfs/safsechandmeds.pdf - commended by the DHSSPS and endorsed by the Pharmaceutical Society of Northern Ireland). Neither of these documents is concerned specifically with controlled drugs and readers are also encouraged to refer to them for guidance on more general aspects of medicines management.

This guidance has been organised into chapters dealing with the legislative requirements, governance arrangements and guiding principles. Chapters that deal with the management of controlled drugs in wards, operating theatres and pharmacies follow. A chapter on special situations has been included to accommodate a number of situations that do not obviously fit elsewhere. There is also a brief chapter on training. Separate sections have not been written for each hospital department, because the requirements for the safe management of controlled drugs do not differ between medical and surgical wards or general wards and high-dependency wards. Although the guidance includes most of the commonly-encountered situations, inevitably, as practice continues to develop, users will on occasions find gaps or points which fit uneasily with their situation. In such cases it is hoped that the principles listed in Chapter 3 will provide a basis for policy formulation.

The style of the *Revised Duthie Report* (March 2005) has been adopted. The term “should” has been used for recommendations that relate to good practice and “must” for those governed by legal requirements. Recommendations have also been

inserted that “may” be followed as matters of good practice, if they are relevant to local circumstances.

This document has been designed both for those who are involved in management of controlled drugs in secondary care and for those who are responsible for ensuring that controlled drugs are managed appropriately in their organisations or in their part of the organisation. It should be of value in a number of settings where controlled drugs are used including:

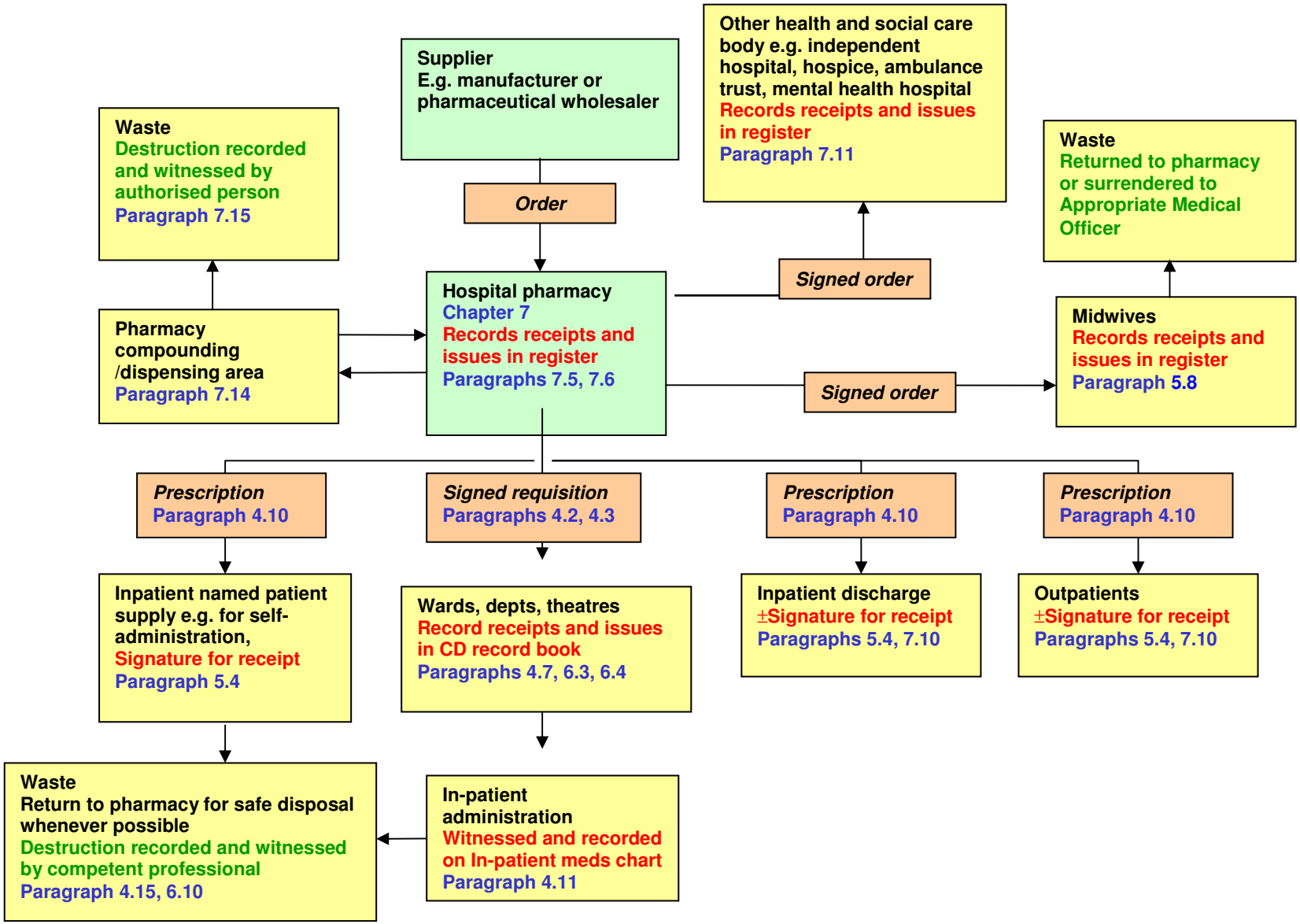
- Pharmacies
- Hospital wards and departments including operating theatres
- Midwifery units
- Other health and social care bodies

This guidance should also be of value in a number of settings outside the secondary sector such as hospices, community hospitals, rehabilitation centres and other similar organisations where controlled drugs are used and managed.

Questions relating to the management of controlled drugs may often be resolved by referring to guidance published by professional bodies. Advice may also be sought from the Pharmaceutical Advice and Services Branch of the DHSSPS. Appendix 4 includes professional organisations that provide advice for their members. Regular reference should be made to the following websites to check for up-to-date information:

The Department’s website: www.dhsspsni.gov.uk
The Department of Health website: www.dh.gov.uk/controlleddrugs
The Home Office websites:
www.homeoffice.gov.uk and www.drugs.gov.uk/drugslaws
The Pharmaceutical Society of Northern Ireland website: www.psni.org.uk
The Royal Pharmaceutical Society website www.rpharms.com as available

Figure 1 The product journey – Controlled drugs in secondary care



2 Legislation and governance arrangements

Legislation

2.1 Legislative framework for controlled drugs

The management of controlled drugs is governed by the Misuse of Drugs Act (1971) and its associated Regulations.

Additional statutory measures for the management of controlled drugs are laid down in the Health Act (2006) - and its associated legislation the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

The relevant legislation and guidance is summarised briefly in Appendix 1. Readers are encouraged to refer to the relevant websites for detailed, up-to-date information.

The legal requirements pertaining to the different Schedules of controlled drugs are summarised in Table 1. Schedule 1 drugs have been omitted from the table because drugs in this group have virtually no therapeutic uses.

Table 1: Summary of legal requirements applying to controlled drugs in Schedules 2, 3, 4 & 5 of the Misuse of Drugs Regulations

Schedule (refers to schedules of the Misuse of Drugs Regulations)	**Schedule 2** Includes – Opioids, (e.g. diamorphine, morphine, methadone), major stimulants (eg amphetamines) remifentanil secobarbital	**Schedule 3** Includes minor stimulants, temazepam, buprenorphine, flunitrazepam, midazolam, barbiturates except secobarbital	**Schedule 4 pt I** Includes benzo-diazepines	**Schedule 4 pt II** Includes anabolic steroids, clenbuterol, growth hormones	**Schedule 5** Includes low strength opioids
Designation	CD or CD2 (BNF)	CD No Reg or CD3 (BNF)	CD Benz or CD4-1 (BNF)	CD Anab or CD4-2 (BNF)	CD Inv
Safe custody	Yes, except secobarbital	Yes, with certain exemptions (see MEP, details below)	No	No	No
Prescription requirements – apply to OP and discharge prescriptions	Yes	Yes, except temazepam	No	No	No
CD Requisitions necessary?	Yes	Yes	No	No	No
Records to be kept in CD register	Yes	No	No	No	No
Pharmacist must ascertain the identity of the person collecting CD	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbital for epilepsy*	Yes*	Yes*	Yes*
Validity of prescription	28 days from the appropriate date**	28 days from the appropriate date**	28 days from the appropriate date**	28 days from the appropriate date**	6 mths (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	

Table adapted from (previous edition) Medicines, Ethics and Practice Guide (MEP). Further information can be found in the MEP, in the British National Formulary (www.bnf.org/bnf/) and on PSNI website www.psni.org.uk/documents/600/GuideLegalRequirements+MedsHumanUseControlledDrugs.pdf

* Up to a quantity sufficient for 5 days treatment
** "Appropriate date" means the later of the date on which the prescription was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied.

2.2 Supply and administration of controlled drugs

There are a number of mechanisms for the supply and administration of controlled drugs in secondary care. Controlled drugs can be

- Prescribed by a doctor, dentist, nurse independent prescriber or pharmacist independent prescriber
- Supplied and administered under Patient Group Directions
- Supplied and administered by a midwife

Certain restrictions apply to each of these routes of supply.

2.2.1 Supply and/or administration of controlled drugs under Patient Group Directions

A Patient Group Direction (PGD) allows a range of specified healthcare professionals to supply and/or administer a medicine directly to a patient with an identified clinical condition within an identified set of circumstances without the patient first seeing a prescriber. Individual professionals who are to work within a PGD must be named on it and have received appropriate training for operating the PGD.

Named nurses, paramedics and other specified health professionals can supply and administer certain controlled drugs in restricted circumstances in accordance with a PGD and the additional requirements of the Misuse of Drugs (Amendment) (No.3) Regulations (Northern Ireland) 2003 (SR 2003 No. 420) www.uk-legislation.hmso.gov.uk/sr/sr2003/nisr_20030420_en.pdf (See also for background information the *Home Office Circular 049 / 2003. Controlled Drugs Legislation - Nurse Prescribing And Patient Group Directions*.) www.homeoffice.gov.uk/about-us/corporate-publications-strategy/home-office-circulars/circulars-2003/049-2003/

There are currently only limited circumstances in which certain controlled drugs may be administered or supplied under a PGD by certain named health professionals. These are:

- Registered nurses and pharmacists (but no other healthcare practitioners) can supply or offer to supply diamorphine or morphine where administration of such drugs is required for the immediate, necessary treatment of sick or injured persons in accordance with a PGD.
- Registered nurses, pharmacists, paramedics, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists, radiographers, occupational therapists and orthotists or prosthetists can supply or administer any schedule 4 or 5 controlled drug or midazolam in accordance with a PGD, except

- The anabolic steroids in Schedule 4, part 2
- Injectable formulations for the purpose of treating a person who is addicted to a drug

2.2.2 Midwive's exemptions

Registered midwives may administer parenterally, a number of specified controlled drugs in the course of their professional practice. These are:

- Diamorphine
- Morphine
- Pethidine hydrochloride

(See - The Human Medicines Regulations 2012 (SI 2012 No. 1916). The Misuse of Drugs Regulations (Northern Ireland) 2002 (SR 2002 No. 1))

(See also paragraph 5.8 Controlled drugs for midwives)

Governance arrangements

2.3 Accountability and responsibility

At local level, all healthcare organisations or designated bodies {see the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009; (SR 2009 No. 225) available at the website www.legislation.gov.uk} are accountable, through the Accountable Officer (AO, see below), for ensuring the safe management of controlled drugs. In Northern Ireland, the following are designated bodies:

- The Regional Health and Social Care Board
- A Health and Social Care Trust
- The Northern Ireland Ambulance Service Trust
- An Independent Hospital

All designated bodies, including HSC Trusts, and independent healthcare organisations, are accountable for the monitoring of all aspects of the use and management of controlled drugs by all healthcare professionals whom they employ, with whom they contract or to whom they grant practice privileges. This will be done through normal governance arrangements such as analysing baseline data and clinical governance visits (for example by clinical governance leads).

Where one organisation provides services to another, responsibility for governance arrangements should be specified in the contract (or service level agreement). Reporting should be to the Accountable Officer for the organisation that is receiving the service. (Once the Controlled drugs have been received responsibility for them passes to receiving organisation.) In setting up and reviewing these governance arrangements, the AO will want to

pay particular attention to and prioritise key areas of risk which will include the interface with other health and social care providers.
Each designated body may also consider establishing a Controlled Drug Review Group. Such groups may be part of the arrangements that AOs are required to have in place for analysing and responding to adverse incidents involving the management or use of controlled drugs.

2.4 The Accountable Officer

The Accountable Officer is responsible for all aspects of the safe and secure management of controlled drugs in his organisation. This includes ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigation of concerns and incidents related to controlled drugs.

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations Northern Ireland) 2009; (SR 2009 No.225) and a summary of the main provisions is provided at Appendix 3 of this document. See also 'Safer Management of Controlled Drugs: A Guide to Strengthened Governance Arrangements in Northern Ireland' in the Accountable Officer section of the Department website www.dhsspsni.gov.uk

2.5 Monitoring and inspection

Regular inspections of hospital pharmacies related to the management of controlled drugs are conducted by inspectors from the DHSSPS. Core activities examined include secure storage facilities, statutory and informal record keeping and the arrangements made for robust audit trails.

2.6 Standard operating procedures

Each of the activities that relate to controlled drugs, regardless of where in the organisation they occur, should be described in a standard operating procedure (SOP). SOPs for controlled drugs became mandatory in Northern Ireland, rather than good practice, with the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, which came into operation on 1st October 2009. SOPs are particularly important if tasks are delegated to others. For example, issue and receipt of stock controlled drugs in the pharmacy may be delegated to a competent pharmacy technician. However, responsibility lies with the pharmacist who authorised the activity.

SOPs must be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived.

All staff who are involved in the prescribing, supplying, administering or disposing of controlled drugs must be familiar with the SOPs.

The standard operating procedures must, in particular, cover the following matters:

(a) who has access to the controlled drugs;

(b) where the controlled drugs are stored;

(c) security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;

(d) disposal and destruction of controlled drugs;

(e) who is to be alerted if complications arise; and

(f) record keeping, including:

(i) maintaining relevant controlled drugs registers under misuse of drugs legislation,

(ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2002 (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

SOPs within a health care organisation should be formally approved by the Accountable Officer for that organisation. This task may be delegated to a suitably qualified person, however, the final responsibility lies with the Accountable Officer.

Additional Information

A comprehensive list of drugs included within the Schedules to the Misuse of Drug Regulations 2002 can be accessed at:

- www.legislation.gov.uk/
- Home Office www.homeoffice.gov.uk/publications/alcohol-drugs/drugs/drug-licences/controlled-drugs-list?view=Binary
- Medicines and Healthcare products Regulatory Agency (MHRA) www.mhra.gov.uk

Some of the following sites may contain material which may be useful to inform practice in Northern Ireland.

- DHSSPS will also publish guidance for the safer management of controlled drugs in primary care. www.dhsspsni.gov.uk/safer-management-of-controlled-drugs-a-guide-to-good-practice-in-primary-care-version-2-july-2011.pdf
- The Care Quality Commission is responsible for overseeing the management of controlled drugs by healthcare organisations in England and a section of the website is dedicated to controlled drugs: www.cqc.org.uk
- Department of Health Controlled Drugs pages: www.dh.gov.uk/controlleddrugs
- Pharmaceutical Society of Northern Ireland www.psni.org.uk

- Pharmaceutical Services Negotiating Committee (PSNC) www.psnc.org.uk
- Nursing and Midwifery Council (www.nmc-uk.org). Standards for Medicines Management (February 2008); NMC Circular 25/2005 *Midwives Supply Orders*; NMC Circular 1/2005, *Medicine legislation: what it means for midwives.*

3 General principles

There are a number of overarching principles that guide the use of medicines in general and controlled drugs in particular. They underpin and inform the decisions that are made about the safe management of controlled drugs within the current legal framework. The following principles should apply in relation to the management of controlled drugs.

3.1 Patients have timely access to the medicines prescribed for them

3.2 Organisations and individuals comply with the current legal requirements for controlled drugs

3.3 Patients are partners in their treatment and share decision-making with healthcare professionals about their treatment.

3.4 Patients are adequately informed about their treatment

3.5 Controlled drugs are used and managed safely and securely

3.6 There is a clear audit trail for the movement and use of all controlled drugs

3.7 The use of controlled drugs is audited and action is taken if necessary

3.8 Controlled drugs are prescribed by professionals who are competent to do so and who receive regular training and support on the safe management of controlled drugs

3.9 Local procedures and protocols are designed to be as clear and accurate as possible. They should be practical in use and not impose an intolerable administrative burden

3.10 The stock levels of controlled drug preparations held in wards and departments match what is routinely used in that clinical area

3.11 Healthcare staff have access to up-to-date information about CD legislation and official (Home Office, DHSSPS, professional body and other) guidance

3.12 Healthcare staff in the organisation work to standard operating procedures, approved by the Accountable Officer, that are appropriate to their area of work

3.13 Healthcare and appropriate ancillary staff receive adequate training and are competent in the management of controlled drugs (appropriate to their sphere of activity and level of responsibility)

3.14 Access to controlled drugs is restricted to appropriate, designated and legally authorised personnel

4 Management of controlled drugs in wards and departments

This chapter deals with the management of controlled drugs in wards and departments. The management of controlled drugs in operating theatres is covered in Chapter 6.

Contents of this chapter:

This section deals with measures concerned with the management of controlled drugs that are applicable in most wards and departments, including diagnostic departments. The requirements for pharmacy departments can be found in Chapter 7.

Where additional information can be found in other paragraphs, cross-references are also included.

4.1 Accountability and responsibility

4.1.1 Accountable individuals

The senior registered nurse or registered operating department practitioner (ODP) in charge of a ward or department is responsible for the safe and appropriate management of controlled drugs in that area. The senior registered nurse or ODP in charge can delegate control of access (i.e. key-holding) to the CD cabinet to another, such as a registered nurse or another ODP. However, responsibility remains with the registered nurse or ODP in charge. Whilst the task can be delegated, the responsibility cannot.

4.1.2 Standard operating procedures

There must be standard operating procedures (SOPs) covering each of the activities concerned with controlled drugs such as requisitioning, receipt, administration, record keeping and destruction.

SOPs must be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Relevant staff should be conversant with the SOPs.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains finally accountable for all the systems for the safe management of Controlled drugs. (See Appendix 3)

4.2 Controlled drug stocks

There should be a list of the controlled drugs to be held in each ward or department as stock items. The contents of the list should reflect current patterns of usage of controlled drugs in the ward or department and should be agreed between the pharmacist or pharmacy technician responsible for stock control of medicines on the ward and the senior registered nurse or registered operating department practitioner in charge.

4.2.1 The list should be modified if practices change and should be subject to regular review at agreed intervals.

4.3 Requisitioning of controlled drugs

The senior registered nurse or registered operating department practitioner (ODP) in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in that area.

4.3.1 The senior registered nurse or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or another ODP (See Chapter 6; The management of controlled drugs in operating theatres and Appendix 2). However, legal responsibility remains with the senior registered nurse or ODP in charge.

4.3.1.1 Orders must be in writing and should be on suitable stationery (e.g. a controlled drug requisition book with duplicate or triplicate pages) and must be signed by an authorised signatory. Stationery should be designed to facilitate a robust audit trail. (See also 4.3.3 Electronic systems)

4.3.1.2 A copy of the signature of each authorised signatory should be available in the pharmacy department for validation. Where electronic systems are in use, there should be a reliable means of validating the identity of individuals who requisition controlled drugs.

4.3.1.3 Requisitions must contain the following:

- Name of hospital
- Name of Ward / Department
- Drug name, form, strength, ampoule size if more than one available
- Total quantity
- Signature of senior registered nurse or ODP in charge

The requisition should also contain:

- Date on which it was written
- The printed (as in a legible version) of the name of the senior registered nurse or ODP in charge who signed the requisition

When the drug has been supplied the requisition must:

- Be marked in such a manner to show that it has been complied with.

4.3.1.4 The person making the supply should sign and date the requisition when it has been complied with, if that has not been part of the compliance marking, above.

4.3.1.5 The person who accepts the controlled drugs for transit should sign for receipt. This may be on the duplicate requisition (if space permits) or may be in a separate book kept for this purpose.

4.3.1.6 The person who receives the controlled drugs on the ward should sign the duplicate copy of the requisition.

4.3.1.7 Requisitions must be retained at the dispensary at which the drug was supplied and a copy of the requisition or a note of it must be retained by the recipient (the senior registered nurse or ODP in charge.)

4.3.2 CD Top-up schemes

In some situations pharmacy-led CD top-up schemes for replenishing stocks of controlled drugs on wards and departments are a practical and convenient mechanism of stock control. These are usually carried out by a pharmacy technician or senior assistant technical officer (SATO), but may also be carried out by other suitably-trained, competent members of the pharmacy staff.

4.3.2.1 When a CD top-up scheme is in operation, the responsibility for controlled drugs in a ward or department remains with the senior registered nurse or ODP in charge.

4.3.2.2 In a top-up scheme a member of the pharmacy staff is responsible for checking the stock balances in the ward controlled drug record book against the levels in the agreed stock list and preparing the CD requisition forms in order to replenish the stock. These requisition forms should be signed by the senior registered nurse or ODP in charge.

4.3.3 Electronic systems

Where electronic systems for the requisitioning of controlled drugs are introduced, safeguards in the software should be put in place to ensure that:

- Only individuals who are authorised to requisition controlled drugs from the pharmacy can do so
- The author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

4.4 Receipt of controlled drugs

When controlled drugs are delivered to a ward or department they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of controlled drugs). A local procedure should define the appropriate persons who are permitted to receive controlled drugs and the way in which messengers identify them. As a matter of good practice the receiving person should not be the same person who ordered the controlled drugs. The person receiving the supply should sign the duplicate sheet in the requisition book, having checked the items received.

4.4.1 As soon as possible after delivery the senior registered nurse or ODP in charge should:

- Check the controlled drugs against the requisition – including the quantity ordered and received. If this is correct then the duplicate sheet in the controlled drug requisition book should

be countersigned in the "received by" section. If the controlled drugs received do not accord with the requisition then the pharmacy should be contacted immediately. Any tamper-evident seals on packs should be left intact when they are received from pharmacy. (Note, however, that some pharmacies open sealed packs to check for breakage before issue to wards.) Intact seals will simplify and speed up routine checks. A seal should only be broken when the pack is required for administration.

- Place the controlled drugs in the appropriate CD cabinet
- Enter the controlled drugs into the controlled drug record book, update the running balance and check that the balance tallies with quantity that is physically present.
- If, when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the senior registered nurse or ODP in charge should contact the pharmacy department as soon as possible.
- Ensure that appropriate records are made in the ward controlled drug record book and all necessary action taken to resolve the discrepancy. See 5.9 Discrepancies and diversion.

4.4.2 Depending on local circumstances, some healthcare organisations may wish to stipulate that receipt of controlled drugs and updating of the controlled drugs record book should be witnessed by a second competent professional.

See also paragraph 6.4 Receipt of controlled drugs in Theatre

4.5 Storage of controlled drugs

The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 (SR 1973 No 179) cover the safe custody of controlled drugs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store controlled drugs. Apart from specified excepted circumstances, the Regulations also require that all controlled drugs to which the Regulations apply, must be in locked storage which can only be opened by a person who can lawfully be in possession of the controlled drugs or a person working under their authority.

4.5.1 Ward CD cupboards should conform to the British Standard reference BS2881:1989 ("Specification for cupboards for the storage of medicines in healthcare premises" ISBN 058017216 3) or be otherwise approved by the pharmacy department. Cupboards should provide a level of security at least comparable to that laid down in the Safe Custody Regulations. This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case further security measures should be introduced.

4.5.2 In certain circumstances, for example when controlled drug discharge medicines are sent to the ward several hours before the patient leaves, the medicines should be stored securely in the CD cupboard. These medicines should be segregated from the ward CD stock. (See paragraph 5.4 Management of controlled drugs that are patients' property)

4.5.3 General measures for the storage of controlled drugs include the following:

- Controlled drugs must be locked away when not in use
- Cupboards must be kept locked when not in use
- The lock must not be common to any other lock in the hospital
- Keys must only be available to authorised members of staff and at any time the key-holder should be readily identifiable
- There must be arrangements for keeping the keys secure. This is particularly important for areas such as day surgery units and five-day wards that are not operational at all times.
- No other medicines or items should normally be stored in the CD cupboard. Occasionally, in response to local circumstances healthcare organisations may decide to allow other drugs that are not controlled drugs to be stored in the CD cupboard. Trusts should carry out a risk assessment and have clear guidelines and SOPs in place to cover this

4.6 Key-holding and access to controlled drugs

4.6.1 **Responsibility for CD keys**

The senior registered nurse or ODP in charge is responsible for the CD key.

4.6.1.1 Key-holding (in the sense of giving the key to another for immediate access to the cupboard) may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the senior registered nurse or ODP in charge.

4.6.1.2 The controlled drug key should be returned to the senior registered nurse or ODP in charge immediately after use by another registered member of staff.

4.6.1.3 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff (e.g. the pharmacy technician responsible for stock control of medicines on the ward).

4.6.2 Missing CD keys

If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible e.g. by contacting staff who have just gone off duty.

4.6.2.1 A procedure should be in place to ensure that an appropriate level of nursing/midwifery/theatre management and the duty pharmacist are informed as soon as possible. The procedure should specify the arrangements for preserving the security of CD stocks and for ensuring that patient care is not impeded e.g. by issuing a spare key.

4.6.2.2 If the keys cannot be found then the Accountable Officer should be informed. Depending on the circumstances, a decision may be made to contact the police. The DHSSPS Head of Medicines Regulatory Group should be made aware of the situation. Locks may need to be replaced to prevent unauthorised access to the drugs.

4.7 Record-keeping

Each ward or department that holds stocks of controlled drugs should keep a record of controlled drugs received and administered in a controlled drug record book (CDRB).

The senior registered nurse, or ODP, in charge is responsible for keeping the CDRB up to date and in good order.

4.7.1 Controlled drug record books

4.7.1.1 The controlled drug record book (CDRB) should be bound (not loose-leaf) with sequentially numbered pages and it should have separate pages for each drug and each strength, so that a running balance can be easily maintained. Entries should be made in chronological order, in ink or be otherwise indelible.

4.7.1.2 All entries should be signed by a registered nurse, midwife or ODP and should be witnessed preferably by a second registered nurse, midwife or ODP. If a second registered nurse, midwife or ODP is not available, then the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist,) or by a pharmacy technician, or an appropriately trained healthcare assistant, who has been assessed as being competent for the purpose. In defining local policy NMC Medicines Management Standards may be consulted related to witnessing by student nurses or midwives.

4.7.1.3 On reaching the end of a page in the CDRB, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. The finished page number should be indicated

at the top of the new follow-on page. As a matter of good practice this transfer should be witnessed.

4.7.1.4 If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed by a second registered nurse, midwife, ODP or other registered professional or by an appropriately trained healthcare assistant. The witness should also sign the correction. An explanation may be made if necessary by a marginal note or footnote.

4.7.2. Records of controlled drugs received

A record should be kept of all Schedule 2 controlled drugs that are received or administered.

4.7.2.1 For controlled drugs received, the following details should be recorded on the appropriate page in the CDRB:

- Date on which the controlled drug was received.
- Name of pharmacy making supply and the serial number of requisition
- Quantity received
- Form (name, formulation and strength) in which received
- Name/signature of nurse/authorised person making entry
- Name/signature of witness
- Balance in stock

4.7.2.2 When recording controlled drugs received from pharmacy, the number of units received may be recorded in words not figures (e.g. ten, not 10) to reduce the opportunity for entries to be altered.

4.7.2.3 After every administration, the stock balance of an individual preparation should be confirmed to be correct and the new balance recorded in the CDRB. The entry should be signed and dated.

For records of controlled drugs administered see paragraph 4.11 Administration

4.8 Controlled drug stock checks

The stock balance of all controlled drugs entered in the CDRB should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out. If reconciliation is being conducted related to shift change, where possible, a representative from each shift may be involved. In addition, regular documented stock checks should be carried out by pharmacy staff (see paragraph 7.7.2 - Checks of CD stocks held in wards, theatres or departments).

4.8.1 The senior registered nurse or ODP in charge is responsible for ensuring that the regular CD stock check is carried out by staff in the ward or department

4.8.1.1 Two registered nurses, midwives, ODPs or other registered health professionals should perform this check. Both must see the drugs and the records for witnessing to be meaningful. Where possible, the staff assigned to do this check should be changed periodically. The check should take account of the following points:

- Checking of controlled drugs involves the checking of the balance in the CDRB against the contents of the CD cupboard, not the reverse, to ensure that all balances are checked.
- It is not necessary to open packs with intact tamper-evident seals for stock-checking purposes.
- Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks may be helpful. The balance must be confirmed to be correct on completion of a bottle.

4.8.1.2 A record indicating that this reconciliation check has been carried out and confirming the stock is correct may be kept in a separate bound record book or in the CDRB. This record should as a minimum state the date and time of the reconciliation check and include wording such as, “check of stock level” and be signed by the registered nurse, midwife, ODP or other registered health professional and the witness.

4.8.1.3 If a discrepancy is found it should be investigated without delay. (See paragrapht 5.9 Discrepancies and diversion) The local investigation and reporting procedures should be followed.

4.9 Archiving of controlled drug records

Healthcare organisations must make arrangements to store records in accordance with legislation and the schedules in *Good Management Good Records*. www.dhsspsni.gov.uk/gmgr The current guidance that applies to retention of hospital pharmacy CD registers is eleven years. This retention period also applies to ward CDRBs. The retention period is reckoned from the date when the last entry was made.

Many local documents designed to track and/or monitor controlled drug usage should be kept for two years after the last entry/date of use.

See also paragraph 7.9 - Archiving of controlled drug records (and 4.3.1.7 and 5.1.5.2)

4.10 Prescribing

4.10.1 Prescribing for inpatients

For hospital inpatients directions for administration of controlled drugs from ward stocks may be written on the inpatient medicines chart or case sheet (sometimes called the inpatient prescription and administration chart) or the anaesthetics card in line with local policies and procedures.

4.10.1.1 The written requirements for controlled drugs on these charts are the same as for other medicines and include:

- Start date
- Drug name, form and strength where appropriate
- Route of administration, and where appropriate, the site of application
- Dose
- Time of administration or frequency (if prescribed "when required" e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum daily dose)
- Include a finish date where appropriate
- Signature of prescriber

The patient's name, date of birth, unit number and/or address and any known drug sensitivities or drug allergies should also be written on the chart.

4.10.1.2 If controlled drugs are administered or self-administered from supplies prescribed and dispensed for individual patients (rather than from items ordered as ward stock), then in addition to the requirements of 4.10.1.1, in order to comply with the Misuse of Drugs Regulations (Regulation 15), the total quantities of the controlled drugs prescribed for the individual patients must be present in both words and figures on the patient chart. (See section 5.4.4 Self-administration of controlled drugs.)

4.10.2 Prescribing for discharge patients

Prescriptions for controlled drugs for patients who are going home (discharge medicines) should be written on locally-approved prescription forms for dispensing by the pharmacy. These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a controlled drugs prescription (see section 4.10.3).

4.10.2.1 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe controlled drugs (and other POM medicines) on these prescription forms for

inpatient use so far as this is necessary for the purposes of their employment as defined in the Medical Act 1983. In line with GMC guidance for general practice, it is recommended that such issues of delegation by supervising practitioners must be clearly documented to avoid any confusion. Further guidance with some explanation of the legislation is available from the GMC at www.gmc-uk.org/Provisionally_registered_doctors_on_GP_placements_prescribing_rights.pdf_26990223.pdf

4.10.2.2 A clinically appropriate amount, up to a maximum of 30 days supply should be prescribed, as a matter of good practice. There may be circumstances where there is a genuine need to prescribe for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a record of the reasons in the patient's notes. Pharmacists may legally supply a prescribed quantity of greater than 30 days' supply, if appropriate. (Prescriptions for methadone or buprenorphine for treatment of opiate dependence for instalment dispensing in the community are limited by legislation to a maximum of 14 days supply.)

4.10.3. Prescribing for outpatients

Prescriptions for controlled drugs for outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations (Regulation 15). Such prescribing must occur within locally agreed frameworks. The prescription document can either be a locally-approved outpatient prescription form for the hospital pharmacy to dispense or, in the case of Substitution Treatment for opiate dependence with methadone or buprenorphine, an SP1 or SP2 form for a community pharmacy to dispense.

4.10.3.1 A prescription for Schedule 2 and 3 controlled drugs (with the exception of temazepam and preparations containing it) must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated

- The patient's full name and address
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures

In addition, it is good practice to include the patient's age and NHS number on the prescription.

4.10.3.2 The prescription must be signed by the prescriber with his usual signature, in his own handwriting (this must be handwritten) and dated (the date does not have to be handwritten).

Amendments to the Misuse of Drugs Regulations 2002, which came into force on 16th January 2006, removed the requirement for prescriptions for Schedule 2 and 3 controlled drugs to be written in the prescriber's own handwriting (other than their signature).

CD prescriptions may be computer-generated but **do not have** to be computer-generated. Appropriate prescribers may issue computer-generated prescriptions for all controlled drugs in Schedules 2 and 3. Only the signature has to be in the prescriber's own handwriting. The prescriber should sign any manuscript changes.

4.10.3.3 If the prescription is produced, prior to signature by the prescriber, by someone other than the prescriber then that person should, ideally, be a registered healthcare professional.

4.10.3.4 The use of pre-printed adhesive labels on prescriptions is not recommended. Technically the new legislative requirements for computer generated prescriptions for controlled drugs do not prevent the use of preprinted adhesive labels on prescriptions. If, and where, they are used, such labels should be tamper-evident (i.e. it is obvious if an attempt has been made to remove them). If an adhesive label is used, prescribers should also sign across each label. This is a further safeguard to ensure that such labels are not tampered with or that another label is not placed on top of the one that the prescriber signed for. Relevant procedures should include measures to minimize further risks related to adhesive labels and copies of prescriptions.

4.10.3.5 A clinically appropriate amount up to a maximum of 30 days supply should be prescribed as a matter of good practice. There may be circumstances where there is a genuine need to prescribe a supply for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe a supply for more than 30 days and would not pose an unacceptable threat to public safety, the prescriber should make a record of the reasons in the patient's notes. Pharmacists may legally supply a prescribed quantity of greater than 30 days' supply, if appropriate. (Prescriptions for methadone or buprenorphine for treatment of opiate dependence for instalment dispensing in the community are limited by legislation to a maximum of 14 days supply.)

4.10.4 Supplementary prescribers

Regulations were amended in 2005 to permit supplementary prescribers, when acting under and in accordance with the terms of an agreed individual clinical management plan (CMP) to prescribe and administer and/or supply or direct any person to administer any controlled drug provided that the controlled drug is included in the CMP.

4.10.5 Non-medical independent prescribers

Nurse independent prescribers

Following amendments to the Prescription Only Medicines Order 1997 (SI 1997 No. 1830), the range of drugs that Nurse Independent Prescribers were able to prescribe independently was extended. From 1st May 2006, the Nurse Prescribers' Extended Formulary was discontinued and qualified Nurse Independent Prescribers were able to prescribe any licensed medicine for any medical condition within their competence, including some controlled drugs for specific conditions. The Misuse of Drugs Regulations 2002 were again amended in May 2012 to allow a nurse independent prescriber to prescribe any controlled drug in Schedule 2, 3, 4, and 5 of the Regulations, but not in relation to cocaine, diamorphine or dipipanone for addicts, otherwise than for the purpose of treating organic disease or injury.

4.10.6 Pharmacist independent prescribers

The Misuse of Drugs Regulations 2002 were amended in May 2012 to allow a pharmacist independent prescriber to prescribe any controlled drug in Schedule 2, 3, 4, and 5 of the Regulations, but not in relation to cocaine, diamorphine or dipipanone for addicts, otherwise than for the purpose of treating organic disease or injury.

4.11 Administration

See also paragraph 4.7 Record keeping.

The administration of controlled drugs should comply with all local policies and procedures for the administration of medicines.

Nurses and midwives must follow Nursing and Midwifery Council standards and guidance. (www.nmc-uk.org)

In terms of the Misuse of Drugs Regulations (MDR) any person can administer to a patient any drug specified in Schedule 2, 3 or 4 provided they are acting in accordance with the directions of an appropriately qualified prescriber. (MDR 2002, Regulation 7(3)). Any person can administer to another person any drug specified in Schedule 5 – MDR 2002- Regulation 7 (1)

4.11.1 Healthcare organisations that do not have a system of double checking for administration of controlled drugs should carry out a risk assessment to determine whether the introduction of double checking as an additional risk-reduction measure is necessary, within their organisation.

4.11.1.1 Where two practitioners are involved in the administration of controlled drugs, one of them should be a registered nurse, midwife, doctor or ODP. Both practitioners should be present during the whole of the administration procedure. They should both witness:

- The preparation of the controlled drug to be administered.
- The controlled drug being administered to the patient.
- The destruction of any surplus drug (e.g. part of an ampoule or infusion not required).

A record should be made in the ward or department controlled drug record book (CDRB) when a controlled drug is removed from the CD cupboard.

4.11.1.2 For controlled drugs administered the following details should be recorded:

- Date and time when dose administered (or refused in the case of a controlled drug that was prepared for the patient)
- Name of patient
- Quantity administered and quantity wasted (see 4.11.1.3)
- Form (name, formulation and strength) in which administered
- Name/signature of nurse/authorised person who administered the dose
- Name/signature of witness (where there is a second person witnessing administration)
- Balance in stock

4.11.1.3 If part of a vial is administered to the patient, the registered nurse, midwife or other registered health professional should record the amount given and the amount wasted e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted*." The destruction should be witnessed by a second registered nurse, midwife or other registered health professional who should also sign the record. If a second registered nurse, midwife or other registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist) or by an appropriately trained pharmacy technician or healthcare assistant. In defining local policy NMC Medicines Management

Standards may be consulted related to witnessing by student nurses or midwives.

4.11.1.4 Individual doses of controlled drugs which have been prepared but not administered should be destroyed by a registered nurse, midwife or other registered health professional on the ward or department in the presence of a witness and the reason documented in the CDRB.

(For appropriate methods of destruction see paragraph 4.16 Disposal and destruction of Controlled drugs).

4.12 Management of controlled drugs when patients are admitted

See paragraph 5.4 Management of Controlled Drugs that are the patient's property

4.13 Management of controlled drugs when patients are transferred to other wards or departments

See paragraph 5.2 Transfer of controlled drugs

The circumstances are limited where a controlled drug will move with a patient. This is due to the restriction in the Misuse of Drugs Regulations 2002 which prevents controlled drugs being supplied from ward to ward. Patient controlled analgesia will be one of the cases where a controlled drug may need to move with the patient. There should be a local procedure (see section 6.11, Patient Controlled Analgesia, for details) which covers all aspects of the safe management of patient-controlled analgesia. This should include:

- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved between theatre and/or wards
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

4.14 Management of controlled drugs when patients are discharged

See paragraph 4.10.2 Prescribing for discharge patients and 7.10 Supply to outpatients and discharge patients

4.15 Returning controlled drugs to the pharmacy

4.15.1 Unused CD stock from wards or departments may be returned to the pharmacy. Such CD stock may be re-issued by the pharmacy provided it was initially issued by that pharmacy, is in good condition

and has at all times been under the control of that hospital. The pharmacy department should carry out an assessment of controlled drugs returned to pharmacy to ensure they are fit for re-use.

Controlled Drugs that are time-expired or otherwise unfit for use (e.g. opened liquids) should also be returned to the pharmacy for safe destruction and onward disposal.

Any other controlled drug that is no longer needed on the ward should be returned to pharmacy. This should be done as soon as is practicable. Local policies may define time limits.

4.15.2 Records of controlled drugs returned

The ward or department should keep a record of drugs returned to pharmacy. This may be in the form of a returns advice book with duplicate pages so that both the pharmacy and the ward have a record of the transaction.

The following details should be recorded when controlled drugs are returned to the pharmacy:

- Date
- Name, form, strength and quantity of drug being returned
- Reason for return
- Name and signature of the senior registered nurse or ODP in charge

The top copy will be taken from the book and transported with the drugs to the pharmacy.

In addition, an entry should be made on the relevant page of the ward or department CDRB, showing:

- Date
- Reason for return
- Names and signatures of the senior registered nurse, or ODP responsible and a competent witness
- Quantity removed
- Name, form and strength of drug
- Balance remaining

The drugs should be transferred to the pharmacy in a safe and secure way. (See paragraph 5.2 Transfer of controlled drugs)

4.16 Disposal of controlled drugs in wards and departments

See also paragraph 7.15 Disposal of controlled drugs in pharmacies

In the interests of safety and containment of environmental pollution, controlled drugs should, as far as is practicable, be returned to the pharmacy for safe denaturing and disposal.

Controlled drugs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used. Where denaturing is carried out on wards and departments, the methods used should be those currently recommended by the Pharmaceutical Society of Northern Ireland
See the Pharmaceutical Society of Northern Ireland website:
www.psni.org.uk/documents/600/GuideLegalRequirements+MedsHumanUseControlledDrugs.pdf

Some healthcare organisations may wish to provide denaturing kits for use on wards to destroy controlled drugs that have been used for patients. This may be appropriate on wards or departments where large quantities of controlled drugs are used and where the volume of part-used vials, ampoules, syringes and infusion bags may be high. A risk assessment should be carried out before a decision is made whether denaturing kits should be available on wards. Where denaturing kits are provided to wards or departments, an SOP should be developed for this practice.

4.16.1 Disposal of small amounts of Controlled drugs

4.16.1.1 In principle, only small amounts of Controlled drugs should be destroyed on wards and departments, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used. Policy should be agreed locally regarding denaturing and disposal of larger quantities of controlled drugs, for example, discontinued infusions or patient-controlled analgesia (PCA) syringes. An assessment should be made of risks involved in transport, and of the impact on infection control, prior to establishing any policy that indicates that these items be returned to the pharmacy for safe denaturing and disposal.

4.16.1.2 All destruction must be documented in the appropriate section of the CD record book (see below). It should be witnessed by a second competent professional such as a registered nurse, midwife or ODP. Both persons should sign the CD record book.

4.16.2 Method of disposal

Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer, so long as the terms of the agreement are complied with.

5 Management of controlled drugs – general processes and specific circumstances

Contents of this chapter:

5.1 Controlled drug stationery

All stationery which is used to order, return or distribute controlled drugs (CD stationery) should be stored securely and access to it should be restricted. These measures are important to guard against unauthorised use of the stationery to obtain controlled drugs for inappropriate purposes.

5.5.1 Definition of CD stationery

CD stationery includes:

- CD requisition books
- CD record books
- Local CD documents such as CD returns advice notes, pharmacy distribution documents
- Prescription forms

5.1.2 Secure storage of CD stationery

CD stationery which is kept in wards, theatres or departments should be kept in a locked cupboard or drawer.

Stocks of CD stationery held in pharmacy departments should be kept in a secure area that is locked when there is no one present.

5.1.3 Supply of CD stationery

CD stationery should be issued from the pharmacy against a written requisition signed by an appropriate member of staff. Local policy should define the form of requisition that is required to order such stationery. The local policy should also define the groups of staff who can sign requisitions for CD stationery. It may be appropriate to use the same duplicate book for ordering CD stationery that is used to order controlled drugs. This will ensure that the requisition forms themselves are stored securely.

5.1.3.1 A record should be kept in pharmacy of the supply of CD stationery. It should include:

- Date
- Ward/department
- Name of person ordering the stationery
- Type of stationery issued
- Quantity
- The serial numbers of the stationery
- Signature of the member of pharmacy staff making the supply
- Signature of member of staff receiving the stationery

5.1.3.2 Any unused stationery returned to pharmacy will be recorded as a return, with the details above, in the stationery supply record.

5.1.3.3 Healthcare organisations may wish to number CD requisition books to provide an additional means of tracking.

5.1.4 Loss or theft of CD stationery

Loss or theft of any controlled stationery which may be used to order controlled drugs should be reported immediately to the chief pharmacist and the Accountable Officer. The police should be informed, if appropriate.

5.1.5 Use of CD stationery

Only one CD requisition book per ward or department should normally be in use.

5.1.5.1 When a new CD Record Book is started, the balance of controlled drugs in stock should be written into the new book promptly by ward staff. This transfer should be witnessed by a registered nurse, midwife, ODP or authorised member of staff e.g. pharmacy technician.

5.1.5.2 Completed ward requisition books must be retained for a minimum of two years from the date of the last entry. CD record books should be kept for a period of 13 years from the date of the last entry. (See paragraphs 4.9 and 7.9 Archiving of records)

5.2 Transfer of controlled drugs within and outside the hospital

Transfer of controlled drugs is likely to involve the following situations:

- Collection by ward staff from the pharmacy
- Collection by porters from the pharmacy
- Delivery by pharmacy staff to wards, departments, theatres
- Collection by patient or representative for outpatient items only
- Delivery by Trust porter/driver
- Delivery by commercial courier (e.g. taxi out-of-hours)
- Delivery using (trackable) recorded delivery Postal Service (The use of postal services should not be routine but should be limited to exceptional situations such as when there is an urgent clinical need.)

5.2.1 Methods of transfer

Wherever possible, controlled drugs should be transferred or conveyed in a secure, locked or sealed, tamper-evident container.

5.2.1.1 Depending on local circumstances, some healthcare organisations may choose to use bags with numbered seals for delivery and require a signature for receipt of the bag with the correctly numbered seal. Whichever system is used it must be fully auditable and explicit as to who has custody of the controlled drugs at any point in time.

5.2.1.2 Controlled drugs may not be transported in pneumatic tubes. If consideration is being given to the use of such a system, prior discussion should take place with the Department inspectors.

5.2.2 Records of transfer

At each point where a controlled drug moves from the authorised possession of one person to another, a signature for receipt should be obtained by the person handing over the drug and the person receiving it.

5.2.2.1 Healthcare organisations may wish to design local distribution/transport documentation as a means of keeping a full audit trail.

5.2.3 Messengers

The person who conveys the controlled drug acts as a messenger, that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container.

5.2.3.1 The person acting as the messenger should:

- Ensure destination is known
- Be aware of safe storage and security, the importance of handing over the item to an authorised person and obtaining a signature for delivery on the delivery document.
- Have valid ID badge

5.2.3.2 Healthcare organisations may wish to stipulate that controlled drugs should only be handed to members of staff who are wearing valid ID badges.

5.2.3.3 Where a commercial courier or taxi driver is responsible for conveying a controlled drug he should be asked to show his valid company ID, as he would for any other medicine.

- Taxi drivers or commercial couriers should not be made aware that controlled drugs are being transported as this may increase the potential for diversion.
- As a matter of good practice the taxi registration or taxi licence number may also be recorded.

5.2.3.4 Healthcare organisations may wish to keep a list of porters who are authorised to transfer controlled drugs. A list of their names with sample signatures may be kept in pharmacy for validation purposes.

5.2.4 Transfer from ward to ward or theatre to ward

In general, the Misuse of Drugs Regulations 2002 prevent controlled drugs being supplied from ward to ward. However, local procedures should define safe, secure and auditable methods to transfer controlled drugs from ward to ward in circumstances where a controlled drug is required to move, for example, when a patient moves to another ward. The three situations in which this is most likely to arise are:

- When a patient is receiving a controlled drug by means of syringe pump (patient controlled analgesia) or infusion or a transdermal patch
- When a patient has his/her own controlled drugs for self-administration
- When a controlled drug has been dispensed on a “named-patient” basis

5.2.4.1 Patients' own controlled drugs should be transferred from ward to ward with the patients in line with local procedures for transferring all other medicines and property belonging to those patients.

5.2.4.2 There should be a local procedure (see section 6.11, Patient Controlled Analgesia, for details) for all aspects of the management of patient controlled analgesia. This should include:

- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved from theatre/ward to ward
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

See also paragraph 5.4 Managing controlled drugs that are the patient's property

5.2.5 Transfer from ward to pharmacy

When controlled drugs have to be returned to the pharmacy they should be placed in a secure container and handed to an authorised messenger. (See paragraph 4.15 Returning controlled drugs to the pharmacy)

5.3 Clinical trials

The procedures for the use of controlled drugs in clinical trials must comply with the Misuse of Drugs Regulations 2002 and with local policies governing the management of clinical trial medicines, in addition to clinical trials legislation and Medicines and Healthcare products Regulatory Agency (MHRA) guidance on clinical trials (www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/index.htm)

5.3.1 Storage and records

5.3.1.1 All clinical trial controlled drugs should be stored separately from stock controlled drugs. They do not necessarily need to be stored in a separate CD cupboard. A separate page in the register should be used to record receipt and issues in addition to clinical trial documentation so that a running balance of trial stock can be kept.

5.3.1.2 If a discrepancy is identified then it should be reported on the internal incident reporting system in accordance with local

procedures. A note to file should be stored with all the clinical trials documentation. The sponsor and investigator should be informed and also the chief pharmacist and Accountable Officer. (See also paragraph 5.9 Discrepancies and diversion)

5.3.1.3 For double blind trials in which only one arm involves a controlled drug, pharmacy staff may be unaware which packs contain controlled drugs. In this situation, all supplies should be treated as controlled drugs until the end of trial.

5.3.1.4 For trials that involve the use of Schedule 1 controlled drugs, such as cannabinoids, a licence from the DHSSPS must be obtained before the item is received into stock or supplied. The licence should normally be held by the chief pharmacist. A copy should be kept with the trial protocol.

5.3.2. Labelling

All clinical trial controlled drugs must be labelled and dispensed in accordance with the specific trial protocol in addition to the Misuse of Drugs Regulations 2002 requirements.

5.3.3 Disposal

Clinical trial controlled drugs must be destroyed in the same way as other controlled drugs. (See section 7. 15 Destruction of controlled drugs in pharmacies) However, this destruction may need to be carried out following the monitoring instructions from the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation (in addition to the check and reconciliation carried out by the pharmacy department) prior to any destruction.

5.3.4. Clinical trial controlled drugs returned by patients

The pharmacy should establish secure arrangements for the storage (and destruction) of CD clinical trial medicines returned by patients. Drug accountability records should be completed promptly when a patient returns the CD clinical trial medicine and opportunities for diversion should be minimised.

5.3.5 Arrangements for research departments

If a hospital pharmacy supplies controlled drugs to a research department, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

5.4 Management of controlled drugs that are the patient's property

A local procedure should be in place for the management of controlled drugs that are the patient's property.

5.4.1 Use of a patient's own controlled drugs on the ward

It may be appropriate to use a patient's own controlled drugs (i.e. controlled drugs brought into the hospital by the patient on admission) whilst they are in hospital, for example, if the patient is self-administering other medicines. On such occasions the drugs should be checked for suitability according to the local procedure for patients' own drugs (PODs) to ensure that they are fit for purpose. (See paragraph 5.4.4 Self-administration of controlled drugs)

5.4.1.1 If patients' own controlled drugs are not required for use in this way then one of the following procedures should be followed and all actions should be recorded:

- If the patient or the patient's representative agrees, medicines may be sent to the pharmacy for safe destruction. Such assent may be recorded with the signature of the patient or their representative if appropriate. The pharmacist should take responsibility for destruction.
- If the patient wishes, the medicines may be returned home via an identified adult. That adult should be given advice regarding the necessity for safe storage of the medicines and that other people must not use them. If the medicines are no longer safe and/or appropriate for future use by the patient, then the patient and/or patient's representative should be advised, and they should be encouraged to allow them to be destroyed in the hospital pharmacy (or to take them to a community pharmacy for safe destruction.)

5.4.1.2 Patients' own controlled drugs that are not to be used for self-administration should not routinely be stored on the ward.

5.4.1.3 Temporary storage of patients' own controlled drugs on the ward may be necessary whilst they are awaiting collection and removal to the pharmacy or to the patient's home. In this situation, they should be placed in the CD cupboard but should be clearly marked and kept separate from ward stock. The presence on, and departure from, the ward of these controlled drugs should be recorded according to local policy.

5.4.1.4 Patient's own controlled drugs must never be used to treat other patients.

5.4.2 Controlled drug discharge medicines

When CD discharge medicines are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. These medicines should be segregated from the ward CD stock and clearly marked and should remain in a sealed bag. Healthcare organisations may wish to stipulate that a record of the receipt and supply of these medicines from the ward should be maintained.

When Schedule 2 controlled drug discharge medicines are collected from the pharmacy, the person collecting them should be asked to sign for receipt as a matter of good practice.

5.4.3 Receipt of controlled drugs by outpatients

Patients or their representatives may be asked to provide evidence of identity when collecting controlled drugs.

From July 2006, there has been a requirement for persons asked to supply controlled drugs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the supplier:

- **May** request evidence of that person's identity and
- **May** refuse to supply the medicine if he is not satisfied as to the identity of the person
- Where it is a healthcare professional acting in his professional capacity on behalf of the patient, the supplier:

- **Must** obtain the person's name and address
- **Must,** unless he is acquainted with that person, request evidence of that person's identity; but
- **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The new requirement placed on the supplier therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if, for example, they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicines dispensed.

From 1st February 2008, it has been a requirement to record the following information in the CD register for Schedule 2 controlled drugs supplied:

- Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional
- If the person who collected the drug was a healthcare professional, that person's name and address [*Guidance* – work address - not home]
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the supplier did not ask may be included, but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

Depending on local circumstances, some healthcare organisations may wish to stipulate that outpatients receiving controlled drugs should sign for receipt of a specified number of doses.

5.4.4 Self-administration of controlled drugs

A local procedure should be in place for wards or departments where patients self-administer their own medicines including controlled drugs.

5.4.4.1 When patients who self-administer controlled drugs require additional supplies, these should be dispensed as for discharge controlled drugs. Prescription details must comply with the requirements of the Misuse of Drugs Regulations 2002. Healthcare organisations may wish to consider whether the administration of these controlled drugs is recorded in the CDRB or in a separate book for recording of controlled drugs that are self-administered.

5.4.4.2 Patients receiving controlled drugs for self-administration should sign for receipt of a specified number of doses.

5.4.4.3 Healthcare organisations may wish to stipulate that these controlled drugs are entered in and out of the ward CDRB so that there is an auditable record of their arrival on the ward. A daily count of the quantity of the controlled drugs in the patient's individual medicines cabinet may be made by the registered nurse, midwife or other healthcare professional and recorded on the medicines chart or in the CDRB.

5.4.4.4 The controlled drugs for patients who self-administer their medicines should be kept in a locked metal receptacle immediately adjacent to their bed, or in their bedside locker. The receptacle should not be easily portable. Healthcare organisations may wish to consider the use of electronic patient medicines lockers accessed by means of programmable transponders. Such systems provide a high

level of security and a clear record of who accessed the locker and when.

5.4.4.5 Useful sources of information about controlled drugs for patients are listed at Appendix 5.

5.5 Out-of-hours supply

Under the current Regulations, the senior registered nurse in charge of a ward can only supply controlled drugs to a patient on that ward or department, in accordance with the written instructions of an authorised prescriber.

Every effort should be made to ensure that adequate stock levels are maintained to meet likely needs.

Local arrangements for emergency issues of controlled drugs should be discussed with the Accountable Officer and/or chief pharmacist. Where such systems exist, a standard operating procedure should be developed.

5.6 Temporary ward closure and transfer of wards

5.6.1 Temporary ward closure

There should be a local procedure for the management of controlled drugs during short and long term ward closures. The procedure should ensure the security of the controlled drugs and should be auditable.

5.6.1.1 The procedure should include:

- A provision for a risk assessment to be carried out
- Documented stock reconciliation conducted by senior registered nurse and ward pharmacist
- Arrangements for removal and temporary storage of controlled drugs by the pharmacy, if appropriate
- Arrangements for return of controlled drugs to the pharmacy for re-use, if appropriate
- Specification of the entries required in the CDRB
- Arrangements for secure storage of current (i.e. in use) CD stationery during closure
- Arrangements for return of stocks, including reconciliation with list of controlled drugs removed, if appropriate
- Arrangements for restocking, if appropriate

5.6.1.2 As a matter of good practice, the list of authorised signatories for the ward that is kept in the pharmacy should be annotated by the pharmacist or pharmacy technician responsible for stock control of medicines on the ward so that the pharmacy and audit staff are aware that the ward is temporarily closed. The list will need to be reviewed by the ward pharmacist when the

ward reopens, to ensure that signatures are valid and up to date.

5.6.2. Transfer of wards

When a ward moves to another location, a decision must be made as to whether its controlled drugs and CDRBs may be transferred or, where swapping of wards occurs, left on the ward. This will depend upon the appropriateness of the stock list, the periods for which ward premises will be unoccupied and the security of the drugs during this time. (See paragraph 5.6.1 Temporary ward closures).

5.6.2.1 There should be a local procedure for the management of controlled drugs during ward moves. This procedure should ensure the security of the controlled drugs and should be auditable.

5.6.2.2 The procedure, which should have been agreed with the pharmacy department should include:

- A provision for a risk assessment to be carried out
- Arrangements for transfer of controlled drugs and CDRBs, if appropriate
- Arrangements for checking and reconciliation of stocks, in particular when ward staff transfer but controlled drugs and CDRBs are left in place
- Specification of the entries required in the CDRB, in particular when ward staff transfer but controlled drugs and CDRBs are left in place

5.6.2.3 The pharmacist or pharmacy technician responsible for stock control of medicines on the ward should ensure that the ward signatory lists and stock lists are updated to reflect the new ward location/name/number.

5.7 Paediatrics

The management of controlled drugs in paediatrics does not differ significantly from the management in adult care and so all the general provisions apply. There are, however, a few specific situations when the management of controlled drugs may require a slightly different approach.

5.7.1 Part vials of controlled drugs

On many occasions in paediatrics, the dose required for the patient is smaller than that which is contained in a single vial or ampoule. When a dose is given to a child, an amount may be left, which needs to be discarded. In order to minimise the opportunities for diversion, the following steps should be taken:

- When a dose is given, the nearest suitable dose volume should be selected, so that the minimum volume has to be discarded.
- When only part of the contents of a vial or ampoule is used, the entry made in the ward CD record book (CDRB) should clearly show how much was given to the patient and how much was discarded. For example, if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, “2.5mg given and 2.5mg wasted.” This should be witnessed by a second registered health professional who should also sign the record.
- The controlled drug to be discarded should be rendered irretrievable, in the presence of a witness as above, by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the “CD waste receptacle” is sent for destruction, it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer, so long as the terms of the agreement are complied with.
- A risk assessment should be carried out before a decision is made as to whether denaturing kits should be available on the wards. This is particularly relevant within children’s services. Where denaturing kits are provided, an SOP should be developed for this practice.
- The person who administers the dose is responsible for making the entry in the CDRB and this must be done immediately or as soon as is practicable after administration.

- The destruction should be recorded in the CDRB by both the person who undertook the destruction and the witness.

5.7.2 Child protection

Parents who are substance misusers sometimes bring their prescribed controlled drugs on to hospital premises. Healthcare organisations may wish to consider whether, on a parent's request, they may want to store the controlled drug in the CD cupboard and the parent requests the nurse to supply when a dose is required. These controlled drugs should be clearly labelled and kept separate from other controlled drugs.

Where there are concerns about potential diversion, staff should be alert that this may be a possibility and if appropriate, reference should be made to the appropriate child protection services

5.8 Controlled drugs for midwives

A registered midwife may possess diamorphine, morphine and pethidine in her own right so far as is necessary for the practice of her profession.

5.8.1 Acquisition of controlled drugs by midwives

Supplies of diamorphine, morphine and pethidine may only be made to a midwife on the authority of a midwife's supply order signed by the Supervisor of Midwives, or other Appropriate Medical Officer who is a doctor authorised in writing by the local supervising authority.

5.8.1.1 The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate).

5.8.1.2 The order must specify the name and occupation of the midwife, the purpose for which the controlled drug is required and the total quantity to be obtained.

5.8.1.3 Supplies of pethidine, morphine and diamorphine may be obtained from a hospital pharmacy if the midwife is engaged in the business of the Trust. (Matters of pharmacy registration or wholesale dealing must be considered if the midwife is not engaged in the business of the Trust.) The pharmacist who makes the supply must ensure that medicines are only supplied on the instruction of an authorised person.

5.8.1.4 The pharmacy must retain the midwife's supply order for two years.

5.8.2 Storage and records

Midwives must record full details of supplies of diamorphine, morphine and pethidine received and administered in their controlled drugs register. This register should be used solely for that purpose and be made available for inspection as required by the Supervisor of Midwives.

5.8.2.1 Once medicines are received by midwives working in the community or self-employed midwives, they become the responsibility of the midwife, and must be stored safely and securely.

5.8.2.2 Where it is necessary for midwives to keep medicines in their homes, the medicines must be placed in a secure, locked receptacle. If necessary, this should be provided by the employing body.

5.8.2.3 Administration of controlled drugs by midwives should be in accordance with locally agreed procedures.

5.8.2.4 A record of administration of the controlled drugs should also be kept in the woman's records.

5.8.3 Returns and disposal

When a midwife is in possession of controlled drugs that are no longer required they may be surrendered to the Appropriate Medical Officer, who should make arrangements for safe disposal, or the drugs may be returned to the pharmacy from which they were obtained. (The Appropriate Medical Officer is a doctor authorised in writing by the Health and Social Care Board who may sign midwives' supply orders, or the person appointed by the Board to exercise supervision over registered midwives.) A record of the return should be made in the midwife's controlled drugs register.

5.8.3.1 When a Schedule 2 controlled drug has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current guidance. Where possible a member of the family should witness the destruction. A record of the destruction should be made in the midwife's register. Some healthcare organisations may wish to provide denaturing kits to midwives to ensure safe destruction.

5.8.3.2 Controlled drugs that have been prescribed for a woman by her doctor for use in her home confinement are her own property and are not the midwife's responsibility. Even when no longer required they should not be removed by the midwife, but the woman should be advised to return them to a community pharmacy for destruction. Where this is not possible, the midwife should obtain the patient's agreement in writing before removing it from the patient's home and

returning it to a pharmacy for safe disposal, on behalf of the woman.

5.9 Discrepancies and diversion

The balances in the controlled drug record books (CDRBs) should always tally with the amounts of controlled drugs in the cupboard. If they do not, the discrepancy must be reported, investigated and resolved. It is important to remember that a discrepancy can indicate diversion. There should be a procedure for dealing with discrepancies and this should specify the arrangements for reporting and investigation.

In the first instance checks should be carefully made that:

- All requisitions received have been entered into the correct page of the CDRB
- All controlled drugs administered have been entered into the CDRB correctly
- Items have not been accidentally put into the wrong place in the cupboard
- Arithmetic is correct, to ensure that balances have been calculated correctly

If the error or omission is traced, the registered nurse or ODP in charge should make an entry in the CDRB, clearly stating the reason for the entry and the corrected balance. This entry should be witnessed by a second registered health professional. Both persons will sign the CDRB.

If no errors or omissions are detected then the discrepancy should be reported to the chief pharmacist and the Accountable Officer without delay and a local incident form completed in line with the healthcare organisation's policy or procedure for reporting incidents. Depending on the seriousness of the discrepancy and the early investigation findings, the DHSSPS Inspectorate and the police should be informed.

5.10 Illicit substances

DHSSPS has issued guidelines to help in the development of local policy and associated documents with respect to suspected illicit controlled substances recovered from patients. Although the guidance was provided for mental healthcare settings it will be of relevance to any secondary care facility. The DHSSPS Head of Medicines Regulatory Group should be consulted with respect to destruction of illicit substances. Please refer to *Drug and Substance Misuse in Mental Healthcare Settings – Guidelines for Service Providers*, DHSSPS, September 2004
www.dhsspsni.gov.uk/substance-misuse-guidance.pdf

6 Management of controlled drugs in in-house operating theatres

Contents of this chapter:

This chapter describes measures for management of controlled drugs in in-house operating theatres and departments where controlled drugs are used primarily by anaesthetists.

6.1 Accountability and responsibility

6.1.1 Accountable individuals

The senior registered nurse or Operating Department Practitioner (ODP) in charge of an operating theatre or theatre suite is responsible for the safe and appropriate management of controlled drugs.

The senior registered nurse, or ODP in charge can delegate control of access (i.e. key-holding) to the CD cupboard to another, such as a registered nurse or another ODP. A nurse or ODP may then only remove controlled drugs from the cupboard and/or return them to the cupboard on the specific authority of either the senior registered nurse or ODP in charge. Legal responsibility remains with the senior registered nurse or ODP in charge. Whilst the task can be delegated, the responsibility cannot. (The person to whom the task has been delegated is still professionally accountable for his/her actions).

Similar considerations apply to requisitioning and checking of controlled drugs.

6.1.2 Standard operating procedures

Healthcare organisations should ensure that all the procedures for the management of controlled drugs in in-house operating theatres and recovery wards are included in written standard operating procedures and that all staff, including anaesthetists, are aware of these procedures. It is good practice to ensure all staff who have to work in accordance with SOPs have an opportunity to comment on draft versions before the SOPs are finalised to ensure ownership. This is especially important in areas where many different staff are working for, perhaps, only a small part of their working week. Relevant staff must be conversant with the SOPs.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains accountable for the safe management of controlled drugs

6.2 Controlled drug stocks

There should be a list of controlled drugs to be held in each theatre as stock items. The contents of the list should reflect current patterns of usage of controlled drugs in the theatre and should be agreed between the pharmacy technician or pharmacist responsible for stock control of medicines in the theatre and the Operating Department manager, appropriate medical staff and the senior registered nurse or ODP in charge.

The list should be modified if practices change and should be subject to regular review at agreed intervals.

6.3 Requisitioning of controlled drugs

The senior registered nurse or ODP in charge of an operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in the theatre. (See Appendix 2)

The senior registered nurse, or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or another ODP. However, legal responsibility remains with the senior registered nurse, or ODP in charge.

Wherever practicable, different persons should be responsible for requisitioning and receipt of controlled drugs.

Requisitions must comply with the requirements for stationery, authorised signatories and content set out in paragraph 4.3 Requisitioning of controlled drugs

Healthcare organisations may consider the introduction of a pharmacy-led top-up scheme as an efficient way of maintaining adequate stock levels of controlled drugs in theatres

6.4 Receipt of controlled drugs

When controlled drugs are delivered to a theatre or theatre suite they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of Controlled drugs). A local procedure should define the persons who are permitted to receive controlled drugs and the way in which messengers identify them. As a matter of good practice the receiving person should not normally be the same person who ordered the controlled drugs.

Receipt of controlled drugs in theatre should follow the provisions set out in section 4.4 Receipt of controlled drugs

6.5 Storage of controlled drugs

The storage arrangements for controlled drugs in theatres should conform to the general provisions set out in section 4.5 Storage of controlled drugs

It may also be necessary to install separate, secure, CD fridges for aseptically-prepared parenteral doses of controlled drugs.

6.6 Record-keeping

The records for controlled drugs in theatres should conform to the general provisions set out in section 4.7 Record-keeping

There should be a separate CD record book for each theatre.

In addition to the standard CD record books, some healthcare organisations may wish to stipulate the use of stationery that permits more detailed records of controlled drugs issued, administered and destroyed.

6.7 Controlled drug stock checks

The stock balance of all controlled drugs entered in the CD Record Book should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out.

The senior registered nurse or ODP in charge is responsible for ensuring that stock checks are carried out and recorded. Pharmacy staff should carry out a documented stock check at regular intervals. This should be at least every three months.

Controlled drug stock checks should follow the provisions set out in paragraph 4.8 Controlled drug stock checks

6.8 Archiving of controlled drug records

The archiving of CD records in theatres should conform to the general provisions set out in paragraph 4.9 Archiving of controlled drug records

6.9 Prescribing of controlled drugs

The anaesthetist on duty is usually responsible for prescribing controlled drugs but other prescribers may also be involved. Nurse Independent Prescribers may also be responsible for prescribing or administration of diamorphine and morphine for post-operative pain.

Where separate charts are used e.g. epidural charts, anaesthetic charts, they should be cross-referenced on the patient's main medicines chart.

Prescribing of controlled drugs should follow the general provisions set out in paragraph 4.10 Prescribing of controlled drugs.

6.10 Administration

The practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the theatre CD record book, should be avoided. [See *Controlled Drugs in Perioperative Care. January 2006.* www.aagbi.org] An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed and witnessed e.g. if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted* "

- Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*". Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer so long as the terms of the agreement are complied with.
- Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.
- A record of administration should be made on the appropriate chart immediately after administration by the person who administered the controlled drug. This should include the identity of the person, the dose administered and the time of administration.

6.11 Patient-controlled analgesia

There should be a local procedure for all aspects of the management of patient controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (e.g. pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved from theatre/ward to ward
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

6.12 Returning controlled drugs to the pharmacy

The arrangements for return of controlled drugs to the pharmacy should conform to the provisions set out in paragraph 4.15 Returning controlled drugs to the pharmacy

In general, date-expired or controlled drugs that are otherwise unfit for use should be returned to pharmacy for safe disposal.

Surplus stock should be returned to the pharmacy as described in section 4.15.

6.13 Disposal of controlled drugs

The disposal of controlled drugs in theatres should conform to the general provisions set out in section 4.16 Disposal of controlled drugs in wards and departments.

Unused part-doses should be destroyed promptly and witnessed by a registered nurse or ODP.

- Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in

a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*". Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer so long as the terms of the agreement are complied with.

- If large quantities of part used controlled drugs are routinely generated, some healthcare organisations may wish to provide denaturing kits for use in theatres to destroy controlled drugs that have been used for patients. A risk assessment should be carried out before a decision is made as to whether denaturing kits should be available in theatres. Where denaturing kits are provided to theatres, an SOP should be developed for this practice.

7 Management of controlled drugs in hospital pharmacies

Contents of this chapter:

This chapter deals with the management of controlled drugs in hospital pharmacies and between pharmacies and other departments or health and/or social care bodies.

7.1 Accountability and responsibility

The chief pharmacist is responsible for the safe and appropriate management of controlled drugs in the pharmacy. Day-to-day management of controlled drugs (e.g. receipt into and issue from dispensary stock) in the pharmacy may be delegated to a suitably-trained, competent pharmacy technician or another pharmacist. Where technicians are delegated the management function, legal responsibility for the controlled drugs remains with the delegating pharmacist.

7.2 Security of controlled drugs/Standard Operating Procedures

The pharmacy should have standard operating procedures (SOPs – see also page 15) covering each of the aspects of the safe management of controlled drugs including: ordering, receipt, safe custody, record-keeping, auditing, issuing of stock, dispensing prescriptions, transporting of supplies, and destruction of unwanted drugs.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived.

SOPs should be approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains finally accountable for all the systems for the safe management of Controlled drugs. (See Appendix 3)

Relevant staff should be conversant with the SOPs.

7.3 Ordering and receipt

Ordering of controlled drugs from wholesalers and manufacturers and receipt of controlled drugs should follow the principles of good procurement. Local procedures should ensure that there is a robust audit trail and that the opportunities for diversion are minimised.

7.3.1 Ordering

Routine orders to wholesalers and manufacturers for controlled drugs for stock are usually placed electronically. Some healthcare organisations may, for reconciliation and accounting purposes, make a decision to produce paper records.

Stock levels should be determined by need and kept to a minimum, but should not be so low that there is a danger of running out at busy periods. This will normally be calculated by the pharmacy stock management system. It may be necessary to increase stock levels temporarily when it is anticipated that demand may outstrip the normal supply arrangements, for example, during long holiday breaks.

7.3.2 Receipt

There should be a locally agreed procedure for the receipt of controlled drugs into the pharmacy department. The procedure should ensure the security of controlled drugs and should be auditable. It should include:

- Who should sign for receipt (- ideally not the same person who generated the order.)
- How the goods should be checked (e.g. matching of the details on the delivery note to the goods and the original order) and appropriate stock control documentation completed. Any tamper-evident seals on packs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks.
- What action is to be taken if a tamper evident seal is broken or the contents of a pack do not match the stated amount
- What action is to be taken if the item received is incorrect

- What arrangements are made for storage of incorrect items for return, if appropriate
- The specifications for the record required in the CD register, including who should make the register entry and whether a witness is required

7.3.2.1 It is good practice to record receipt at the first opportunity, and in any event the record must be made no later than the day next following the day of receipt.

7.3.2.2 As a matter of good practice the balance in stock should be checked and recorded as correct by the person making the entry.

7.3.2.3 The stock must be put away promptly into the appropriate section of the CD cabinet. Controlled drugs must never be left outside of the cabinet unsupervised.

7.4 Storage

Pharmacy CD cabinets must conform to, or exceed the requirements of the Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973.

The Regulations should be regarded as a minimum security standard and may not be sufficient for areas where there are large amounts of controlled drugs in stock at a given time and/or there is not a 24-hour staff presence or easy control of access. When new hospital pharmacies are being designed, purpose built, compliant strong-rooms should be incorporated in the plans and it is essential to consult in this respect with the DHSSPS Head of Medicines Regulatory Group.

7.5 Issuing of Controlled drugs to wards and departments

There should be a local procedure for the issuing of controlled drugs to wards and departments. The procedure should ensure the security of the controlled drugs and should be auditable. It should include:

- The procedure for checking that the requisition is valid (complete and signed by an authorised signatory)
- The mechanism for correcting an incomplete or inaccurate requisition
- Specifications of the details required on labels (see below)
- Specification of entry required in the register including who should make the register entry
- Whether a witness is required. The decision as to whether a witness is required or not should be made following a risk assessment.
- Arrangements for transfer of the controlled drugs to the ward or department

7.5.1 Electronic systems

Where electronic systems for the requisitioning of controlled drugs are introduced, safeguards in the software should be in place to ensure that:

- Only individuals who are authorised to requisition controlled drugs from the pharmacy can do so
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes

7.5.2 Labelling of Controlled drugs (Stock)

There should be a standardised procedure for labelling controlled drugs.

The label should state:

- Drug name, form and strength
- Quantity
- “Store in CD cupboard”
- Department / ward name or number
- Date of issue
- Expiry date if dispensed from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g., Oramorph).
- Manufacturer’s Batch Number if dispensed from bulk
- “Keep out of reach and sight of children”
- Address of pharmacy

Depending on local circumstances, some pharmacies may also wish to add

- The requisition number

Each carton, syringe or bottle must be labelled individually. In addition, labels may also be placed on outer wrappers or containers.

7.6 Record-keeping

7.6.1 CD registers

Pharmacy departments are required to keep registers of receipts and supplies of Schedule 2 controlled drugs.

7.6.1.1 Register entries must be made in consecutive, chronological order. The entry must be made on the day when the drug is received or supplied, or on the next day. Entries must be in ink or be otherwise indelible

7.6.1.2 If a mistake is made the entry should not be crossed out, deleted, obliterated or defaced; liquid paper must not be used. Correction must be made by footnote or marginal note. The note must specify the date on which it was made and should be accompanied by the signature of the person making the correction. It is acceptable to bracket the incorrect entry. The resulting record in the register must be unambiguous.

7.6.1.3 The following staff may complete the CD register:

- Any registered pharmacist under their own authority
- Any competent member of Pharmacy staff, ideally a regulated healthcare professional, under the authority of the chief pharmacist, provided this is included in the SOP
- Any person who is being trained by a competent member of pharmacy staff such as a trained technician or a pharmacist, under their supervision. The supervisor should countersign the entry

7.6.1.4 The Misuse of Drugs Regulations 2002 were amended in 2007 with changes which came into force **from 1 February 2008**. The "Form of the Register" as specified in Schedule 6 of the 2002 Regulations was removed and replaced with a requirement to maintain, where appropriate, a CD Register with specified headings/ titles by which to capture mandatory fields of information. Additionally in the CD Register or separate part of the CD Register used for each class of drug, separate pages for each strength and form of controlled drug are now required. The name, strength and form of the drug must be entered at the top of each page and the mandatory fields of information recorded under the specified headings. An index should be maintained, together with "carried forward to/from page" details on register pages where appropriate, to enable easy navigation through the register.

7.6.1.5. The fields of information are somewhat expanded from the previous requirements. Entries in respect of drugs supplied and drugs obtained may be made on the same page or separate pages within the CD Register. The fields are as follows:

7.6.1.6 For controlled drugs **supplied** the register entry must include:

- Date supplied
- Name/Address of person or firm supplied
- Details of authority to possess - prescriber or licence holder's details
- Quantity supplied
- Person collecting Schedule 2 controlled drug (patient/patient's rep/healthcare professional) and if healthcare professional, name and address *[Guidance – work address - not home address]*
- Was proof of identity requested of patient/patient's rep (Yes/No)
- Was proof of identity of person collecting provided (Yes/No)

7.6.1.7 For Controlled drugs **obtained** the following details must be recorded in the CD Register:

- Date supply received
- Name and address from whom received
- Quantity received

7.6.1.8 The stock balance in the register should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system. The frequency of such checks should be determined locally following a risk assessment.

7.6.1.9 The Misuse of Drugs Regulations 2002 were amended in July 2006 to make clear that the details required to be kept in a controlled drug register are a minimum and do not prevent any person required to keep a register from including additional relevant information. This principle is unchanged.

7.6.1.10 The Misuse of Drugs And Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007 can be found at www.legislation.gov.uk/nisr/2007/348/pdfs/nisr_20070348_en.pdf

7.6.2 Liquid preparations

Discrepancies can arise with liquid controlled drugs as a result of manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations should be recorded and the running balance adjusted. In dealing with discrepancies, be alert to the possibility of, or potential for, diversion. Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle. It may be appropriate to carry out volume checks at regular intervals. When spillages occur, every effort should be made to find another person who can verify that the spillage has occurred and this should be recorded and initialled by both the person making the spillage and the second person, if there is one. Spilled product should be treated as controlled drug waste; denatured and rendered irretrievable.

7.6.3 Computerised registers

The Misuse of Drugs Regulations 2002 were amended in January 2006 to allow (not require) the CD register to be held on an approved computerised system. The Regulations require that entries in computerised registers must be attributable and auditable.

If the CD register is held in computerised form, the following should be in place:

- Safeguards should be incorporated in the software to ensure the author of each entry is identifiable
- Entries cannot be altered at a later date

- All entries are attributable to an individual making the entry
- A log of all data entered is kept and can be recalled for audit purposes
- Adequate backups are made
- Systems are in place to minimize the risk of unauthorised access to the data
- Systems which permit inspection of the register by authorised persons without disruption to the workflow of the pharmacy.

For further details see The Misuse of Drugs and the Misuse of Drugs (Notification of and Supply to Addicts) (Amendment) Regulations (Northern Ireland) 2005. (SR 2005 No. 564)
www.opsi.gov.uk/**Sr**/**sr2005**/ni**sr_20050564**_en.pdf

7.7 Checks of CD stocks performed by pharmacy staff

7.7.1 Checks of CD stocks held in the pharmacy

All controlled drugs in the pharmacy should be checked periodically e.g. every three months. The frequency of such checks should be determined following a risk assessment by the pharmacist with operational responsibility for managing controlled drugs and this should be included in an SOP.

7.7.1.1 This check may be undertaken by any competent person approved by the pharmacist with operational responsibility for controlled drugs, the store supervisor, or by a trainee working under their direct supervision and this should be included in an SOP.

7.7.1.2 The check should be recorded indelibly in the CD register by means of signature, date and an appropriate entry, e.g., "*Stock checked. Balance correct*".

7.7.1.3 Some healthcare organisations may also wish to stipulate periodic checks of controlled drugs by pharmacy managers who do not routinely work in the dispensary.

7.7.2 Checks of CD stocks held in wards, theatres or departments

All stocks of controlled drugs held in wards and departments should be checked by a pharmacist or pharmacy technician at least every three months and at other times when requested by the ward or department manager.

7.7.2.1 The stock check procedure should cover the following:

- A check that the levels of drugs in stock tally with the balances recorded in the CDRB.
- A check of a sample of CD requisition originals (brought from pharmacy) together with sample supply/administration

information to ensure that records have been correctly made in the CDRB

- A review of the security and quality of record keeping
- Checking and updating (if required) of the list of authorised signatories for CD requisitions
- A check for exceptional usage or peculiar patterns of usage of controlled drugs
- A check of the physical security arrangement for the storage of controlled drugs, CD stationery and the key-holding policy.

7.7.2.2 The procedure may also include a check of patients' own controlled drugs held on the ward at the time.

7.7.2.3 A record of the stock check should be made clearly and indelibly in the CDRB. The entry should be signed and dated by the person who carried it out.

7.7.2.4 Local documentation may be designed to record all aspects of the CD stock-check procedure (e.g. ward CD inspection report forms) for audit purposes.

7.8 Discrepancies

The balance recorded in the hardcopy register and/or, where relevant, the electronic register/pharmacy stock control system, should be reconciled against the stock of every product in the CD cupboard. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate diversion. The discrepancy should be reported to a senior pharmacist within one working day.

There should be a careful check of transactions in the register and in the stock control system to trace an error or omission.

If an error is traced then a register entry should be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and the witness.

If no error or omission can be traced the Chief Pharmacist and the Accountable Officer should be informed. They should decide what action to take.

7.9 Archiving of controlled drug records

Every requisition, order or private prescription on which a controlled drug is supplied must be preserved by the Pharmacy department in accordance with legislation **and** the guidance contained in *Good Management Good Records* (GMGR) (www.dhsspsni.gov.uk/gmgr). The extensive disposal schedule to the GMGR document contains detailed information about retention of records, not only in pharmacy, but throughout HPSS. It is important to be aware of the wider content in addition to the section on "Pharmacy". Healthcare organisations

should note that even though a short mandatory period of retention may be specified in regulations, cases often come to court at a much later date.

The time periods in GMGR for archiving CD documentation are:

Requisitions	2 years
Registers and CDRBs	11 years from last entry
Extemporaneous preparation worksheets	6 years
Patient Controlled Analgesia worksheets	5 years (or 11 years after expiry where product liability exists)
Discharge and specialist medicines prescriptions	2 years
Clinical trials	See GMGR

Refer to GMGR for detailed guidance on retention of records relating to children. www.dhsspsni.gov.uk/gmgr

Future Regulations may increase the period of time for the storage of records. Readers are advised to refer to the DHSSPS website for up-to-date information.

7.10 Supply to outpatients and discharge patients

For outpatient prescriptions being given directly to the patient or their representative:

- Patients or their representatives may be asked to provide evidence of identity when collecting controlled drugs

From July 2006, there has been a requirement for persons asked to supply controlled drugs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the supplier:

May request evidence of that person's identity and

- **May** refuse to supply the medicine if he is not satisfied as to the identity of the person

Where it is a healthcare professional acting in his professional capacity on behalf of the patient, the supplier:

- **Must** obtain the person's name and address
- **Must**, unless he is acquainted with that person, request evidence of that person's identity; but
- **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The requirement placed on the supplier therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.

From 1 February 2008, it has been a requirement to record the following extra information in the CD register for Schedule 2 controlled drugs supplied:

- Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional
- If the person who collected the drug was a healthcare professional, that person's name and address
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

The patient's date of birth may be used as a second check if necessary.

Depending on local circumstances, some healthcare organisations may wish to stipulate that outpatients and discharge patients should not only sign for receipt of a dispensed item but also for receipt of a specific number of doses.

7.11 Supply to external units

Section 10(7) of the Medicines Act 1968 was repealed in August 2012 to comply with EU legislation. Section 10(7) provided an exemption for registered pharmacies from the requirement to hold a Wholesale Dealers Licence when medicines were traded in certain circumstances. A hospital pharmacy wishing to make a supply to an external organisation must now ensure that it follows the MHRA guidance for supply of medicines by pharmacy to healthcare professionals or it must hold a Wholesale Dealers Licence. The guidance may be found at: www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON152604

Before making a supply to an external unit the hospital should satisfy itself that it may lawfully supply the controlled drug and that the recipient may lawfully possess controlled drugs. A private hospital that is not maintained by voluntary funds or by a registered charity needs a DHSSPS Licence to hold schedule 2 CD stocks. The supplier should only make the supply if such a licence is held. (For further information see the Home Office Drug Laws and Licensing pages: www.homeoffice.gov.uk The DHSSPS Head of Medicines Regulatory Group may be consulted regarding local licence holders.

Where the external unit or body is a designated body as defined in the Regulations it will have an Accountable Officer and the AO must ensure that his designated body has up-to-date SOPs for the use and management of Controlled drugs. Where the external unit acts on behalf of, or provides services under arrangements made with, the Trust, the Trust's Accountable Officer must ensure that the external unit has established and operates appropriate arrangements for securing safe management and use of controlled drugs. These arrangements include adequate and up-to–date SOPs.

Where a service level agreement (SLA) is drawn up for a service to supply controlled drugs to an external body or unit, the SLA should specify the SOPs that are to be followed (i.e. those of the provider or purchaser).

7.11.1 Supply to external units

External units include, for example, hospices, prisons and the ambulance trust.

The other unit must comply with the legislation for controlled drugs and should also follow the guidance in this document.

7.11.2 Written agreement (Service Level Agreement [SLA])

When the hospital pharmacy is providing services to another health and social care body the details should be specified in a written agreement or contract (service level agreement).

In relation to controlled drugs the following points should be included in the written agreement (SLA):

- What is to be supplied; stock controlled drugs and/or patients' own controlled drugs (e.g., for external units where patients are encouraged to self-administer their own medicines including controlled drugs).
- An outline of the ordering and supplying processes and the documentation used.
- The arrangements for obtaining supplies of controlled drugs in emergencies and out of hours.
- Specification of responsibilities and accountability in relation to controlled drugs medicines management including governance arrangements.
- A statement that the pharmacy department and receiving unit produce SOPs for the ordering and issuing processes including transit at their respective facilities. This should include the different ordering processes for stock controlled drugs and patient-specific controlled drugs (see below).
- It is good practice for the other health and social care body to ensure that its SOPs have been reviewed and agreed by a pharmacist. (Note that not all external organisations employ a pharmacist).

- That both parties review each others' SOPs to ensure a consistent, safe and auditable management process for controlled drugs.
- If two different Accountable Officers cover the issuing and receiving units then each Accountable Officer should take responsibility for the SOPs relating to his organisation.
- That the representatives from the issuing pharmacy and the other health and social care body meet on a regular basis to discuss any problems and agree any remedial action to resolve these and review services.
- That the issuing pharmacy and receiving unit conduct audits across the interface to ensure that processes and procedures follow the SOPs and that any gaps in the systems, processes and procedures are identified and rectified. It is good practice to provide the Accountable Officer(s) with the audit reports and action plans.

7.11.3 Ordering of stock controlled drugs by another hospital or a nursing home

Ordering of controlled drugs must comply with the current Misuse of Drugs Regulations.

Where a pharmacist is employed, the purchase of controlled drugs must be under his or her direct supervision and this includes authorising orders to suppliers. Where no pharmacist is employed a doctor or dentist employed by or engaged by the body must countersign orders for controlled drugs raised by the person in charge or acting person in charge of the other hospital or nursing home.

All stock controlled drugs should be ordered as stock items only and contain no patient names.

7.11.3.1. Arrangements when the hospital pharmacy provides a supply service only to another hospital or nursing home

The person or acting person in charge of a hospital or nursing home, can complete the controlled drugs requisition book and sign this order, which must also be countersigned – see below. The stock controlled drugs order must contain:

- Signature of the person to whom the drug is to be supplied (the recipient),
- The name, address and profession or occupation of the recipient
- Name, formulation, strength and quantity (whole pack sizes) of the controlled drug,
- Purpose for use,
- Countersignature of a doctor (or dentist) who is employed or engaged at the other hospital or nursing home.

The requisition should be dated and should include sufficient information to identify the hospital or nursing home and the ward or department.

The doctor will sign the order as an independent verification that the controlled drugs ordered are to be used within the requesting ward or department within the other hospital or nursing home. Responsibility and accountability should be written into the SLA and be in accordance with the Misuse of Drugs Regulations.

There are circumstances where a doctor may request controlled drugs and is also responsible for the management of the controlled drugs within the department of the other organisation.

7.11.4 Ordering of patient specific controlled drugs by external units

7.11.4.1 Ordering from a hospital pharmacy

Patient specific controlled drugs can be ordered for either use within an inpatient unit (e.g. as part of self-administration scheme) or as discharge medication.

It is acceptable for the external unit to use locally designed and approved prescription forms for prescribing a patient's medication. The hospital pharmacy should manage these prescription forms in the same way as they would internal prescription forms.

A full audit trail should be maintained when transferring the dispensed controlled drugs to the external unit.

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

7.11.4.2 Ordering from a community pharmacy

A similar arrangement of using locally designed and approved prescription forms can be used when a community pharmacy is supplying patient-specific controlled drugs under a written agreement to an inpatient unit such as a prison or hospice.

(It should be noted that these prescriptions are not private prescriptions but part of a system for supplying patients/prisoners with appropriate dispensed and labelled medicines including controlled drugs on discharge from that unit or as part of a patient self-administration scheme).

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

7.12 Transfer of controlled drugs

At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties.

Wherever possible, the drug must be transported in a secure, lockable container and
a suitable delivery document completed to provide a full audit trail.

See paragraph 5.2 - Transfer of controlled drugs

7.13 Controlled drugs returned from wards

There should be a local procedure and auditable documentation for the management of controlled drugs returned from wards.

See also paragraph 4.15 – Returns to Pharmacy

7.14 Production and Quality Control

Where pharmacy production or aseptic units are preparing products that contain controlled drugs, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

7.15 Disposal/destruction

See also section 4.16 disposal of controlled drugs in wards and departments

Unwanted controlled drugs should be denatured in a pharmacy, and when required by legislation, in the presence of an authorised witness. Treated waste should be placed in appropriate containers for eventual incineration and should not be allowed to enter the sewerage system. [See *Handling and Disposal of Pharmaceutical and Clinical Waste* (Health Estates 2002) www.dhsspsni.gov.uk/pharmaceutical-waste-guidance.pdf] Reference has previously been made (e.g. section 4.16.2) to circumstances whereby small quantities of waste liquid controlled drugs at ward or department level may be disposed of to sewer. Note that this pertains where hospitals have individual agreements with Northern Ireland Water, and act within the parameters of those agreements.

Controlled drugs should be disposed of in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used again.

There should be a local policy for disposal of controlled drugs and this policy must be in accordance with current Home Office guidance, Waste Management Regulations and Environment and Heritage Service guidance. The methods used for denaturing should be in accordance with PSNI guidance.

The Environment Agency (EA), which covers England and Wales, has decided that it is not in the public interest to expect pharmacies to obtain a waste management licence for denaturing Controlled drugs as this is seen by the EA as a 'low risk' activity. The Environment and Heritage Service in Northern Ireland has taken the following position: "EHS have considered the risks posed by the destruction of controlled drugs in a pharmacy and have concluded that it will not normally take enforcement action against persons carrying out this activity providing the subsequent movement and disposal of the denatured drugs is in compliance with all relevant waste legislation… Pharmacies must ensure that the activities they undertake to denature controlled drugs protect the environment, workers and others within the pharmacy." The EHS may take appropriate action where it considers that there is a risk to human health and/or the environment. It may also amend its position if there are regulatory changes, future government guidance or in the

light of experience of this type of activity. It is therefore essential that local policies and procedures for destruction of Controlled drugs not only ensure effective destruction but also protect the environment and people in the pharmacy.

7.15.1 Destruction of stock controlled drugs

Any pharmacy-held stock of obsolete, expired or unwanted Schedule 2 controlled drugs not returned by patients, that requires destruction can only be destroyed in the presence of a person authorised by the DHSSPS.

7.15.1.1 Authorised witnesses currently include pharmacy inspectors,and other named persons employed by Trusts, who have been authorised and trained by DHSSPS.

7.15.1.2 Until they can be destroyed, obsolete, expired and unwanted stock controlled drugs requiring safe custody, according to arrangements appropriate to their schedule, must be kept segregated from other controlled drugs in the CD cupboard. Stock controlled drugs awaiting destruction should be clearly marked in order to minimise the risk of errors and inadvertent supply.

7.15.1.3 When stock Schedule 2 controlled drugs are destroyed, the following details must be entered into the CD register:

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed
- Date of destruction
- Signature of the authorised person in whose presence the drug was destroyed

7.15.1.4 It is good practice for the person carrying out the destruction to also sign against this record.

7.15.2 Destruction of controlled drugs returned by patients

These are controlled drugs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used by the patient or their representative to the pharmacy.

Controlled drugs that have been returned by patients do not form part of the pharmacy stock and can be destroyed without the presence of an Authorised Person.

7.15.2.1 Although recording of patient-returned controlled drugs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2002 it is good practice to keep a record.

7.15.2.2 A record of controlled drugs returned by patients should be kept as above and a record of their destruction should be made. As a matter of good practice, destruction should be witnessed, preferably by a pharmacist or pharmacy technician.

7.15.2.3 The record of these destructions should be made somewhere other than the CD register – for example in a separate "Destruction Book" designated for that purpose. It is recommended that the following details are recorded:

- Date of return of the controlled drugs
- Name, quantity, strength and form of the controlled drugs
- Role of the person who returned the controlled drugs (if known)
- Name and signature of the person who received the controlled drugs
- Patient's name and address (if known)
- Names, positions and signatures of the person destroying the controlled drugs and the witness
- Date of destruction
- Any other comments relevant to the receipt or destruction of that particular dispensed medicine

7.15.2.4 Controlled drugs requiring safe custody awaiting destruction should be stored in the CD cabinet separately from pharmacy stock controlled drugs.

7.15.2.5 Destruction of controlled drugs should occur regularly and with sufficient frequency to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment.

7.15.3 Methods of disposal for Controlled drugs

Denatured controlled drugs for disposal should be placed in suitable waste containers which are then sent for incineration and should not be disposed of in the sewerage system. The containers of waste should be labelled, "*contains pharmaceutical waste – for incineration*".

The Home Office has advised that Schedule 2, 3 and 4 Part I controlled drugs must be denatured before being placed into waste containers.

7.15.3.1 Wherever practicable, CD denaturing kits should be used to denature controlled drugs. Where this is not possible or practical other methods of denaturing may be used. Used denaturing kits should be placed in pharmaceutical waste bins that are destined for incineration. Regardless of the methods used, measures should be taken to ensure safety of personnel and non-contamination of the environment.

7.15.3.2 Details of suitable methods for destruction of Controlled drugs in different dosage forms can be found in Pharmaceutical Society of Northern Ireland guidance www.psni.org.uk/documents/600/GuideLegalRequirements+MedsHumanUseControlledDrugs.pdf and it is strongly recommended that these methods are used.

7.15.3.3 Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

Where denaturing kits are used, their use should be included in an SOP.

Small unrequired excesses are most likely to arise when products are being prepared. In these circumstances, the controlled drug has already been issued to the extemporaneous preparation area or aseptic preparation area and is no longer part of the pharmacy CD stock. A full audit trail should be maintained. The worksheet should show the amount used and the amount wasted, for example: "2.5ml used 0.5ml wasted".

As a matter of good practice, the disposal of the part dose should be witnessed and recorded on the worksheet. Both people should sign the worksheet.

8 Staff training for management of controlled drugs

The Accountable Officer is responsible for ensuring that members of staff who are involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training to enable them carry out their duties.

Staff should receive appropriate training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs and then regularly thereafter. The frequency of training should be determined locally.

Staff should be informed and, if necessary, receive additional training when SOPs are revised or amended and when new CD products or systems are introduced.

Glossary of terms

Administer	To give a medicine either by introduction into the body, whether by direct contact with the body or not, (eg orally or by injection) or by external application (eg application of an impregnated dressing). There are specific definitions in medicines legislation as follows: “external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations; "parenteral administration" means administration by breach of the skin or mucous membrane.
Chief Pharmacist	In the context of this document the term is used to describe the pharmacist with overall responsibility for the hospital pharmacy. In some circumstances consultation may be necessary with a higher level of pharmacy management.
Controlled Drugs (CDs)	The drugs listed in Schedule 2 to the Misuse of Drugs Act 1971. These drugs are categorised in schedules 1-5 of the Misuse of Drugs Regulations (Northern Ireland) 2002 (as amended). Drugs listed in the different MDR schedules are subject to differing levels of control but all are controlled drugs.
CD record book (CDRB)	Bound book in which records are made of controlled drugs received and supplied in wards, theatres and departments.
CD register	A “register” as specified in the Misuse of Drugs Regulations 2002 (as amended) means either a bound book, which does not include any form of loose leaf register or card index, or an approved computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.
Discrepancy	Difference between the amount shown in the register or record book and the amount that is physically present.
Designated body/bodies	Health care organisations - the Board, HSC Trusts, the Northern Ireland Ambulance Service, Independent Hospitals – as defined in Regulation 3 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.
Dispense, dispensing	Dispensing of controlled drugs: preparation (including compounding, dissolving, diluting, packing and labelling.) In some contexts it may include the transfer (supply) of medicines to individual patients.

Diversion	Removal of controlled drugs for unauthorised use; theft
Duty Pharmacist	Senior pharmacist on duty for the time being
Healthcare organisations	Organisations responsible for the delivery of healthcare. Includes Trust hospitals and independent hospitals.
Local Intelligence Network	A network lawfully established by the Accountable Officers for sharing information regarding the management and use of controlled drugs.
"may"	Used in this document in connection with recommendations concerned with good practice if they are relevant to local circumstances.
MDR	Misuse of Drugs Regulations – Regulations made under the Misuse of Drugs Act (1971).
"must"	Used in this document in connection with legal requirements e.g. "records of schedule 2 controlled drugs received and supplied by a pharmacy must be kept in a CD register."
Operating Department Practitioner (- Registered Operating Department Practitioner)	Operating Department Practitioner whose name is on the register of the Health Professions Council and should be a member of the College of Operating Department Practitioners – see Appendix 2
Order	In the context of controlled drugs: To make a formal order for controlled drugs. Can only be done by someone who is entitled to be in possession of controlled drugs (as defined in current MDR). Must be addressed to a suitable pharmaceutical supplier.
Patient Group Directions (PGD).	Written directions from a senior doctor (or dentist) and a senior pharmacist and a representative of the appropriate organisation giving specified registered nurses, pharmacists and other specified health professionals a general authority to supply and administer specified medicines to patients, who are not individually identifiable, in specified clinical situations.
PCA	Patient-controlled analgesia
Pharmacist (– Registered Pharmacist)	Person registered in the register of pharmacists maintained by the Pharmaceutical Society of Northern Ireland
Pharmacy technician	Pharmacy technicians in Northern Ireland are not currently registered with the Pharmaceutical Society of Northern Ireland and are not, therefore, regulated professionals. Their activities related to controlled drugs should be circumscribed by standard operating procedures and must be carried out under the authority of a pharmacist.
PODs	Patient's own drugs. In this context - controlled drugs brought into the hospital by the patient on admission.
Prescribe	Prescribing is the ordering of a medicine for an individual patient. In medicines legislation, certain medicines may be supplied only in accordance with a prescription by a doctor, dentist or other appropriate practitioner, and which meets the conditions specified in the Human Medicines Regulations 2012. The term has however become commonly used to describe authorising - by means of an NHS prescription - the

	supply of any medicine (Prescription Only Medicine, Pharmacy or General Sales List medicine) at public expense to a named patient;
Registered nurse in charge	The registered nurse who is in charge for the time being (senior registered nurse on duty) and is therefore responsible for management of controlled drugs.
Relevant persons	Are defined in the Health Act 2006 and see also the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009
Requisition	In the context of controlled drugs: To make a formal, written request, compliant with Regulation 14(6) of the Misuse of Drugs Regs (NI) 2002, for a supply of a controlled drug for use in a ward or department. The requisition must be signed by an authorised signatory. Requisitions are usually made on stationery designed specifically for that purpose. Confusingly these books are often called "Controlled Drug Order Books".
Responsible body	Bodies listed in regulation 22 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. Includes: Designated bodies, the Department, the Regulation and Quality Improvement Authority, the Regional Business Services Organisation, the Police Service, Regulatory Bodies.
Senior Assistant Technical Officer	In this context, a member of the pharmacy staff who has received in-house training for specific duties. Not a pharmacy technician.
Service Level Agreement (SLA)	Written agreement between two parties that specifies the service to be provided
"should"	Used in this document in connection with recommendations concerned with good practice
Standard Operating Procedure (SOP)	A standard operating procedure specifies in writing what should be done, when, where and by whom in order to manage safely and accountably any set of processes, in this case around the total management of controlled drugs.
Supervisor of midwives	A person appointed by the local supervising authority to exercise supervision over midwives in its area in accordance with rule 11(1) of the Nursing and Midwifery Council (Midwives) Rules 2004 (SI 2004/1764) www.hmso.gov.uk
Supply	In the context of legal supply of controlled drugs: making a supply against a signed order, requisition, Patient Group Direction or a prescription.
Transcribe	To copy the details of one document on to another.

Appendix 1: Legislation for the management of Controlled drugs

Misuse of Drugs Act 1971

The Misuse of Drugs Act (MDA) 1971 and its Regulations provide the statutory framework for the control and regulation of controlled drugs. The primary purpose of the MDA is to prevent misuse of controlled drugs. The MDA 1971 makes it unlawful to possess or supply a controlled drug unless an exception or exemption applies. A controlled drug is defined as any drug listed in Schedule 2 to the Act.

Misuse of Drugs Regulations (Northern Ireland) 2002 (MDR)

The use of controlled drugs in medicine is permitted by the Misuse of Drug Regulations (MDR). The MDR classify the drugs in five schedules according to the different levels of control required (see below). Schedule 1 controlled drugs are subject to the highest level of control, whereas Schedule 5 controlled drugs are subject to a much lower level of control.

The MDR are periodically amended and revised. The MDR currently in force and its amendments can be found at the website of the Office of Public Sector Information (www.opsi.gov.uk)

Schedule 1 (CD Licence)

Schedule 1 drugs include hallucinogenic drugs such as coca leaf, lysergide and mescaline. Production, possession and supply of drugs in this Schedule are limited, in the public interest, to research or other special purposes. In Northern Ireland only certain persons can be licensed by the DHSSPS to possess them for research purposes. Practitioners (e.g. doctors, dentists and veterinary surgeons) and pharmacists may not lawfully possess Schedule 1 drugs except under licence from the DHSSPS.
The drugs listed in Schedule 1 have no recognised medicinal use although Sativex© (a cannabis based product), for which there is an open general licence, is currently being supplied on a named-patient basis.

Schedule 2 (CD POM)

Schedule 2 includes more than 100 drugs such as the opioids, the major stimulants, secobarbital and amphetamine.

Safe custody
Schedule 2 controlled drugs (except secobarbital) are subject to safe custody requirements (under the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973, (see below)). They must be stored in a locked receptacle, such as

an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the controlled drug or a person authorised by them.

Schedule 2 controlled drugs may be manufactured or compounded by a licence holder, a practitioner, a pharmacist or a person lawfully conducting a retail pharmacy business acting in their capacity as such.

A nurse independent prescriber acting in her capacity as such, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2, 3, 4 and 5 for the purposes of administration in accordance with regulations and any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2, 3, 4, and 5 for the purposes of administration in accordance with the regulations.

A pharmacist may supply schedule 2 controlled drugs to a patient only on the authority of a prescription in the required form issued by an appropriate prescriber.

Schedule 2 controlled drugs may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of an appropriately qualified prescriber who is authorised to prescribe Schedule 2 controlled drugs

Nurse Independent Prescribers and Pharmacist Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer any controlled drug in Schedule 2, 3, 4, and 5 of the Regulations, but not in relation to cocaine, diamorphine or dipipanone for addicts, otherwise than for the purpose of treating organic disease or injury.

Record-keeping
There is a statutory requirement for pharmacy departments to keep a register for Schedule 2 controlled drugs and this register must comply with the requirements of the Misuse of Drugs Regulations 2002. Wards and departments should also keep a Controlled Drugs Record Book (often loosely referred to as a register) for Schedule 2 controlled drugs
Midwives must keep a register for the Schedule 2 controlled drugs that they are permitted to possess and administer.

A licence is required to import or export drugs in Schedule 2.

Destruction
The destruction of Schedule 2 CD stock must only take place in the presence of an appropriately authorised person.

Schedule 3 (CD No Register)

Schedule 3 includes a small number of minor stimulant drugs and other drugs, which are less likely to be misused than drugs in Schedule 2, or are less harmful if misused.

Safe custody
Some Schedule 3 controlled drugs are exempt from safe custody requirements and may be stored on the open dispensary shelf. Non-exempt examples include flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

Record keeping
There is no legal requirement to record transactions involving Schedule 3 controlled drugs in a CD register. Some organisations keep a non-statutory register as a matter of good practice.

Invoices must be retained for a minimum of two years.

Schedule 3 controlled drugs are subject to full import and export control.

Destruction
The requirements for destruction do not apply unless the controlled drugs are manufactured by the entity in legal possession. However, Home Office has advised that drugs in Schedules 3 and 4 Part 1 should be denatured before disposal.

Schedule 4 (CD Benz and CD Anab)

Schedule 4 is split into two parts.

Part 1 (CD Benz) contains most of the benzodiazepines, plus eight other substances including zolpidem, fencamfamin and mesocarb.

Part 2 (CD Anab) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoreceptor stimulant) and growth hormones (5 polypeptide hormones).

Unauthorised possession or supply of a drug in Schedule 4 Part 1 (CD Benz) is an offence. Possession and supply by practitioners and pharmacists acting in their professional capacities is authorised.

There is no restriction on the possession of a Schedule 4 Part 2 (CD Anab) drug. Unauthorised supply to a third party is unlawful.

Drugs in Part 1 (CD Benz) are subject to full import and export control and a DHSSPS licence is also required for the importation and exportation of substances in Part 2 (CD Anab) unless the substance is imported in person and is for administration by the person to himself.

All substances in Schedule 4 are exempt from safe custody requirements, with destruction requirements only applying to importers, exporters and manufacturers. It is good practice to store securely excess stock of Schedule 4 controlled drugs.

Prescription-writing requirements for these controlled drugs do not apply, except those requirements laid out in the Human Medicines Regulations 2012. CD registers do not need to be kept for Schedule 4 drugs, although records should be kept if such controlled drugs are compounded, or if a licensed person imports or exports such drugs (see Regulation 22 of the Misuse of Drugs Regulations 2002).

Schedule 5 (CD Invoice)

Schedule 5 contains preparations of certain controlled drugs (e.g. codeine, pholcodine, morphine), which are exempt from full control when present in medicinal products of low strengths, as their risk of misuse is reduced.

There is no restriction on the import, export, possession, administration or destruction of these preparations and Safe Custody Regulations do not apply.

Preparations containing not more than 0.1% cocaine are no longer exempt from prohibitions on import, export and possession.

A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any controlled drug in Schedule 5.
A nurse independent prescriber acting in her capacity as such, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2, 3, 4, and 5 for the purposes of administration in accordance with regulations and any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2,3,4, and 5 for the purposes of administration in accordance with the regulations.

Invoices must be retained for a minimum of two years.

Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973

The Safe Custody Regulations 1973 impose controls on the storage of controlled drugs. The degree of control depends on the premises within which the drugs are being stored.

All Schedule 2 and certain non-exempted Schedule 3 controlled drugs should be stored securely in accordance with the Misuse of Drugs (Safe Custody) Regulations. These Regulations state that such controlled drugs must be stored in a cabinet or safe, locked with a key. It should be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts that are not accessible from outside the cabinet.

Misuse of Drugs (Notification of and Supply to Addicts) (Northern Ireland) Regulations 1973

These Regulations prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under DHSSPS licence. A licence is not required with such drugs for the treatment of organic disease or injury. Doctors must notify the DHSSPS of patients whom they consider to be addicted to specified controlled drugs.

Medicines Act 1968 and the Human Medicines Regulations 2012

This Act (much of it repealed in August 2012), and particularly the Human Medicines Regulations 2012 set out the requirements for the legal sale, supply and administration of medicines. They also allow certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, enable midwives to supply and/or administer diamorphine, morphine, or pethidine. A number of healthcare professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups, but not all, are permitted to possess, supply or administer controlled drugs in accordance with a PGD under Misuse of Drugs legislation

Health Act 2006

The key provisions of the Act are:

- Designated bodies (as prescribed by regulations) are required to appoint an Accountable Officer with responsibilities (prescribed by regulations) in connection with the safe and effective management of controlled drugs
- A duty of collaboration is placed on responsible bodies (as prescribed by regulations) to share intelligence on controlled drug issues
- A power of entry and inspection is granted for the police and other nominated people to enter premises to inspect stocks and records of controlled drugs

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

These regulations, made under the Health Act 2006, set out the requirements for certain healthcare organisations and independent hospitals to appoint an Accountable Officer and describe the duties and responsibilities of Accountable Officers related to the management and use of controlled drugs.
The Regulations also require specified bodies to co-operate with each other, including with regard to sharing of information about concerns related to the use and management of controlled drugs, and set out further arrangements relating to powers of entry and inspection.

Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007

This Regulation amends the Misuse of Drugs Regulations (Northern Ireland) 2002 and the Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973 to (among other matters):

Update the references to premises covered by the Safe Custody Regulations

Update references to “sister” to “senior registered nurse”

Replace the prescribed form of the CD register with prescribed headings for entries in the register

Permit ODPs to possess and supply Controlled drugs in accordance with prescriber directions

Appendix 2: Operating Department Practitioners

Operating Department Practitioner (ODP) is defined in the Misuse of Drugs Regulations 2002 (as amended by SR 2007/348) as a person who is registered under the Health Professions Order 2001 (SI 2001/254 as amended by SI 2004/2033) as an operating department practitioner. The amendment to the Misuse of Drugs Regulations afforded to this group of registered professionals similar (but not identical) authority to that already granted to the "senior register nurse (formerly 'sister') or acting senior registered nurse for the time being in charge of a ward, theatre or other department…" The ODP was granted authority to possess and supply controlled drugs supplied to him by the person responsible for dispensing and supply of medicines at the hospital. The ODP may supply to a patient in a ward, theatre or other department only in accordance with the directions of an appropriate prescriber who may legally prescribe that drug. The amendment to the Misuse of Drugs Regulations did not specify that the ODP had to produce the same requisition as required of the senior registered nurse in charge. Because the ODP's authority to "possess and supply" implies the ability to obtain the drugs, the Home Office has stated that the ODP's authority is sufficient to "order" controlled drugs from the hospital pharmacy. Until such time as the Misuse of Drugs Regulations are further amended to require the same requisition from the ODP as the nurse in charge of a ward, hospitals should ensure that, as a matter of good practice and/or in order to comply with SOPs, supply of controlled drugs to ODPs should still be dependant upon the receipt by the hospital pharmacy of a requisition of exactly the same nature that a nurse in charge of a ward would present. Furthermore hospitals should specify in policy and SOPs which registered professional (senior nurse in charge or ODP) is responsible for the stock of controlled drugs in the particular ward, theatre or other department. Whereas the legislation grants authority to the senior (or acting senior) registered nurse in charge, **any** ODP is permitted to possess and supply controlled drugs under certain conditions. This guidance document has followed the position of the Department of Health document in referring to the senior registered nurse in charge or **ODP in charge** although it is recognised that this goes beyond the actual wording of the legislation. The intention is to indicate that it should be crystal clear in policy and procedures who is responsible for the controlled drug stock held in any theatre, ward or other department.

Appendix 3: The Accountable Officer

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 SR2009/225 ; www.legislation.gov.uk_ Further detail is also given in 'Safer Management of Controlled Drugs: A Guide to Strengthened Governance Arrangements in Northern Ireland' in the Accountable Officer section of the Department website www.dhsspsni.gov.uk

The following paragraphs provide a summary of the main provisions.

Persons who may be appointed as Accountable Officers

Each HSC Trust and other designated bodies must appoint an Accountable Officer who is a fit, proper and suitably experienced person in a senior role within the organisation. Where designated bodies are large organisations, the Accountable Officer may consider appointing Designated Officers to assist in the day-to-day discharge of responsibilities.

The Accountable Officer should not be personally involved in the routine prescribing, supply, administration or disposal of controlled drugs. An organisation can have an Accountable Officer who has occasional need to handle Controlled drugs (for example, in emergencies), but if this is the case, their use of Controlled drugs should be open to the scrutiny of another senior member of the organisation or Accountable Officer of another body. Individuals such as Chief Nurses, Medical Directors and Chief Pharmacists can be appointed as Accountable Officers if they meet these criteria. Accountable Officers should call on other Accountable Officers if a conflict of interest arises.

The organisation's controlled drugs policy should specify the person whom staff should approach if they have concerns about the practice of their Accountable Officer.

The Accountable Officer for an HSC Trust should liaise with the Chair of the Local Intelligence Network.

Responsibilities of the Accountable Officer

In discharging his responsibilities, an Accountable Officer must have regard to best practice in relation to the management and use of controlled drugs.
The Accountable Officer must:

- Secure the safe and effective use and management of controlled drugs within local organisations subject to his oversight (i.e. the organisation and those with which it contracts).

(For some of the following duties and responsibilities the regulations frequently use the form of words, "The Accountable Officer must ensure/establish …, or ensure that his designated body ensures/establishes …")

- Establish, operate and periodically review appropriate systems for the safe management of controlled drugs
- Ensure that all arrangements comply with relevant statutory requirements
- Ensure that adequate and up-to-date standard operating procedures are in place for the management and use of controlled drugs
- Establish and operate appropriate arrangements for securing the safe destruction and disposal of controlled drugs
- Ensure monitoring and auditing of the management and use of controlled drugs within the organisation and take action where necessary. The following must be in place:
    - Systems to alert the Accountable Officer to complaints or concerns involving the management of controlled drugs
    - An incident reporting system to capture untoward incidents involving the management or use of controlled drugs
- Establish and operate arrangements for analysing and responding to untoward incidents involving the management or use of controlled drugs
- Ensure that individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training. Arrangements must be in place for relevant individuals:
    - to receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs
    - to be informed when any local standard operating procedures for controlled drugs are subsequently reviewed or amended
- Monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance. The Accountable Officer must, where appropriate, provide for the following:
    - Recording concerns raised in relation to the management or use of controlled drugs by a relevant individual
    - Assessing and investigating concerns raised regarding the management or use of controlled drugs by a relevant individual
    - Determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers should be shared with a responsible body.

The Accountable Officer should be aware that unusually high usage of some Controlled drugs or unusually high numbers of breakages could indicate misuse.

The Accountable Officer in Secondary Care should also monitor prescriptions that are written in hospital but dispensed in the community.

- Maintain a record of concerns regarding relevant individuals. Such records may be paper-based or electronic. The Accountable Officer must:
    - Establish and operate appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a relevant individual. This must include a system to ensure that access to such records is limited to the Accountable Officer, his staff and others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.
    - Ensure that adequate records are compiled, which must include (but not be limited to), as appropriate:
        - the date on which the concern was made known to the accountable officer;
        - dates on which the matters that led to the concern took place;
        - details regarding the nature of the concern;
        - details of the relevant individual in relation to whom the concern was expressed;
        - details of the person who, or body which, made known the concern;
        - details of any action taken by the designated body in relation to the concern;
        - the assessment of whether information in relation to the concern should be disclosed to another responsible body
        - if information regarding the concern is disclosed to another responsible body, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.

- Assess and investigate concerns. The accountable officer must:
    - Establish and operate appropriate arrangements for assessing and investigating concerns about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual
    - Take appropriate action if there are well-founded concerns

- Establish and operate appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards designated body, a relevant individual, appear to be well-founded.

- Establish arrangements for sharing information. The Accountable Officer must:
  - Establish and operate appropriate arrangements for ensuring the proper sharing of information, by his designated body with other responsible bodies regarding the management and use of controlled drugs
  - Provide a quarterly report to the Chair of the Local Intelligence Network
  - Cooperate with other organisations including the Department, the RQIA, the Business Services Organisation and the police as circumstances require.

- Participate in the Local Intelligence Network

Appendix 4: Useful contacts

British Medical Association
BMA House
Tavistock Square
London
WC1H 9JP
Tel: 0207 387 4499
Fax: 0207 383 6400
Website: www.bma.org.uk/

Community Practitioners' and Health Visitors Association
33-37 Moreland Street
London
EC1V 8HA
Tel: 0207 505 3000
Website:
www.amicustheunion.org/cphva/

Council for Healthcare Regulatory Excellence
157-197 Buckingham Palace Road
London
SW1W 9SP
Tel: 0207 389 8030
Fax: 0207 389 8040
Website: www.chre.org.uk

Department of Health
Richmond House
79 Whitehall
London
SW1A 2NS
Tel: 0207 210 4850
Website: www.dh.gov.uk

Department of Health, Social Services and Public Safety
Pharmaceutical Advice and Services
Room D4.5,
Castle Buildings
Stormont
Belfast
BT4 3SQ
Tel: 028 9052 8688
Fax: 028 9052 2335
Website: www.dhsspsni.gov.uk

Dispensing Doctors' Association
Low Hagg Farm
Starfitts Lane
Kirbymoorside
North Yorkshire
YO62 7JF
Tel: 01751 430835
Fax: 01751 430836
Website: www.dispensingdoctor.org

General Medical Council
Regent's Place
350 Euston Road
London
NW1 3JN
Tel: 0845 357 3456
Website: www.gmc-uk.org

Health and Social Care Board
Headquarters
12-22 Linenhall Street
Belfast
BT2 8BS
Tel: 028 9032 1313
Website: www.hscboard.hscni.net

Home Office Drugs Licensing Branch
2 Marsham Street
London
SW1P 4DF
Tel: 0207 035 0483
Website: www.homeoffice.gov.uk/drugs/licensing/

Home Office Drug Legislation Team
2 Marsham Street
London
SW1P 4DF
Tel: 0207 035 0464
Website: www.homeoffice.gov.uk

Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Tel: 0207 084 2000
Fax: 0207 084 2353
Website: www.mhra.gov.uk

National Clinical Assessment Service
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn BT28 1TW
Tel: 02892663241
Website: www.ncas.nhs.uk

National Patient Safety Agency
4-8 Maple Street
London
W1T 5HD
Tel: 0207 927 9500
Website: www.npsa.nhs.uk

National Pharmacy Association
Mallinson House
38-42 St Peter's Street
St Albans
Hertfordshire
AL1 3NP
Tel: 01727 832161
Fax: 01727 840858
Website: www.npa.co.uk

National Prescribing Centre
The Infirmary
70 Pembroke Place
Liverpool
L69 3GF
Tel: 0151 794 8134
Fax: 0151 794 8139
Website: www.npc.co.uk (Internet)
www.npc.nhs.uk (NHSNet)

National Treatment Agency
8th Floor, Hercules House
Hercules Road
London
SE1 7DU
Tel: 020 7261 8801
Fax: 020 7261 8883
Website: www.nta.nhs.uk

Nursing and Midwifery Council

23 Portland Place
London
W1B 1PZ

Tel: 020 7637 7181
Fax: 020 7436 2924
Website: www.nmc-uk.org

Pharmaceutical Society of Northern Ireland

73 University Street
Belfast
BT7 1HL

Tel: 028 9032 6927
Fax: 028 9043 9919
Website: www.psni.org.uk

Prescribing Support Unit

The Health and Social Care
Information Centre
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

Tel: 0113 254 7041
Fax: 0113 254 7097
Website: www.ic.nhs.uk/psu

Regional Business Services Organisation

2 Franklin Street
Belfast
BT2 8DQ

Tel: 028 9032 4431
Website: www.hscbusiness.hscni.net/

The Regulation and Quality Improvement Authority

9th Floor Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

Tel: 028 9051 7500
Website: www.rqia.org.uk

Royal Pharmaceutical Society

1 Lambeth High Street
London
SE1 7JN

Tel: 0207 572 2737
Fax: 020 7735 7629
Website: www.rpharms.com

Appendix 5: Patient Information

NHS Direct

The NHS Direct website has developed a Common Health Question about Controlled drugs specifically to inform the public. It is entitled 'What is a controlled drug (medicine)?' and is available at
www.nhs.uk/chq/Pages/1391.aspx?CategoryID=73&SubCategoryID=101
The text defines a controlled drug in legal terms, how the Regulations apply to them and directs patients to information about requirements for travelling abroad.

HOME OFFICE
Useful advice for patients travelling with controlled drugs can be accessed at
www.homeoffice.gov.uk/drugs/licensing/personal/

Medicines Guides

Medicine Guides provide a source of information for members of the public who are looking for information about individual medicines that is up-to-date, reliable and easy to understand. Medicine Guides are being developed as part of the Medicines Information Project which aims to provide people with information about medicines, conditions and the different treatment options available.

The Medicine Guides on controlled drugs can be found on the www.medicines.org.uk website which is published by Datapharm Communications. There is a link to the NHS Direct Common Health Question within each Guide. Guides for the controlled drugs that have been published to date can be accessed at www.medguides.medicines.org.uk/cd.

Appendix 6: Contributors

The following individuals and organisations are among those who contributed to the design and content of this guidance and/or the original Department of Health document:

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Appendix 7

Suggestions for Future Revisions

Name:	
Organisation:	
Section number Indicate **page/section heading** or **'general'** if your comment relates to the whole document	**Comments** **Please insert each new comment in a new row.**
P.24, Record keeping	*In our hospital we refer to…*

Department of
Health, Social Services
and Public Safety
www.dhsspsni.gov.uk

Safer Management of Controlled Drugs

A Guide to Strengthened Governance Arrangements in Northern Ireland

Introduction

1. This guidance sets out strengthened governance arrangements for the management and use of controlled drugs in Northern Ireland. These arrangements are underpinned by the Health Act 2006 and the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 as amended by the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015 (the Regulations).

The guidance has been developed from original guidance issued by Department of Health (DH) (England) and the Scottish Executive to support the work of their Accountable Officers. The Department of Health, Social Services and Public Safety (the Department) is grateful to DH (England) and the Scottish Executive for the use of their guidance documents and for the support provided to the Department in the preparation of this document.

Please note that the Department does not accept responsibility for inaccuracies in this guidance. Organisations must seek their own independent legal advice.

2. The Fourth Report of the Shipman Inquiry[1] identified a number of serious shortcomings in the systems used for the management of controlled drugs and made recommendations to improve their management. The Northern Ireland response to the Shipman Inquiry's Fourth Report was set out in "Improving Patient Safety – Building Public Confidence"[2]. It is recognised that the recommendations within the Fourth Report related, in the main, to the situation in Great Britain at the time of the Inquiry and that the controlled drug monitoring arrangements operating in Northern Ireland were most favourably commented upon by the Inquiry Chair at that time.

3. The Shipman Inquiry identified the key strengths of the current Department's Medicines Regulatory Group (formerly known as the Medicines Inspection and Investigation Team) as its centralised nature, integration within the Department, expertise and multi-disciplinary nature, existing integration and collaboration with other professional bodies and investigation/enforcement authorities.

4. The Department favoured a system which would work within and alongside the existing governance arrangements and build on, and use, the expertise of the current inspection and investigation resources.

5. It was anticipated that the procedures would result in a significant improvement to existing arrangements, being better co-ordinated and integrated within the overall framework for improving quality in healthcare. They are intended to encourage good practice in the management of

[1] See *The Regulation of Controlled Drugs in the Community, The Fourth Report of the Shipman Inquiry* (http://www.the-shipman-inquiry.org.uk/4rpage.asp)
[2] "Improving Patient Safety – Building Public Confidence" www.dhsspsni.gov.uk/improving_patient_safety_-_building_public_confidence.pdf

controlled drugs as well as help to detect unusual or poor clinical practice or systems, criminal activity or risk to patients.

Legislative changes

6. Parliament considered that new legislation was necessary to respond to a number of the recommendations in the Shipman Inquiry report. Therefore, the Health Act 2006, which received Royal Assent in July 2006, included measures to improve and strengthen the management and use of controlled drugs.

7. The Regulations made under the Health Act 2006 are called The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009[3] which came into operation on 1 October 2009. These Regulations were subsequently amended by the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015 which came into operation on 16 July 2015.

8. The governance arrangements have been implemented in a way that supports healthcare professionals, encourages good practice and does not deter the use of controlled drugs when clinically required by patients. Furthermore it is essential that the arrangements ensure potential criminality is identified and reported to the police at the earliest opportunity.

9. This guidance describes the arrangements in Northern Ireland.

Implementation

10. The three key elements of the legislation are:

- Accountable Officers and their duties
- Powers of entry and periodic inspections
- Co-operation between health bodies and other organisations

11. The Health Act 2006 requires “Designated Bodies” to appoint or nominate an Accountable Officer, either one per organisation or, within parameters, shared between organisations. For the purposes of the Act, “Designated Bodies” are those that are “directly or indirectly concerned with the provision of health care (whether or not for the purposes of the health service)”, or “otherwise carrying on activities that involve, or may involve, the supply or administration of controlled drugs”.

12. Designated Bodies include:

- the Health and Social Care Board (HSCB)
- Health and Social Care Trusts

[3] The Regulations can be accessed at http://www.opsi.gov.uk/sr/sr2009/nisr_20090225_en_1

- relevant independent Hospitals
- the headquarters in Northern Ireland of regular or reserve forces (armed forces)

13. The Act also introduces a duty of co-operation which requires Responsible Bodies to share information and concerns about the management and use of controlled drugs. Responsible Bodies include:

- Designated Bodies, as above
- the Department
- the Regulation and Quality Improvement Authority (RQIA)
- Police Service of Northern Ireland
- The Counter Fraud Unit of Business Services Organisation (BSO)
- regulatory bodies (including the Pharmaceutical Society of Northern Ireland, General Dental Council, General Medical Council, Nursing and Midwifery Council, Health and Care Professions Council and the Northern Ireland Social Care Council)

(Refer to Annex B for full list of Responsible Bodies).

14. The Act contains a power of entry and inspection for certain authorised persons to inspect controlled drugs and associated records. The inspection process is intended to monitor compliance, improve quality and support individual and organisational development. It may identify concerns which will be brought to the attention of the Accountable Officer.

15. More detailed information on the above aspects of the legislation can be found in the following Annexes.

Annex A - Accountable Officer
Annex B - Duty of Co-operation/Local Intelligence Network
Annex C - Monitoring
Annex D - Entry and Inspection
Annex E - Investigations
Annex F - Controlled drug declarations and self-assessments

Annex A

Accountable Officer

1. The Health Act 2006 and the Regulations require Designated Bodies to nominate or appoint an Accountable Officer (regulation 4 (as amended)) to be responsible for a range of measures relating to the monitoring of the safe management and use of controlled drugs within the organisation and take appropriate action where necessary. Designated Bodies include the Health and Social Care Board, Health and Social Care Trusts, relevant independent hospitals and the armed forces.

2. An Accountable Officer must be an officer or employee of the Designated Body who is a fit, proper and suitably experienced person and, other than for the armed forces, be a senior manager, or someone who is answerable to a senior manager, of the Designated Body.

3. In the case of the armed forces the Accountable Officer must be a senior officer with rank of lieutenant colonel, or a person of equivalent or superior rank.

4. For relevant independent hospitals it is likely that the Accountable Officer will be the registered manager. The decision will however be dependent on the person meeting the three conditions for appointment (regulation 4 (as amended).

5. Two or more Designated Bodies which are of the same type may jointly nominate or appoint one person to be their Accountable Officer so long as that person meets the requirements of regulation 4 (as amended). Each Designated Body must be satisfied that the Accountable Officer can discharge his/her responsibilities in relation to both.

6. The Accountable Officer must only exceptionally prescribe, supply, administer or dispose of controlled drugs as part of their duties. A Designated Body can nominate or appoint an Accountable Officer who has an occasional, exceptional role in the use of controlled drugs (for example, in emergencies). However, their use of controlled drugs should be open to the scrutiny of another person to whom they are answerable. They should have credibility with all healthcare and social care professionals and be of a sufficient seniority to be able to take action regardless of how a concern is raised. Individuals at levels equivalent to Medical Directors, Pharmacy Directors or Directors of Nursing, can be appointed as Accountable Officers if they meet the above criteria. The Accountable Officer can be a stand-alone or additional role depending on local circumstances. Designated Bodies should make it clear, as part of their monitoring systems whom people should approach if they have concerns about the practice of their own Accountable Officer.

7. A Designated Body (or, in the case of a joint appointment, the Designated Bodies acting jointly) must remove its Accountable Officer if he no longer satisfies the conditions set out above or if he is no longer considered fit to be an Accountable Officer (regulation 6 (as amended)). For the purposes of the Regulations, an Accountable Officer is found to be unfit if he wilfully,

negligently or through lack of competence breaches his duties as an Accountable Officer. A Designated Body must have in place a procedure (which may be part of its internal disciplinary procedures) for due consideration of matters which may lead to the removal of its Accountable Officer.

8. The Regulations set out Accountable Officers' responsibilities. The Accountable Officer will hold a senior post in the Designated Body and will carry overall responsibility for ensuring compliance with the arrangements in relation to the management of controlled drugs. Regulation 4 (as amended) requires that a Designated Body must provide its Accountable Officer with the funds and other resources necessary to enable him to carry out his responsibilities. Resources may include staff and it is anticipated that the Accountable Officer may identify individuals to assist them in the day-to-day discharge of their responsibilities.

9. Designated Bodies must inform the Department in writing of their nominations or appointments of Accountable Officers and of any subsequent changes. The Department maintains an up to date list of Accountable Officers in Northern Ireland which is published on the Departmental website (regulation 6A) and can be accessed at
www.dhsspsni.gov.uk/accountable-officer-contact-list.pdf
.

Accountable Officer Responsibilities

10. As set out in Regulations 8-18 (as amended), Accountable Officers need to ensure that they have systems in place for routinely monitoring the management and use of controlled drugs through pro-active analysis, identification of triggers for concern, and taking action (regulation 11). They also need to ensure that appropriate arrangements are in place for assessing and investigating concerns and that they are alerted to any significant findings (regulations 11 and 16). Where criminality is suspected the police should be notified.

11. Accountable Officers must have arrangements in place for the review of the management and use of controlled drugs within their Designated Body or ensure that the Designated Body does so. They must also ensure that any person or body acting on behalf of, or providing services under arrangements made with their Designated Body, establishes, operates and reviews appropriate arrangements for the management and use of controlled drugs.

12. The Accountable Officer will need to have or be able to access certain skills and expertise, including data analysis, investigative skills and networking. They may require investigative and administrative support and support from others such as the clinical governance lead, Medicines Management Adviser, the Department or the police as appropriate (see Annex C).

13. Designated Bodies may wish to consider consortia arrangements to support Accountable Officers in areas such as data analysis and investigative skills. These arrangements will be for local determination and should take into

account any previous history of concerns about controlled drugs misuse and predictions of the likely workload.

14. The Accountable Officer should also make sure that their Designated Body and contractors have suitable arrangements in place for the disposal of controlled drugs (regulation 10).

15. Accountable Officers are required to ensure that appropriate training is received by those carrying out their responsibilities under the Regulations and this should include regular and comprehensive training applicable to the role of the person involved in the prescribing, supplying, administering and disposal of controlled drugs.

16. Accountable Officers shall provide appropriate training on local standard operating procedures and ensure that anyone involved in working under the standard operating procedures is informed when a formal review takes place e.g. after the designated time period or after a critical incident.

17. The structures set up for the Accountable Officer should integrate with existing local performance structures and should relate to groups such as Drug and Therapeutic Committees and clinical governance committees. Accountable Officers are encouraged to share best practice and learn from each other through contact with other Accountable Officers.

Annex B

Duty of Co-operation

1. To maximise the effectiveness of the Regulations it is important that healthcare organisations, the police service, and others work together to share concerns on controlled drugs issues. The Regulations place a duty of co-operation on specified organisations ("Responsible Bodies" set out in regulation 22) permitting them to share information giving rise to concerns about the management or use of controlled drugs by any "relevant person".

The Health Act 2006 (Section 19) and the Regulations (regulation 23 (as amended)) made under the Act define the term "relevant person" and include any individuals, whether or not health care professionals, who are involved in any way with the management or use of controlled drugs on behalf of or providing services under arrangements with a designated body.

Furthermore the term "relevant person" includes any health care professional who provides services to private patients which involves the supply or administration of controlled drugs. Additionally any individual, whether or not they are a health care professional, who is engaged in any activity carried on with or on behalf of that health care professional is included in the definition of a "relevant person".

2. Under the arrangements the following are Responsible Bodies:

Primary Care

- Health and Social Care Board

The Accountable Officer may liaise with key members of staff including prescribing, medical, dental, nursing advisers and HR where appropriate to collate detailed information for the Local Intelligence Network (LIN).

Secondary Care

- Belfast Health and Social Care Trust
- Northern Health and Social Care Trust
- Southern Health and Social Care Trust
- South - Eastern Health and Social Care Trust
- Western Health and Social Care Trust

The Accountable Officer may liaise with key members of staff including clinical directors, pharmaceutical directors and HR, where appropriate, to collate detailed information for the LIN.

Other Designated Bodies

- Northern Ireland Ambulance Service Trust
- relevant independent hospitals
- armed forces

The Accountable Officer may liaise with key members of staff within their Designated Body to collate detailed information for the LIN.

Other Responsible Bodies

- Department
- RQIA
- Counter Fraud Unit of BSO
- Police Service of Northern Ireland
- Pharmaceutical Society of Northern Ireland
- General Medical Council
- General Dental Council
- Nursing and Midwifery Council
- Health and Care Professions Council
- Northern Ireland Social Care Council

Information-Sharing

3. A Responsible Body may disclose to any other Responsible Body any information which may help identify cases where action may need to be taken in respect of the management or use of controlled drugs. This enables bodies that have a concern to share it as soon as possible with any other bodies who may be affected or who may have complementary information.

4. Confidential information about patients must be removed where possible. If it is not possible to remove patient identifying details from confidential information, then the patient's consent should be sought wherever practicable (regulations 25 & 26 (as amended)).

5. In sharing such information, Responsible Bodies must have regard to the Data Protection Act 1998 and codes of practice on confidentiality - in particular the Caldicott principles i.e.

- Justify the purpose
- Do not use patient identifiable information unless it is absolutely necessary
- Use the minimum necessary patient identifiable information
- Access to patient identifiable information should be on a strict need to know basis
- Everyone should be aware of their responsibilities
- Understand and comply with the law.

6. Care should also be taken when sharing information about identifiable relevant persons and, where possible, individuals should be made aware of concerns raised about them unless, for example, disclosure would jeopardise the conduct of an investigation.

The Code of Practice on Protecting the Confidentiality of Service User Information www.dhsspsni.gov.uk/confidentiality-code-of-practice0109.pdf may be a helpful resource.

Local Intelligence Network (LIN)

7. The HSCB Accountable Officer is required to establish a network (a Local Intelligence Network) in which Responsible Bodies participate for sharing information regarding the management and use of controlled drugs. There is a single Local Intelligence Network, covering Northern Ireland.

8. The LIN will facilitate timely and appropriate sharing of information, and enable bodies that have a concern about the activities covered by this legislation to liaise at an early stage with other local agencies who may be affected or who have complementary information.

9. Members of the LIN may also want to involve others as appropriate such as Drug Action Teams and Local Supervising Authority Midwifery Officers. However, this list is not exhaustive and it is crucial that this forum takes account of the diversity of interests both within and outwith the health service including manufacturers, wholesalers and Veterinary Practitioners.

10. The LIN meets on a quarterly basis and members have agreed their Terms of Reference and guidance to support the managing and sharing of concerns. An Accountable Officer may request that an incident panel be convened by the HSCB Accountable Officer to investigate a concern and to

make recommendations. Each body will retain responsibility for taking appropriate action where required.

11. In addition to the quarterly meetings, members of the LIN may develop a centrally maintained, confidential database to support the effective sharing of information throughout the network.

Occurrence Reports

12. Accountable Officers must provide the HSCB Accountable Officer with a quarterly occurrence report (regulation 29 (as amended)). The HSCB Accountable Officer may require an Accountable Officer to provide occurrence reports more often than quarterly should he have a concern about that Designated Body. This report shall provide details of any concerns that the Designated Body may have identified regarding the management or use of controlled drugs or confirm that it has not identified any such concerns.

Request for Additional Information

13. There may be instances when a Responsible Body considers that it may require additional information from another Responsible Body in order to determine whether or not action is necessary (regulation 26 (as amended)). This additional information may be specific to the management or use of controlled drugs or could be, for example, fitness to practise information. Where a Responsible Body has received such a request in writing it must decide within a reasonable period of time whether or not to disclose the additional information. The decision about disclosure should take account of issues of confidentiality.

Restrictions Relating to Disclosures

14. Where a Responsible Body has an Accountable Officer, any information disclosed under the Regulations must ONLY be made by or to the Accountable Officer or his staff. The information may ONLY be used for identifying cases, considering and taking action in respect of concerns relating to the management or use of controlled drugs (regulation 27). In particular, the Responsible Body must ensure that appropriate measures are taken to prevent unauthorised access, processing, or disclosure of the information.

Record Keeping

15. Responsible Bodies must keep records (either paper or electronic) of any decisions to disclose information, details of the nature of the information disclosed, details of the Responsible Body to which the information was disclosed and any other relevant details (regulation 28).

16. Responsible Bodies must also keep a record (either paper or electronic) of any requests received from another Responsible Body to disclose information, details of the nature of the information disclosed, details

of the Responsible Body to which the information was disclosed and any other details considered to be relevant (regulation 28).

17. Responsible Bodies should refer to "Good Management, Good Records" for guidance on managing records in Health and Personal Social Services organisations in Northern Ireland.
http://www.dhsspsni.gov.uk/index/gmgr.htm

Taking Action

18. Responsible Bodies have a duty to co-operate in identifying cases, considering action and taking action, in respect of matters arising in relation to the management or use of controlled drugs by a relevant person (regulation 24). Action might include further investigation of issues of concern or the initiation of processes to protect the safety of the public, including professional disciplinary processes. Each organisation will be separately accountable for action within its own remit.

19. If a Responsible Body shares information under Regulations 25 and 26 (as amended) that indicates a concern about inappropriate or unsafe use of controlled drugs by a "relevant person", the Accountable Officer(s) concerned may make recommendations to the Responsible Body as to the actions that should be taken. For these purposes, the relevant Accountable Officer would be the Accountable Officer of the Designated Body responsible for entering into any arrangements (either directly or through another individual or body) with the person to provide services. The Responsible Body is any Responsible Body that could take appropriate action, including regulatory bodies and the police. Where the person does not provide services to a Designated Body, the HSCB Accountable Officer must seek to take reasonable steps to protect the safety of patients and the general public. If appropriate, the HSCB Accountable Officer must refer the matter to a relevant Responsible Body, e.g. a regulatory body or the police (regulation 30 (as amended)). Further information about undertaking investigations can be found in Annex E.

Annex C

Monitoring

Routine monitoring

1. Accountable Officers must establish and operate or ensure that their Designated Body and any persons or bodies acting on behalf of, or providing services under arrangements made with the Designated Body, establishes and operates arrangements for monitoring and auditing the management and use of controlled drugs (regulation 11). This can be through normal governance and management arrangements. Where one organisation provides services to another, the commissioner of the services has responsibility for ensuring that appropriate governance arrangements are specified in the contract.

2. The arrangements made by the Accountable Officer in relation to controlled drugs must include provision for the following:

- monitoring and analysing of prescribing
- ensuring that the Designated Body (or its service providers[4]) has systems in place to alert the Accountable Officer of any complaints or concerns
- ensuring that the Designated Body (or it's service providers[4]) has an incident reporting system in place for untoward incidents
- ensuring that the Designated Body (or it's service providers[4]) has appropriate arrangements in place for analysing or responding to untoward incidents

Monitoring of prescribing may include COMPASS Prescribing Reports and allied data analysis tools. The COMPASS prescribing reports are produced from data that are captured by the Business Services Organisation from dispensed prescriptions. Prescribing reports are generated for individual practices, locality groups and the HSCB as a whole for each quarter and each financial year. Practice reports are circulated to all practices each quarter. The report allows practices to see how their prescribing compares to that of other practices in NI and how they have changed compared to the previous year. The COMPASS system is also used to generate control charts which allow Medicines Management Advisers to identify "out-lying" practices which require follow up in relation to their prescribing of Controlled Drugs.

Monitoring in secondary care can include, but is not restricted to, analysing:

- ward/department usage
- in-patient/out-patient discharge dispensing
- use in out of hours services.

The responsibility for prisons lies with the AO of the South Eastern Health and Social Care Trust

[4] any persons or bodies acting on behalf of, or providing services under arrangements made with the Designated Body

3. The Care Quality Commission produced a Controlled Drug Governance Self-Assessment Toolkit[5] to allow Designated Bodies to assess how they are doing in terms of controlled drug governance and to suggest actions for areas of improvement. The toolkit was developed predominantly for general practice in England, but can be used in other settings.

Controlled drug declarations and self assessments

See Annex F

Standard Operating Procedures (SOPs)

4. The Accountable Officer must ensure that his Designated Body (and service providers[4]) has adequate and up-to-date SOPs in place in relation to the management and use of controlled drugs.

Regulation 9 (as amended) requires the SOPs to cover (unless not applicable to the Designated Body):

- who has access to the controlled drugs;
- where the controlled drugs are stored;
- security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;
- disposal and destruction of controlled drugs;
- who is to be alerted if complications arise, and
- record-keeping, including –

  (i) maintaining relevant controlled drugs registers under the misuse of drugs legislation, and

  (ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations (Northern Ireland) 2002[6] (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

Accountable Officers must also ensure that they have in place sufficient and up to date SOPs which cover prescribing, supply and administration of CDs and the clinical monitoring of patients who have been prescribed controlled drugs.

[5] See http://www.cqc.org.uk/content/controlled-drugs

[6] SR 2002/1 as amended

Annex D

Entry and Inspection

Routine periodic inspections

1. Inspections of a wide range of relevant premises are already undertaken by the Department's Medicines Regulatory Group and the Regulation and Quality Improvement Authority (RQIA). In addition to this, the Health Act 2006 contains a power of entry and inspection, subject to certain criteria, for constables and certain authorised persons to enter any relevant premises to inspect controlled drugs and any associated records. These authorised persons include Accountable Officers and persons authorised by the Designated Body.

2. Formal inspection involving an 'on-site' visit is only part of the monitoring and inspection arrangements which also include controlled drug declarations and self assessments. Nonetheless, inspection remains a useful tool to check physical arrangements for the storage, record keeping and management of controlled drugs. The inspection process is intended to monitor compliance, improve quality and support individual and organisational development.

3. For those premises that are periodically inspected by RQIA and the Department, the Accountable Officer does not have a duty to undertake **periodic** inspections (regulation 19(as amended)). However, as part of his monitoring, the Accountable Officer may undertake additional inspections to give assurance that controlled drugs are being managed and used safely. The number and frequency of these additional inspections are at the discretion of the Accountable Officer. In undertaking any additional inspections, the Accountable Officer should take account of the Government's policy that the inspection process should not be over burdensome and should avoid duplication. RQIA and the Department will inform relevant Designated Bodies on the frequency of the routine inspections and also the format and frequency of assurances following such visits.

Primary Care

4. As part of their monitoring and auditing arrangements, the HSCB Accountable Officer should arrange for a small number of inspections of a random sample of "relevant premises"[7] where controlled drugs are stored, dispensed, supplied or used. Inspections will be informed by information received by the Accountable Officer including inspection reports, declarations, and other monitoring of data. The Accountable Officer may choose to integrate controlled drug inspections into the current monitoring activities. Adverse issues may be investigated as detailed in Annex E.

5. The Department's Medicines Regulatory Group will undertake periodic inspections of community pharmacies and these will include stock audits of

[7] See clause 20 of the Health Act 2006 and Regulations 19 and 20 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (as amended).

controlled drugs. The HSCB will undertake periodic inspections of General Practitioners who are commissioned by the HSCB to provide medical services under the health service and of those Dental Practitioners who provide exclusively health and social care services. The RQIA undertakes inspections of private Dental Practitioners. These inspections may be informed by self assessment and other available information.
The inspecting authority will advise the relevant Accountable Officer of any issues in relation to controlled drugs.

Secondary Care

6. In secondary care pharmacies, periodic inspections will be carried out by the Department's Medicines Regulatory Group and these will include stock audits of controlled drugs. Inspection of other wards and departments will be the subject of agreement between RQIA/Department and the Trust.

These inspections will be informed by self assessment and other available information. The inspecting authority and the relevant Accountable Officer will determine the level and frequency of feedback following such visits

Independent Healthcare and Care Homes

7. In Independent Hospitals the RQIA, as part of their existing inspection processes, will carry out periodic inspections. The Department also carry out controlled drug visits to some Independent Hospitals. The inspecting authority and the relevant Accountable Officer will determine the level and frequency of feedback following such visits.

8. The Regulations enable an Accountable Officer to request in writing that another Accountable Officer from a Designated Body of the same type inspects any premises of his Designated Body (regulation 20(6). This is intended to provide Accountable Officers with a system of mutual audit and support.

Records

9. Inspecting authorities must keep a record, either paper or electronic, of all inspections (regulation 19 (as amended)). Where reports of routine inspections are made available to the premises concerned these may give assurance of existing good practice and may high-light areas where improvement is necessary. The relevant Accountable Officer should make arrangements with the inspecting body in relation to the sharing of reports following inspection visits.

Annex E

Investigations

1. Accountable Officers must ensure that robust systems are in place across their areas of responsibility to enable concerns or incidents involving controlled drugs to be identified and, where appropriate, investigated (regulations 15 and 16).

Adequate records must be compiled and kept, in either paper or electronic form, in relation to any concerns expressed. Access to these records must be restricted to:

- the Accountable Officer and his staff; and
- others who need access for the purpose of ensuring the safe management and use of controlled drugs

The record must include, but is not limited to, as appropriate:

- the date on which the concern was made known to the Accountable Officer
- any dates on which the matters that led to the concern took place
- details regarding the nature of the concern
- details of the relevant individual in relation to which the concern was expressed
- details of the person who, or body which, made known the concern
- details of any action taken by the Designated Body (or a body or person acting on behalf of, or providing services under arrangements made with , the Designated Body) in relation to the concern
- the assessment of whether information in relation to the concern should be disclosed to another Responsible Body under regulation 25 (as amended) or 26 (as amended); and
- if information regarding the concern is disclosed to another Responsible Body under regulation 25 (as amended) or 26 (as amended) the details of any such disclosure, including the name of the Responsible Body to which the disclosure was made and the nature of the information disclosed to the body.

2. Where a concern involves a registered professional's fitness to practise or where patient safety may be compromised, information should be passed immediately to the appropriate Regulatory Body. Guidance can be found on the Regulatory Bodies websites, examples of which are listed below.

General Dental Council (www.gdc-uk.org) *Our Guide to Local Practitioner Advice and Support Schemes*

General Medical Council (www.gmc-uk.org) *Referring a doctor to the GMC: A guide for individual doctors, medical directors and clinical governance managers*

Nursing and Midwifery Council (www.nmc-uk.org) *Reporting unfitness to practise: A guide for employers and managers*

Health and Care Professions Council (www.hpc-uk.org) *Making a complaint about a health professional*

The Pharmaceutical Society of Northern Ireland (www.psni.org.uk)

The Northern Ireland Social Care Council (www.niscc.info/index.php) *Referring a Complaint to NISCC - Employer's Guide*

3 Regulation 17 details where advice may be sought and what actions should be taken in response to well-founded concerns.

Incident Panel

4 Where concerns have come to light, initial consultation with the members of the Local Intelligence Network (LIN) may be helpful as an alternative or prior step to requesting the HSCB Accountable Officer to establish an Incident Panel. An Incident Panel would be convened by the HSCB Accountable Officer. The membership is drawn from the LIN and will depend on local circumstances and the nature of the concern. The Incident Panel can recommend a number of actions as detailed in regulation 17(3) (as amended), including ongoing monitoring, referral of concerns to the Regulatory Body or the police.

5 In all cases, care should be taken that any evidence gathered during the course of an investigation is preserved in an appropriate manner to ensure its integrity. Such evidence may be required for proceedings instituted by the police, other enforcement agencies, Disciplinary Committees or Regulatory Bodies.

Escalating concerns

6 There may be cases where concerns cannot be resolved locally and need to be escalated or passed to another organisation. The table below summarises where issues should normally be referred. On occasion concerns may need to be passed to more than one organisation.

Concern	**Consider referring to:**
Criminality suspected (including fraud and theft)	Police / Department / Counter Fraud Unit (BSO) (where appropriate)
Individual fitness to practise issue	Regulatory Body
Organisational/systems issue	Department

7 If a concern is passed to another organisation(s) the relevant Accountable Officer must record the referral (regulation 28).

8 When patient safety is thought to be at risk, immediate action must be taken. HSC bodies should follow their local serious untoward incident

procedures. Immediate referral to the relevant regulatory body should be considered where there are serious concerns about an individual's fitness to practise.

9 Actions taken consequent upon the investigation findings and relevant policies in the Designated Body should be clearly documented.

Targeted inspection

10. Either following an Incident Panel or as a direct result of a concern, the Accountable Officer may decide that a formal inspection at the premises is required. The Accountable Officer can seek support from the Department's Medicines Regulatory Group and RQIA in conducting such an inspection to provide independent assurance.

Raising concerns

11 Individuals raising concerns should be supported in doing so. Cases where health service fraud is suspected can be reported to Counter Fraud Unit either by contacting cfps@hscni.net or 08000 963396.

12 Individuals should also be supported where concerns have been raised about them or where they wish to raise concerns about their own performance.

Closure of cases

13. Cases considered by an Accountable Officer should be recorded with a clear account of the findings and any action taken (regulation 15). The Accountable Officer should ensure that concerns, and any lessons learned, are shared across the Local Intelligence Network. Wider sharing of information (excluding the names of relevant persons) may be appropriate through the Cross Border Group[8]. Where there is evidence that a controlled drug has been diverted, it may also be appropriate to inform the manufacturer or wholesaler.

14 Reports containing information about the storage and movement of controlled drugs should not normally be disclosed under Freedom of Information legislation as this could aid criminal activity and so would come within the "law enforcement" exemption.

[8] The Cross Border Intelligence Group comprises representatives from the UK and the Republic of Ireland. This Group has been formed as a result of the 5 Nations meeting in 2007 (under the Health Act 2006). The remit of the Group is to support the development of appropriate systems through dissemination of information and sharing of good practice in order to achieve statutory compliance and to feed back this information to members' home organisations.

Annex F

Controlled Drugs declarations and self-assessments

Those who will send declarations and self-assessments can devise forms to suit their needs. The declaration and self-assessment form for registered pharmacies can be found below (Regulation 12 (as amended))

	Yes/No		Yes/No
1. Do you have specific written SOPs covering the management of CDs, appropriate to the activities carried out at the premises and as required by the Accountable Officer regulations?		7. Do you transport CDs in accordance with an SOP (e.g. patient deliveries)?	
2. Are the staff involved in activities related to CDs appropriately trained and competent?		8. Are all CDs appropriately labelled?	
3. Do you have procedures in place to identify, deal with and learn from significant incidents involving CDs?		9. Are regular date checks of CD stock carried out?	
4a. Have you noted any signs of unusual, excessive or inappropriate supply or prescribing patterns?		10. Is the CD Register maintained in accordance with the Misuse of Drugs Regulations and any relevant guidance?	
4b. **If yes,** have these issues been fully addressed?		11. Are running balances of CDs maintained in the CD register and is there evidence that they are audited?	
5a. Are there any signs of, or do you have concerns about, the diversion of CDs?		12. Are all relevant CDs stored in accordance with the Safe Custody Regulations and are procedures in place to prevent unauthorised access to CDs?	
5b. **If yes,** have these issues been fully addressed?		13. Is date expired and patient returned medication appropriately marked and segregated?	
6a. Have there been any complaints or significant incidents involving CDs in the last 12 months of which you are aware?		14. Are out of date or patient returned CDs destroyed in accordance with legislation and published guidance?	
6b. **If yes,** have these issues been fully addressed?		15. Are prescriptions for Schedule 2 & 3 CDs endorsed with the date of supply at the time of supply?	

DECLARATION

I declare that to the best of my knowledge and belief that the handling, management and use of Schedules 2 and 3 controlled drugs at these premises complies with the provisions of the Misuse of Drugs Act 1971, its associated regulations and the Health Act 2006 and its associated controlled drugs regulations.

Signed **Date**

Name		**Registration Number**	
Position within organisation		**Name of organisation and address of premises**	

Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

www.dhsspsni.gov.uk

The Quality Standards for Health and Social Care

SUPPORTING GOOD GOVERNANCE AND BEST PRACTICE IN THE HPSS

March 2006

FOREWORD BY THE MINISTER

The people of Northern Ireland are entitled to the highest standards of health and social care. Having standards in place to ensure that people have the right care wherever they live in Northern Ireland is a fundamental principle of reform and modernisation of the health and social care system.

I am committed to putting patients, clients and carers first. The *Quality Standards for Health and Social Care* set out the standards that people can expect from Health and Personal Social Services (HPSS). In developing these standards, my aim is to raise the quality of services and to improve the health and social wellbeing of the people of Northern Ireland. At the heart of these standards are key service user and carer values including dignity, respect, independence, rights, choice and safety.

The standards have five key quality themes:

- Corporate leadership and accountability of organisations;
- Safe and effective care;
- Accessible, flexible and responsive services;
- Promoting, protecting and improving health and social well-being; and
- Effective communication and information.

The publication of the quality standards is an important milestone in the process of putting patients first. They will be used by the new Regulation and Quality Improvement Authority to assess the quality of care provided by the HPSS. The new Authority will be looking to see how the HPSS provide quality services and will be reporting their findings both to the Department and to the public.

Given the rapidly changing environment in which the HPSS now operates including changes arising from the Review of Public Administration, it is important that these standards do not become outdated or serve to stifle innovation. Therefore, the standards will be reviewed by the end of 2008.

SHAUN WOODWARD MP
Minister for Health, Social Services and Public Safety

CONTENTS PAGE

Section 1: Introduction to the Development of Standards

1.1 Introduction

Almost 95% of the population of Northern Ireland makes contact with health and social services on an annual basis. This contact may be through primary care services, community care services or through hospitals. In all of these contacts, people are entitled to the highest standards of health and social care.

This document sets out clearly for the public, service users and carers, and those responsible for the commissioning, planning, delivery, and review of services, the quality standards that the Department considers people should expect from Health and Personal Social Services (HPSS). It represents a significant step in the process of placing the needs of the service user and carer, and the wider public, at the centre of planning, delivery and review of health and social care services.

1.2 Background to the development of standards

Quality improvement is at the forefront of the development of health and social care services in Northern Ireland. These improvements are centred around five main areas, which are an integral part of modernisation and reform:

- setting of standards – to improve services and practice;
- improving governance in the HPSS - in other words, the way in which the HPSS manages its business;
- improving the regulation of the workforce, and promoting staff development through life-long learning and continuous professional development;
- changing the way HPSS organisations are held to account for the services they provide; and
- establishing a new, independent body to assess the quality of health and social care.

The consultation document “Best Practice – Best Care”, published in April 2001, sets out the detail of this framework to improve the quality of care. This included links to national standard setting bodies such as the National Institute for Health and Clinical Excellence (NICE) and the Social Care Institute for Excellence (SCIE).

1.3 Improving governance in health and social care

The outcome of the Review of Public Administration, announced in November 2005, signalled major changes to the structure and functions of HPSS organisations. Regardless of these changes there remains a statutory duty of quality on HSS Boards and Trusts. This means that each organisation has a legal responsibility for satisfying itself that the quality of care it commissions and/or provides meets a required standard. This requirement is just as important as the responsibility to demonstrate financial regularity and propriety. Organisations must ensure that there are visible and rigorous structures, processes, roles and responsibilities in place to plan for, deliver, monitor and promote safety and quality improvements in the provision of health and social care. This process is known as *Governance*.

1.4 The setting of standards

In addition to drawing on national and professional standards, a range of local standards is being developed to enhance governance arrangements in the HPSS. These include controls assurance standards, so that by 2006-07, there will be a comprehensive set of specific assurance standards, which the HPSS can use to assess compliance against the required attainment levels. In addition, a number of care standards have been developed to facilitate the inspection and regulation of specific health and social care services provided by the HPSS and the independent sector. These care standards are specified in legislation and will be inspected, regulated and monitored by a new organisation called the Health and Personal Social Services Regulation and Improvement Authority (the Regulation and Quality Improvement Authority - RQIA).

The development of the *Quality Standards for Health and Social Care*, as outlined in this document, is intended to complement standards already issued or currently in development. Consequently, evidence of compliance with existing or new standards, such as professional standards, charter standards, controls assurance and/or care standards will form part of the evidence of practitioner or organisational commitment to these new quality standards.

1.5 What is a standard?

A standard is a level of quality against which performance can be measured. It can be described as ‘essential’- the absolute minimum to ensure safe and effective practice, or ‘developmental’, - designed to encourage and support a move to better practice. The *Quality Standards for Health and Social Care*, which are contained in this document, are classed as essential.

Given the rapidly changing environment in which the HPSS operates, it is important that standards do not become outdated or serve to stifle innovation.

To prevent this, standards need to be regularly reviewed and updated. It will be the Department's responsibility, drawing on the best evidence available, including advice, reports and/or information from the RQIA, to keep the quality standards under consideration, with a formal review being completed by the end of 2008.

1.6 Why are standards important?

Raising and maintaining the quality of services provided by the HPSS is a major objective for all involved in the planning, provision, delivery and review of health and social care services. Currently, there remains unacceptable variation in the quality of services provided, including timeliness of delivery and ease of access.

In order to improve the quality of these services, change is needed, underpinned and informed by a more cohesive approach to standards development.

Standards:

- give HPSS and other organisations a measure against which they can assess themselves and demonstrate improvement, thereby raising the quality of their services and reducing unacceptable variations in the quality of services and service provision;
- enable service users and carers to understand what quality of service they are entitled to and provide the opportunity for them to help define and shape the quality of services provided by the HPSS and others;
- provide a focus for members of the public and their elected representatives, to consider whether their money is being spent on efficient and effective services, and delivered to recognised standards;
- help to ensure implementation of the duty the HPSS has in respect of human rights and equality of opportunity for the people of Northern Ireland; and
- promote compliance, and underpin the regulation and monitoring of services to determine their quality and safety and to gauge their continuous improvement.

By promoting integration, these *Quality Standards for Health and Social Care* will contribute to the implementation of clinical and social care governance in the HPSS and will be used by HPSS and other organisations, service users and carers, the wider public and the RQIA to assess the quality of care provision.

1.7 The five quality themes

There are five quality themes on which the standards have been developed to improve the health and social well-being of the population of Northern Ireland. These themes have been identified through consultation with service users, carers and HPSS staff and through a review of standards developed elsewhere at local, national and international level.

The five quality themes are:

1. Corporate Leadership and Accountability of Organisations;
2. Safe and Effective Care;
3. Accessible, Flexible and Responsive Services;
4. Promoting, Protecting and Improving Health and Social Well-being; and
5. Effective Communication and Information.

1.8 Assessing quality

The RQIA was established by the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 and began work on 1 April 2005. It has two main functions:

- inspection and regulation of specified health and social care services provided by the HPSS and the independent sector; and

- inspection and review of the services provided by the HPSS in Northern Ireland.

The RQIA has a general duty to encourage improvements in the quality of services commissioned and provided by HPSS and other organisations. It will promote a culture of continuous improvement and best practice through inspection and review of clinical and social care governance arrangements.

The RQIA has taken over responsibility for the registration, inspection and regulation of providers of care, for example, residential care, nursing homes and day care facilities. On a phased basis, the RQIA will assume further responsibilities over the coming years, including reporting on the quality of care provided by the HPSS. Where serious and/or persistent clinical and social care governance problems come to light, it will have a key role to play, in collaboration with other regulatory and inspectoral bodies, in the investigation of such incidents. It will report on its findings to the Department and to the public.

1.9 How will the standards be used to measure quality?

The RQIA, in conjunction with the HPSS, service users and carers, will agree how the standards will be interpreted to assess service quality. It is envisaged that specific tools will be designed to allow the RQIA to measure that quality and to assist the HPSS in assessing themselves. Once developed, not only will these tools assess HPSS structures and processes but they will also contribute to the assessment of clinical and social care outcomes.

Whilst it is for the RQIA to provide guidance on what assessment methods it will use, it is recognised that collecting the evidence to demonstrate that relevant standards have been successfully achieved may be a time consuming process for the HPSS. Therefore, information that is currently compiled on existing standards will also be able to be used to contribute to the demonstration of achievement for these standards.

The RQIA will commence reviewing clinical and social care governance within the HPSS in 2006/07, using the five themes contained within this document. RQIA will report on the quality of care provided by the HPSS following its review. This approach will promote quality improvement across organisations.

Section 2: Values and Principles Underpinning the Standards

2.1 Introduction

There are three key premises, which underpin these quality standards and are central to all aspects of planning, provision, delivery, review and improvement of the HPSS. They are that:

- people in receipt of services should be actively involved in all decisions affecting their lives and should fully contribute to any planning for, delivery and evaluation of, services;

- clinical and social care governance in the HPSS must take account of the organisational structures, functions and the manner of delivery of services currently in place. Clinical and social care governance must also apply to all services provided in community, primary, secondary and tertiary care environments;

- service users and carers should be fully valued by HPSS staff who, in turn, should be valued by service users, carers and others.

2.2 The values underpinning the Standards

The quality of a service provided is dependent on managers and HPSS staff basing their practice on the following values and principles; these complement those already outlined in the care standards for independent agencies, establishments and certain other services provided by HPSS organisations.

They are:

DIGNITY AND RESPECT	The uniqueness and intrinsic value of the individual is acknowledged and each person is treated with dignity and respect. This is applicable to service users, carers, staff and others who come in contact with services.
INDEPENDENCE	A balance between the promotion of independence and risk taking is needed. Service users have as much control as possible over their lives. Service users are informed about risk whilst being protected against unreasonable risks.
PROMOTION OF RIGHTS	In the context of services delivered to them, the individual and human rights of service users are promoted and safeguarded. Where necessary, appropriate advocacy arrangements are put in place.
EQUALITY AND DIVERSITY	Equality of opportunity and positive outcomes for service users and staff are promoted; their background and culture are valued and respected.
CHOICE AND CAPACITY	Service users are offered, wherever possible, according to assessed need and available resources, the opportunity to select independently from a range of options based on clear and accurate information, which is presented in a manner that is understood by the service user and carer.
PRIVACY	Service users have the right to be free from unnecessary intrusion into their affairs and there is a balance between the consideration of the individual's safety, the safety of others and HPSS organisational responsibilities.
EMPOWERMENT	Service users are enabled and supported to achieve their potential in health and social well-being. Staff are supported and developed to realise their ability and potential.
CONFIDENTIALITY	Information about service users and staff is managed appropriately and everyone involved in the service respects confidential matters.
SAFETY	Every effort is made to keep service users, staff and others as safe as is possible. In all aspects of treatment and care, service users are free from exploitation, neglect or abuse.

2.3 The principles underpinning the Standards

The following principles are fundamental to the development of a quality service.

PUBLIC AND SERVICE USER INVOLVEMENT	The views and experiences of service users, carers, staff and local communities are taken into account in the planning, delivery, evaluation and review of services. Service users and carers, wherever possible, are involved in, and informed about, decisions made when they seek access to or receive services during their treatment or care.
SAFETY AND EFFECTIVENESS	Systems are in place to ensure that the safety of service users, carers, staff and the wider public, as appropriate, underpin all aspects of health and social care delivery. For example, the imperative to protect children and vulnerable adults may take precedence over the specific wishes of the service user and their carers. In addition, the protection of staff may need to be balanced with the specific wishes of service users, carers, families and friends. Quality systems are in place to enable staff to play a full and active role in providing effective and efficient health and social care services for all who use these services. Staff are fully supported, regularly supervised and appropriately trained and educated, to provide safe and effective health and social care services.
ROBUST ORGANISATIONAL STRUCTURES AND PROCESSES	Robust organisational structures and processes are in place, which are regularly reviewed to promote safe and effective delivery of care. Timely information is shared and used appropriately to optimise health and social care.
QUALITY of SERVICE PROVISION	Policies, procedures and activities are in place to encourage and enable continuous quality improvement. Service developments and provision are based on sound information and knowledge of best practice, as appropriate.

Section 3: Format of the Standards

3.1 The five quality themes

The five quality themes are applicable to the whole of the HPSS, including those services, which are commissioned or provided by HPSS organisations and family practitioner services. They are underpinned by the duty of quality on HSS Boards and Trusts. Where care is commissioned outside Northern Ireland, commissioners must ensure that the quality of care is commensurate with these and other associated standards.

The five quality themes, encompassing the standards, are set out in sections four to eight of this document. These are:-

- Corporate Leadership and Accountability of Organisations (Section 4);
- Safe and Effective Care (Section 5);
- Accessible, Flexible and Responsive Services; (Section 6);
- Promoting, Protecting and Improving Health and Social Well-being (Section 7); and
- Effective Communication and Information (Section 8).

3.2 Format of the standards

Each theme has a **title**, which defines the area upon which the standard is focused. Then, a **standard statement** will explain the level of performance to be achieved. The reason why the standard is seen to be important will be covered by the **rationale**. The standard statement will then be expanded into a series of **criteria**, which will provide further detail of areas for consideration by the HPSS and by RQIA.

Section 4: Corporate Leadership and Accountability of Organisations (Theme 1)

4.1 Standard Statement

The HPSS is responsible and accountable for assuring the quality of services that it commissions and provides to both the public and its staff. Integral to this is effective leadership and clear lines of professional and organisational accountability.

4.2 Rationale

The HPSS must provide effective leadership and a clear direction to make the most of its resources (people, skills, time and money), and to deliver high quality services to the public in as safe an environment as is possible. The aim is to ensure a competent, confident workforce and an organisation that is open to learning and is responsive to the needs of service users and carers. This will facilitate staff in the organisation to take individual, team and professional responsibility in order to promote safe, sustainable and high quality services. The organisation needs to maintain and further enhance public confidence.

4.3 Criteria

The organisation:

a) has a coherent and integrated organisational and governance strategy, appropriate to the needs, size and complexity of the organisation with clear leadership, through lines of professional and corporate accountability;

b) has structures and processes to support, review and action its governance arrangements including, for example, corporate, financial, clinical and social care, information and research governance;

c) has processes in place to develop leadership at all levels including identifying potential leaders of the future;

d) actively involves service users and carers, staff and the wider public in the planning and delivery, evaluation and review of the corporate aims and objectives, and governance arrangements;

e) has processes in place to develop, prioritise, deliver and review the organisation's aims and objectives;

f) ensures financial management achieves economy, effectiveness, efficiency and probity and accountability in the use of resources;

g) has systems in place to ensure compliance with relevant legislative requirements;

h) ensures effective systems are in place to discharge, monitor and report on its responsibilities in relation to delegated statutory functions and in relation to inter-agency working;

i) undertakes systematic risk assessment and risk management of all areas of its work;

j) has sound human resource policies and systems in place to ensure appropriate workforce planning, skill mix, recruitment, induction, training and development opportunities for staff to undertake the roles and responsibilities required by their job, including compliance with:

- Departmental policy and guidance;
- professional and other codes of practice; and
- employment legislation.

k) undertakes robust pre-employment checks including:

- qualifications of staff to ensure they are suitably qualified and are registered with the appropriate professional or occupational body;
- police and Protection of Children and Vulnerable Adults checks , as necessary;
- health assessment, as necessary; and
- references.

l) has in place appraisal and supervision systems for staff which support continuous professional development and lifelong learning, facilitate professional and regulatory requirements, and informs the organisation's training, education and workforce development;

m) has a training plan and training programmes, appropriately funded, to meet identified training and development needs which enable the organisation to comply with its statutory obligations; and

n) has a workforce strategy in place, as appropriate, that ensures clarity about structure, function, roles and responsibilities and ensures workforce development to meet current and future service needs in line with Departmental policy and the availability of resources.

Section 5: Safe and Effective Care (Theme 2)

5.1 Standard Statement

Safe and effective care is provided by the HPSS to those service users who require treatment and care. Treatment or services, which have been shown not to be of benefit, following evaluation, should not be provided or commissioned by the HPSS.

5.2 Rationale

A quality service is one which is safe, effective and sustainable. Diminished standards on safety reflect a poor quality of service. The provision of health and social care is complex and will never be one hundred percent error-free. However, more can always be done to avoid injury and harm to service users, from the treatment and care that is intended to help them. This is an integral part of continuous quality improvement. Services must be delivered in a way that appropriately manages risk for service users, carers, staff, the public and visitors. Where an adverse incident has occurred or has been prevented from happening (a near miss), then systems need to be in place to assist individuals and organisations to learn from mistakes in order to prevent a reoccurrence.

It is acknowledged, however, that in some situations, living with a risk can be outweighed by the benefit of having a lifestyle that the individual really wants and values. In such circumstances, risk taking can be considered to be a positive action. Health and social care staff need to work in partnership with service users and carers to explore choices and agree on how risk can be managed and minimised for the benefit of individual service users, carers, families and communities.

The promotion of safe care must be complemented by the provision of effective care. Care should be based on the best available evidence of interventions that work and should be delivered by appropriately competent and qualified staff in partnership with the service user. Systems and processes within organisations should facilitate participation in, and implementation of, evidence-based practice.

This theme of “Safe and Effective Care” has been subdivided into three areas:

- ensuring safe practice and the appropriate management of risk;
- preventing, detecting, communicating and learning from adverse incidents and near misses; and
- promoting effective care.

5.3 Criteria

5.3.1 Ensuring Safe Practice and the Appropriate Management of Risk

The organisation:

a) has effective person-centred assessment, care planning and review systems in place, which include risk assessment and risk management processes and appropriate interagency approaches;

b) acknowledges and promotes the central place that patients, service users and carers have in the prevention and detection of adverse incidents and near misses;

c) has policies and procedures in place to identify and protect children, young people and vulnerable adults from harm and to promote and safeguard their rights in general;

d) promotes effective interagency working in relation to raising awareness of the risk factors associated with abuse, including domestic violence and in the promotion of effective interagency responses;

e) has a safety policy in place which takes account of the needs of service users, carers and staff, the public and the environment; and

f) has properly maintained systems, policies and procedures in place, which are subject to regular audit and review to ensure:

- efficacy and comparability of outcomes in health and social care;
- compliance with professional and other codes of practice;
- effective and efficient procedures for obtaining informed consent for examination, treatment and/or care;
- accurate, timely and consistent recording of care given or services provided and associated outcomes;
- protection of health, welfare and safety of staff;
- awareness raising and staff knowledge of reporting arrangements for adverse incidents and near misses, and whistleblowing arrangements when poor performance and/or unsafe practice in examination, treatment or care comes to light;
- there is choice where food and/or fluid is provided, which reflects cultural and spiritual preferences and that procedures are in place to promote the safe handling of food and a healthy diet;

- safe practice in the selection, procurement, prescription, supply, dispensing, storage and administration of medicines across the spectrum of care and support provided, which complies with current medicines legislation;

- promotion of safe practice in the use of medicines and products, particularly in areas of high risk, for example:

    - intrathecal chemotherapy;
    - blood and blood products;
    - intravenous fluid management;
    - methotrexate;
    - potassium chloride; and
    - anticoagulant therapy.

- risk assessment and risk management in relation to the acquisition and maintenance of medical devices and equipment, and aids and appliances across the spectrum of care and support provided;

- promotion of general hygiene standards, and prevention, control and reduction in the incidence of healthcare acquired infection and other communicable diseases;

- appropriate decontamination of reusable medical devices;

- safe and effective handling, transport and disposal of waste, recognising the need to promote the safety of service users and carers, staff and the wider public, and to protect the environment;

- interventional procedures and/or any new methods undertaken by staff are supported by evidence of safety and efficacy;

- address recommendations contained in RQIA reports (when available), service and case management reviews; and

- participation in and implementation of recommendations contained in local or national enquiries, where appropriate, e.g. National Confidential Enquiries.

5.3.2 Preventing, Detecting, Communicating and Learning from Adverse Incidents and Near Misses

The organisation:

a) has systems and processes in place to prevent, identify, assess and manage and review adverse incidents and near misses across the spectrum of care and support provided;

b) promotes an open and fair culture, rather than one of blame and shame, to encourage the timely reporting and learning from adverse incidents and near misses;

c) has reporting systems in place to collate, analyse and learn from all adverse incidents, and near misses, share knowledge and prevent reoccurrence of adverse incident or near miss; and

d) has systems in place that promote ongoing communication with service users and carers when treatment or care goes wrong, and puts in place an individual care plan to minimise injury or harm.

5.3.3 Promoting Effective Care

The organisation:

a) provides relevant, accessible, information to support and enhance service user and carer involvement in self-management of their health and social care needs;

b) promotes a person-centred approach and actively involves service users and carers in the development, implementation, audit and review of care plans and care pathways;

c) promotes a culture of learning to enable staff to enhance and maintain their knowledge and skills;

d) ensures that clinical and social care interventions are carried out under appropriate supervision and leadership, and by appropriately qualified and trained staff, who have access to appropriate support systems;

e) uses recognised clinical and social care standards and outcomes as a means of measuring health and social care quality;

f) promotes the implementation of evidence based practice through use of recognised standards and guidelines including guidance from the Department, NICE, SCIE and the National Patient Safety Agency (NPSA);

g) has in place systems to promote active participation of staff in evidence based practice, research, evaluation and audit;

h) has systems in place to prioritise, conduct and act upon the findings of clinical and social care audit and to disseminate learning across the organisation and the HPSS, as appropriate;

i) provides regular reports to the organisation's executive and non-executive board directors on clinical and social care governance arrangements and continuous improvement in the organisation; and

j) promotes the involvement of service users and carers in clinical and social care audit activity.

Section 6: Accessible, Flexible and Responsive Services (Theme 3)

6.1 Standard Statement

Services are sustainable, and are flexibly designed to best meet the needs of the local population. These services are delivered in a responsive way, which is sensitive to individual's assessed needs and preferences, and takes account of the availability of resources.

Each organisation strives to continuously improve on the services it provides and/or commissions.

6.2 Rationale

To meet the needs of local communities and to narrow inequalities in health and social well-being, services should take account of the current and anticipated needs of the local community. Service users, carers, front line staff and the wider public should be meaningfully engaged in all stages of the service planning and decision-making cycle. Assessment of need should be undertaken in partnership with the statutory, voluntary, private and community sectors. This should be informed by the collation and analysis of information about the current health and social well-being status of the local population, unmet need, legislative requirements, and evidence of best practice and review of current service provision. Service planning should also take account of local and regional priorities and the availability of resources.

In order to promote systematic approaches to the development of responsive, flexible and accessible services for the local population and for individuals, this theme has been sub-divided into two main areas:

- service planning processes; and
- service delivery for individuals, carers and relatives.

6.3 Criteria

6.3.1 Service Planning Processes

The organisation:

a) has service planning processes which promote an equitable pattern of service provision or commissioning based on assessed need, having regard to the particular needs of different localities and people, the availability of resources, and local and regional priorities and objectives;

b) integrates views of service users, carers and local communities, and front line staff into all stages of service planning, development, evaluation and review of health and social care services;

c) promotes service design and provision which incorporates and is informed by:

- information about the health and social well-being status of the local population and an assessment of likely future needs;
- evidence of best practice and care, based on research findings, scientific knowledge, and evaluation of experience;
- principles of inclusion, equality and the promotion of good relations;
- risk assessment and an analysis of current service provision and outcomes in relation to meeting assessed needs;
- current and/or pending legislative and regulatory requirements;
- resource availability; and
- opportunities for partnership working across the community, voluntary, private and statutory sectors.

d) has service planning and decision-making processes across all service user groups, which take account of local and/or regional priorities;

e) has standards for the commissioning of services which are readily understood and are available to the public; and

f) ensures that service users have access to its services within locally and/or regionally agreed timescales.

6.3.2 Service Delivery for Individuals, Carers and Relatives

The organisation:

a) ensures that all service users, carers and relatives are treated with dignity and respect and that their privacy is protected and promoted, including, where appropriate, the use of advocates and facilitators;

b) has systems in place to ensure that service users, carers and relatives have the appropriate information to enable them to make informed decisions and choices about their treatment and care, or service provision;

c) ensures that information, where appropriate, is provided in a number of formats, which may include, large print, audio format on tape or compact disc, computer readable format, Braille, etc. and is:

- written in easy to understand, non-technical language;
- laid out simply and clearly;
- reproduced in a clear typeface;
- available on the internet; and
- in the preferred language of the reader, as necessary;

d) incorporates the rights, views and choice of the individual service user into the assessment, planning, delivery and review of his or her treatment and care, and recognises the service user's right to take risks while ensuring that steps are taken to assist them to identify and manage potential risks to themselves and to others;

e) ensures that individual service user information is used for the purpose for which it was collected, and that such information is treated confidentially;

f) promotes multi-disciplinary team work and integrated assessment processes, which minimise the need for service users and carers to repeat basic information to a range of staff; and

g) provides the opportunity for service users and carers to provide comment on service delivery.

Section 7: Promoting, Protecting and Improving Health and Social Well-being (Theme 4)

7.1 Standard Statement

The HPSS works in partnership with service users and carers, the wider public and with local and regional organisations to promote, protect and improve health and social well-being, and to tackle inequalities within and between geographic areas, socio-economic and minority groups, taking account of equality and human rights legislation.

7.2 Rationale

Individuals, families and carers have a major part to play in their own and their dependents' health and social well-being. Although many factors influence the health and social well-being of individuals, many of these factors are societal issues and are outside the control of individuals. Examples include poverty, social exclusion, poor education, unemployment, crime, and poor housing. Resolving these issues requires a broad-based approach and concerted action by a wide range of people and agencies including the statutory, voluntary, community and business sectors. The HPSS, working in partnership with these other agencies and community groups, should actively seek to influence and support better decision-making, and establish systems to promote and improve the health and social well-being of the public and to reduce inequalities. The goal is to improve the health and social well-being of the population of Northern Ireland, by increasing the length of their lives, improving the quality of life through increasing the number of years spent free from disease, illness, or disability, and by providing better opportunities for children and support for families.

7.3 Criteria

The organisation:

a) has structures and processes in place to promote and implement effective partnership arrangements, to contribute to improvements in health and social well-being, and promote social inclusion and a reduction in inequalities;

b) actively involves the services users and carers, the wider public, HPSS staff and the community and voluntary sectors, in the planning and development of local solutions to improve health and social well-being and to reduce inequalities;

c) is committed to human rights, as identified in human rights legislation and United Nations Conventions, and to other Government policies aimed at tackling poverty, social need and the promotion of social inclusion;

d) actively pursues equality screening and, where appropriate, equality impact assessment in compliance with section 75 of the Northern Ireland Act 1998;

e) promotes ownership by service users, carers and communities to enable service users and the public to take responsibility for their own health, care and social well-being, and to participate as concerned citizens in promoting the health and social well-being of others;

f) collects, collates, develops and uses health and social care information to assess current and future needs of local populations, taking account of health and social well-being inequalities;

g) has effective and efficient emergency planning processes and co-ordinated response action plans in place, as appropriate, to deal with major incidents or emergency situations and their aftermath. The planning processes and action plans are compliant with Departmental guidance;

h) has processes to engage with other organisations to reduce local environmental health hazards, as appropriate;

i) has evidence-based chronic disease management programmes and health promotion programmes and, as appropriate, community development programmes, which take account of local and regional priorities and objectives;

j) has systems to promote a healthier, safer, and “family friendly” workforce by providing advice, training, support and, as appropriate, services to support staff;

k) has quality assured screening and immunisation programmes in place, as appropriate, and promotes active uptake among service users, carers and the public;

l) uses annual public health and social care reports in the development of priorities and planning the provision and delivery of services; and

m) provides opportunities for the use of volunteers, as appropriate.

Section 8: Effective Communication and Information (Theme 5)

8.1 Standard Statement

The HPSS communicates and manages information effectively, to meet the needs of the public, service users and carers, the organisation and its staff, partner organisations and other agencies.

8.2 Rationale

Good communication and effective use of information are the basis for decision-making by individuals, the public and organisations. They ensure that all relevant facts are collated and used to inform treatment and care, and the assessment, planning, service delivery and resource allocation processes. For information to be useful, it needs to be in an understandable format, accessible to those who need it and readily available. The communication and information management processes within an organisation must take account of the needs of service users and carers, staff and the public and the media, and any legislative or regulatory requirements. Protecting personal information and confidentiality are important to ensure that information is appropriately communicated to those who need to know and effectively used to inform any decisions made. The HPSS should be sensitive to the range of information needs required to support individuals, communities and the organisation itself.

8.3 Criteria

The organisation has:

a) active participation of service users and carers and the wider public. This includes feedback mechanisms appropriate to the needs of individual service users and the public;

b) an effective information strategy and communication strategy, appropriate to the needs of the public, service users and carers, staff and the size, functions and complexity of the organisation;

c) an effective and integrated information technology and information systems which support and enhance the quality and safety of care and provision of services;

d) system(s) and process(es) in place to ensure that urgent communications, safety alerts and notices, standards and good practice guidance are made available in a timely manner to relevant staff and partner organisations; these are monitored to ensure effectiveness;

e) clear communication principles for staff and service users, which include:

- openness and honesty;
- use of appropriate language and diversity in methods of communication;
- sensitivity and understanding;
- effective listening; and
- provision of feedback.

f) clear information principles for staff and service users, which include:

- person-centred information;
- integration of systems;
- delivery of management information from operational systems;
- security and confidentiality of information; and
- sharing of information across the HPSS, as appropriate;

g) the organisation has effective training for staff on how to communicate with service users and carers and, where needed, the public and the media;

h) effective records management policies and procedures covering access and the completion, use, storage, retrieval and safe disposal of records, which it monitors to assure compliance and takes account of Freedom of Information legislation;

i) procedures for protection of service user and carer information which include the timely sharing of information with other professionals, teams and partner organisations as appropriate, to ensure safe and effective provision of care, treatment and services, e.g. in relation to the protection of children or vulnerable adults, and the safe and efficient discharge of individuals from hospital care;

j) effective and efficient procedures for obtaining valid consent for examination, treatment and/or care;

k) an effective complaints and representation procedure and feedback arrangements, which is made available to service users, carers and staff and which is used to inform and improve care, treatment and service delivery; and

l) a range of published up-to-date information about services, conditions, treatment, care and support options available, and how to access them both in and out of service hours, which are subject to regular audit and review.

APPENDIX 1

GLOSSARY OF TERMS

Adverse incident	Any event or circumstance that could have or did lead to harm, loss or damage to people, property, environment or reputation.
Carer	Carers are people who, without payment, provide help and support to a family member or friend who may not be able to manage at home without this help because of frailty, illness or disability.
Care plan	The outcome of an assessment. A description of what an individual needs and how these needs will be met.
Care Standards	Care Standards are service specific standards currently being developed. They will cover a range of services provided by public, voluntary and private organisations such as nursing homes, residential homes, independent clinics etc.
Clinical and Social Care Governance	A framework within which HPSS is accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment.
Community care	Health and social services aimed at supporting individuals to remain safely in their own homes for as long as possible.
Community development	Consultation with, and involvement of local communities and groups in improving health and social well-being of the community.
Controls Assurance Standards	These standards focus on key areas of potential risk and help HPSS organisations demonstrate that they are doing their reasonable best to manage themselves and protect stakeholders from risk. They support effective governance.
Equality impact assessment	Consideration of a policy having regard to its impact on and the need to promote equality of opportunity between: persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation, men and women generally, persons with a disability and persons without and between persons with dependants and persons without.
Evidence based practice	Provision of services which are based on best practice as proven by research findings, scientific knowledge and evaluation of experience.
Family Practitioner Services (FPS)	The principal primary care services i.e. family doctors, opticians, dentists and pharmacists.
HPSS (Health and Personal Social Services)	An organisation which either commissions or provides health and social services, e.g. HSS Boards, Strategic Health and Social Care Authority, a Trust providing hospital and community services, a local commissioning body, and Family Practitioner Services.

NPSA	The National Patient Safety Agency promotes safe practice in clinical care and supports the development of solutions and the cascade of learning to reduce areas of high risk.
Person-centred assessment	An assessment, which places the individual at the centre of the process and which responds flexibly and sensitively to his/her needs.
Primary care	The many forms of health and social care and/or treatment accessed through a first point of contact provided outside hospitals e.g. family doctors, pharmacists, nurses, allied health professionals (physiotherapists, psychologists, dieticians etc) social workers, care assistants, dentists, opticians and so on.
Secondary care	Specialist services usually provided in an acute hospital setting following referral from a primary or community healthcare professional.
Statutory duty	A legal responsibility.
Statutory sector	Government-funded organisations e.g. HSS Boards, Strategic Health and Social Services Authority, Trusts, Special Agencies and Local Commissioning Groups.
Tertiary care	Highly specialised services usually provided in an acute hospital setting by medical and other staff with expertise in a particular medical specialty.

APPENDIX 2

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Use and Control of Medicines

Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services

Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

www.dhsspsni.gov.uk

April 2004

Foreword

Medicines are the single most widely used technology in the HPSS accounting for some £300M of expenditure.

While these therapeutic agents undoubtedly contribute to improving health they also have associated risks, hence their propensity to be highly regulated.

Notwithstanding legislative controls, health care systems across the world are increasingly committed to develop safer systems of work to minimise the risk of adverse incidents due to medicines.

'Use and Control of Medicines' is one such measure designed to ensure that there are proper systems and procedures in place to limit risk to both practitioner and patients as well as setting out statutory obligations.

This new guidance, therefore seeks to take account of important legislative changes and developments in professional practice and accountability as well as integrating and giving consistency to associated guidelines emanating for professional bodies, agencies, reviews etc. In addition, the guidelines extend beyond the secondary care sector in recognition of the medicines control interface across primary, secondary and community care.

In commending these new guidelines to the Service I wish to acknowledge the multidisciplinary input to their development and the extent and quality of the responses to the consultative draft. Such responses give evidence to the critical and important nature of the matter and its impact across the whole of the HPSS family.

The application of these guidelines will, I believe, make a significant contribution to the clinical and social care governance agenda improving the quality of care and minimising medication related risk. Safety needs no justification and where there is good practice patients are advantaged.

Dr N C Morrow *Chief Pharmaceutical Officer*

This guidance is directed primarily towards those professionals working in a secondary care setting. However, where appropriate, the principles stated are equally applicable to primary care professionals and local health and social care groups.

Except where stated, the document is not to be regarded as a definitive statement of the law on medicines and has no statutory force. Nevertheless, it does seek to present those principles of known and accepted good practice applicable to its subject. In so doing it is not intended to supersede or conflict with professional standards or codes of practice already in place and it is recognised that more detailed guidance on some of the issues included may form part of existing local policies.

In particular, attention is drawn to the Medicines Management Controls Assurance Standard (which requires HPSS bodies to have in place systems ensuring compliance with legislative requirements and best practice.

Contents

1 Objectives

This document aims to provide practical guidelines for the safe and effective supply, storage, prescribing, administration and documented use of medicines in the health service. This may be achieved by ensuring that:-

- prescriptions are authentic and legible;
- dispensing is accurate;
- storage is adequate and secure;
- administration follows recognised procedures eg NMC Guidelines[1];
- documentation is appropriate, accurate and complete;
- misuse is prevented;
- staff and patients are safeguarded;
- all appropriate staff are kept informed of all relevant policies, procedures, guidance and instructions.

Care should be taken to ensure that all medicines are prescribed and administered with the consent of the patient and in accordance with Good Practice in Consent[2].

2 Prescribing

It is essential that prescriptions are unambiguous so that the correct medicine can be administered to the named patient in the correct dose and dosage form, by the route specified, and at the time(s) prescribed.

In order to facilitate this and eliminate errors it is essential that staff become familiar with the documents or process used. Prescription sheets (eg Kardex) are a vital part of a patient's medical records. They must therefore be, and remain, legible and complete. In the secondary sector not more than one main prescription sheet should be in use at any one time for any patient. Where necessary, a continuation sheet should be used and numbered appropriately. In addition to the main prescription sheet, supplementary sheets may be necessary for special prescribing, for example:-

- anticoagulants
- intravenous fluids

- intravenous fluid additives
- insulin
- anaesthetic agents.
- oxygen
- patient controlled analgesia (pca)

Knowledge of the fact that the patient is being treated with these medicines may affect other prescribing and a note of these treatments must always be made on the main prescription sheet. This note should also refer to the existence of any supplementary sheet(s) which would contain details of such medication.

In writing prescriptions the advice given in the British National Formulary (incorporating the Nurse Prescribers' Formulary) (under "General Information" and "Prescription Writing")[3] should be observed.

When completing prescription sheets:-

- each individual prescription must be DATED and PRINTED clearly and entirely in CAPITAL LETTERS
- each prescription sheet must show the PATIENT'S FULL NAME, DATE OF BIRTH, PATIENT REFERENCE NUMBER and/or ADDRESS
- the APPROVED NAME should be used for a medicine wherever possible. Where applicable the proprietary name should also be used, eg for insulins and long acting theophylline preparations where different brands may have varying bioavailability
- the DOSE and dosage FORM must be clearly stated. The dose should be specified in metric units or the number of individual dosage units where appropriate
- the TIME and ROUTE of administration must be indicated and where appropriate the specific site of application eg "left ear", "right ear"
- Where ABBREVIATIONS are used, only those approved by the BNF are appropriate.
- the frequency of administration of "as required" medicines must be indicated by CLEAR AND DEFINITELY STATED MINIMAL INTERVALS AND A MAXIMUM DAILY DOSE.
- when SUPPLEMENTARY SHEETS are used the person initiating the sheet should indicate such action in the appropriate space on the main prescription sheet

- any known DRUG SENSITIVITIES and/or known DRUG ALLERGIES must be clearly indicated on the prescription sheet
- all prescriptions must be SIGNED BY THE PRESCRIBER with a LEGIBLE signature
- prescriptions for medicines must be printed DIRECTLY on to the PRESCRIPTION SHEET. Non-peelable adhesive labels are NOT acceptable.

Under no circumstances should the prescription sheet be defaced. If a prescription requires to be amended in any way, the original entry must be struck out and a new prescription written. In all cases the original entry must remain legible. To DISCONTINUE a prescription (ie to indicate the termination of a specific course of treatment) a single straight line must be drawn through the complete entry, the date inserted in the "discontinued" column and signed. To CANCEL a prescription (ie to delete an erroneous entry) a single straight line must be drawn through the complete entry, which should then be signed and dated, and the word "CANCEL" printed boldly across the "times of administration" column. All prescription sheets are part of the patient's records and must ultimately be retained as such.

Discharge prescriptions for Controlled Drugs must be written in full by the prescriber who, in addition to completion as above, must specify in words and figures the total amount of the drug or preparation to be supplied.

3 Emergency Prescriptions

Only in an emergency may a medicine be administered without a written prescription. IN ALL CASES the administration, alteration or withdrawal of medication must be immediately recorded on the Prescription Sheet and certified by the prescriber within 24 hours. In the event that the prescriber fails to provide appropriate authorisation within 24 hours, further authorisation should be sought before medication is continued.

NMC Guidelines state that instruction by telephone to a practitioner to administer a previously unprescribed substance is not acceptable. In exceptional circumstances, where the medication has been previously prescribed and the prescriber is unable to issue a new prescription, but where changes to the dose are considered necessary, the use of

methods such as fax or e-mail is the preferred. This should be followed up by a new prescription confirming the changes within 24 hours. In any event, the changes must have been authorised before the new dosage is administered

In the case of the order being received from a prescriber by telephone, the message shall be taken by the practitioner who will:

- acquaint the prescriber with the name and dosages of other medicines currently prescribed for that patient,
- write down the message and read it back to the prescriber checking the patient's name, the medicine, the dose, the route and time of administration.

In an emergency situation, where a verbal order for administration of a medicine is given by a prescriber who is present, the nurse must check the medicine and measured dose with the prescriber before administration.

The normal procedures for recording the prescription and administration of the medicine must then be followed.

It should be noted that controlled drugs cannot be administered on the basis of a telephoned order.

If in doubt about a prescription or medicine for any reason the nurse must not administer until the Sister/Acting Sister/ Nurse in Charge or the prescriber has been consulted.

4 Patient Group Directions

A Patient Group Direction (PGD) is a written instruction for the sale, supply and administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment. The majority of clinical care should continue to be provided on an individual, patient-specific basis and the use of PGDs should be reserved for those limited situations where this offers a distinct advantage for patient care and where it is consistent with appropriate professional relationships and accountability. PGDs are drawn up locally by doctors, pharmacists and other health professionals, signed by a doctor or dentist, as appropriate and a pharmacist and approved by an appropriate body.[4]

IMPORTANT NOTES:

Unlicensed medicines

The use of unlicensed medicines is currently excluded from the scope of PGDs

Controlled Drugs

The Misuse of Drugs (Amendment) (No.3) Regulations (Northern Ireland) 2003 allow the PGD scheme to be extended to the following controlled drugs:

- diamorphine, but only for the treatment of cardiac pain by specialized nurses in accident and emergency departments and coronary care units in hospitals; and
- all controlled drugs listed in Schedule 4 (except the anabolic steroids and any injectable drug which is to be used for the purposes of treating addiction) and Schedule 5 of the 2002 Regulations[5].

Details Required for a Valid PGD[6]

The PGD **must**:

- be signed on behalf of the Department, Trust or Board[7];
- designate in writing the individual or individuals who may supply medicines under the PGD, who must belong to one of the classes of person specified below;
- relate to medicines that have a marketing authorisation or a homoeopathic certificate of registration;
- be in effect at the time of supply.
- and must contain the following information:
  - The name of the business to which the direction applies;
  - The period during which the PGD shall have effect; (guidance has indicated that the PGD should be reviewed at least every two years)
  - The description or class of POM to which the PGD relates;
  - The class of health professional to which the PGD relates;
  - Whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what those restrictions are; (This information is not required if the PGD relates to administration only.)
  - The clinical situations which the POM of that description or class may be used to treat;
  - The clinical criteria under which a person shall be eligible for treatment;

  - Whether any class of person is excluded from treatment under the PGD and, if so, what class of person;
  - Whether there are circumstances when further advice should be sought from a doctor or dentist, and, if so, what circumstances;
  - The pharmaceutical form or forms in which the POM of that description or class is to be administered;
  - The strength, or maximum strength, at which the POM of that description or class is to be administered;
  - The applicable dosage and/or maximum dosage;
  - The route of administration;
  - The frequency of administration;
  - Any minimum or maximum period of administration applicable to the POM of that description or class;
  - Whether there are any relevant warnings to note, and, if so, what warnings;
  - Whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;
  - Arrangements for referral for medical advice;
  - Details of the records to be kept of the supply and/or the administration of medicines under the PGD

In addition to the above criteria, it is a requirement of the legislation that the PGD is signed by a doctor or dentist as appropriate, and by a senior pharmacist.

Classes of Persons Permitted to Supply or Administer Medicines under PGDs.

The following is a list of persons who are permitted under the Regulations to supply or administer specified medicines under a PGD:

- State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval;
- Registered Pharmacists;
- Registered health visitors (live on NMC Register);
- Registered midwives (live on NMC Register);
- Registered nurses (live on NMC Register);
- Registered ophthalmic opticians;
- State registered chiropodists;

- State registered orthoptists;
- State registered physiotherapists;
- State registered radiographers.

It is important to note that the above professionals may only supply or administer medicines under a PGD as named individuals.

ADDITIONAL GUIDANCE ON THE DEVELOPMENT, USE AND REVIEW OF PGDs

1. PGDs should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD. It is good practice to involve local Drug and Therapeutics Committees, Area Prescribing Committees and similar advisory bodies.
2. A senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified and trained professionals operate within directions.
3. All professions must act within the scope of their professional practice and according to their appropriate Code of Professional Conduct.
4. Appropriate document(s) should be signed by each member of the multidisciplinary group, the authorising body and the individual health professionals working under the direction. Generally, a direction should be reviewed every two years.
5. There must be comprehensive arrangements for the security, storage and labelling of all medicines. Wherever possible, medicines should be supplied in pre-packs supplied by the Pharmacy Department. In particular there must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient by patient basis. Names of the health professionals providing treatment, patient identifiers and the medicine(s) provided should all be recorded.
6. The EC Leaflet and Labelling Directive 92/27 applies to all supplies of medicines, including those supplied under PGDs.

Antimicrobials

Particular caution should be exercised in any decision to draw up PGDs relating to antibiotics. Microbial resistance is a public health matter of major importance and great care should be taken to ensure that their inclusion in a direction is absolutely necessary and will not jeopardise strategies to combat increasing resistance. A local bacteriologist should be involved in drawing up the PGD. The local Drug and Therapeutics Committee or Area Prescribing Committee should ensure that any such directions are consistent with local policies and subject to regular external audit.

Black Triangle Drugs and medicines used outside the terms of the Summary of Product Characteristics

The use of any medicine should be consistent with the Summary of Product Characteristics (SPC) for the relevant product (save in special circumstances). Black triangle drugs (ie, those recently licensed and subject to special reporting arrangements for adverse reactions) and medicines used outside the terms of the SPCs may be included in PGDs provided such use is supported by best clinical practice. Each PGD should clearly state when the product is being used outside the terms of the SPC and the documentation should include the reasons why, exceptionally, such use is necessary.

5 Control of Medicines in Clinical Trials

Prior to licensing, new medicines are subject to human testing, as are established products for their use in new indications. Unlicensed products may be prescribed by registered medical practitioners for individual patients on a "named-patient" basis. Clinical Trials are within the scope of Research Governance Framework for Health and Social Care[8] which sets out the responsibilities and standards that must be applied to research conducted by or on behalf of the HPSS. In addition, the conduct of clinical trials must be in accordance with published guidelines on Good Clinical Practice (GCP). Under current arrangements, local (Northern Ireland) Ethical Committee approval must be sought prior to trials commencing. The patient/volunteer must be given adequate information about the trial on which to base his/her option to participate or not. All staff directly concerned with the treatment of a patient must be made aware of that patient's involvement in a clinical trial and its nature; this is particularly relevant to the recognition of side effects. The prescription sheet must be annotated to indicate that the patient is involved in a clinical trial. Administration

and dispensing of trial medicines must be in accordance with locally agreed procedures and records must be kept of the dispensing, issue, and administration of all medicines, and their disposal if warranted. Where trials are being conducted in a hospital the pharmacy department should hold a copy of all trial protocols, including codes, and should be involved in the control and audit of the medicines concerned in relation to procurement, storage, documentation and supply. However, local policy must fit in with national guidelines. For example, codes may be held centrally and it may not be possible for the local pharmacy to hold a copy of them. The identity of those staff involved in the trial must be recorded. Separate stocks of trial medicines must not be maintained in wards, clinics or private offices. Clinical Trials involving controlled drugs must be referred to the DHSSPS Misuse of Drugs Inspector to ensure licensing compliance.

It should be noted that from May 2004 the Clinical Trials Directive (2001/20/EC) is effective for all clinical trials conducted in the UK. This requires that clinical trials are conducted in accordance with the principles of GCP which are, for the purposes of the Directive, the current ICH principles[9].

Where patients involved in a clinical trial attend hospital as out-patients, their continuing supply of clinical trials medicines must be obtained direct from the pharmacy department where the appropriate records will be maintained.

6 Medicines Samples

The distribution of samples of medicinal products is not permitted within the hospital. Any samples received from pharmaceutical representatives must be handled through the normal pharmacy stock control system. Local arrangements should ensure that when representatives of pharmaceutical companies are visiting prescribers they should also be referred to the Pharmacy Department.

7 Medicines Brought to Hospital by Patients

Hospital in-patients must be made aware of the need to inform hospital staff of their current medicine therapy. Specific enquiries must be made by a doctor, nurse and/or

pharmacist to determine whether the patient is taking any prescribed medicines or any other medicinal preparations and if the patient has brought them to hospital. These medicines are the property of the patient to whom they were supplied and must not be taken without consent. The patient should however be asked to surrender, for examination by a doctor or pharmacist, any such medicines or other preparations brought to the hospital.

Steps should be taken to have such medicines identified and a decision made as to whether it is advisable for them to be continued. Where the patient is to continue on that medication, suitable provision for this should be made in the interests of economy, safety and good practice. On no account must one patient's medicine be given to another patient. Where these medicines are NOT to be continued, the patient, or nearest relative or representative, should be asked to give consent to their destruction. It should be explained to the patient that while in hospital all medicines will be prescribed by authorised prescribers and administered in accordance with their directions.

Where patients do not surrender their own medicines it is possible that they will continue with unapproved self medication. It should be made clear to patients, and their representatives if any, that the taking of these medicines contrary to medical advice may seriously jeopardise current treatment to the extent that it may not be safe to commence or continue it.

Where the patient has surrendered medicines but does not agree to their destruction, he/she should be asked to send them home with a responsible adult. Responsibility for security then passes to that adult. The patient or representative must be advised if the medicines are not safe for use with or without other medication.

Where the patient does not agree to the destruction of his/her surrendered medicines, and they are not taken home, the pharmacist should make arrangements for their secure storage in hospital until the patient's discharge when a decision will be made to return them to the patient or to dispose of them as appropriate. Records of the receipt of such medicines and their eventual disposal should be kept.
All medicines brought in with a patient suffering from overdose must be sealed, labelled with the patient's full

name, reference number and date of admission before being stored in the pharmacy. These medicines must not be returned to the patient or disposed of on discharge or otherwise until it is established whether they may be required as evidence in legal proceedings.

Each hospital should include with the notice of admission, or in its admission booklet, advice for patients on the following lines:
"MEDICINES. Whilst you are in hospital the clinical staff may want to prescribe new medicines, or other treatment. Before doing so they will want to know what other medicines, including homoeopathic or herbal remedies, you are already taking, or have with you. It is therefore VERY IMPORTANT that you tell the doctor, nurse or pharmacist about such medicines and bring them with you to hospital if possible. It could be dangerous for you to continue to take your own medicines or to take any medicines brought to you by visitors during your stay in hospital. You should always tell the nurse-in-charge of any medicines brought to you in this way. If you hold a SPECIAL CARD which gives details of any current treatment, for example a steroid or warfarin card, or an allergies alert card or any devices please bring these with you into hospital and show them to the doctor, nurse or pharmacist".

Where patients are found in possession of unauthorised drugs or other suspicious substances staff should refer to the guidance issued by the Department[10]

8 Supply of Patients' "Take Home" Medicine

Provision must be made for patients on discharge or weekend leave to receive a sufficient quantity of their prescribing medicines from the hospital pharmacy to continue their therapy. This will normally be for up to 72 hours until further supplies can be prescribed (this policy is, currently, under review). This procedure will also apply to cases where 'one day' surgery schemes operate. The prescription form used for this purpose should contain a complete and accurate list of the patient's prescribed medicines on discharge, having been completed (at least in triplicate) and signed by the responsible prescriber. One copy of the form will be retained for use by the pharmacy department for dispensing, one copy for filing in the

patient's records, and one copy for the patient's GP where appropriate.

However, suitable provision may be made, where applicable, for patients to continue on the medicines which they brought to hospital with them.

Local arrangements should ensure that, prior to discharge, patients are adequately advised and instructed on the use of their medicines (see section 9). Such advice should also be given to parents, guardians, or relatives where appropriate. Written details of the diagnosis and current medication together with details of any known drug allergies should also be provided for the patient's General Practitioner (see section 19).

When a patient is discharged outside normal hospital pharmacy hours, special arrangements should be made with the pharmacy to have available at the ward suitable containers, labels and patient information leaflets for the supply of medicines from the ward stock. All such containers, labels and leaflets must be in a locked cupboard and the medicines in question should be checked by a second person. **A record of all medicines so supplied must be made on the relevant prescription sheet and the copy of the prescription sent to the pharmacy.**

Medicines dispensed from ward stock to patients on discharge must bear a printed label showing the date, the name of the patient, the ward number, the name of the medicine, its strength and precise instructions for its administration.

Any medicines brought into hospital by a patient and lodged in the ward/pharmacy may be returned on discharge if the patient so requests (except for illicit drugs or medicines belonging to patients admitted with an overdose) (see section 7). The patient should be advised regarding any risk of using those medicines concurrently with existing treatment.

9 Patient Information on Medicines

Studies on the use of medicines have clearly shown that patient compliance with instructions for the self-administration of prescribed medicines is relatively poor.

The reasons for this are diverse and include forgetfulness, misunderstanding of directions, lack of motivation, insufficient information and poor communication by health practitioners and others. In order to optimise the safe, effective, rational and economical use of medicines it is important that patients are given sufficient information and skilled counselling to allow them to use their therapy appropriately and with maximum benefit.

In addition to the printed directions on the medicine container, verbal instructions must be clear and precise, and reinforced in writing as appropriate.

Some situations already exist in Northern Ireland where pharmacists in hospital are, by arrangement with the consultants concerned, directly involved in providing advisory services to selected groups of patients in relation to their prescribed therapy during their hospital stay and prior to their discharge from hospital (eg cardiac and oncology patients).

It is essential that clinicians, in association with other health care professionals as appropriate, take the necessary steps to ensure the provision of adequate information to patients to enable them to use their medication effectively, thus promoting the continuity of care from hospital to the community. It is a legal requirement that patients discharged from hospital should receive a patient information leaflet with each medicine supplied to them.

10 Administration

Nurses

Medicines will normally be administered to a patient by a suitably qualified professional, usually a nurse. If there is any doubt, for example, regarding the legibility of the prescription, the dose of the medicine or the purpose for which the medicine is prescribed, the nurse must seek guidance from the ward manager, prescriber or pharmacist concerned, before administering any medicines. Under no circumstances should guesses be made.

Nurses and midwives whose names are on the first level parts of the Register or second level nurses who have successfully completed approved Pharmacology training should be seen by the employing authority as competent to

administer medicines on their own and responsible for their actions in so doing. The involvement of a second person in the administration of medicines with a first level practitioner need only occur where that practitioner is

- adhering to local policies
- administering a neonatal drug
- administering a Schedule 2 controlled drug
- administering an intravenous solution extemporaneously prepared using potassium chloride concentrate or other strong potassium solutions, or
- administering to a patient whose condition makes it necessary.

Where a student of nursing is administering medicines he/she must be supervised by a first level practitioner.

In hospitals or nursing homes, personnel who are not professionally registered, such as nursing auxiliaries or assistants, should not participate in the administration of medicines unless they have undertaken a course of training endorsed by their employing authority.

In a residential care setting staff involved in the administration of medicines should receive any necessary additional training to enable them to administer medicines to residents who are unable to self-administer.

Second level practitioners should not administer medicines on their own unless the employer:

- has provided additional instruction relevant to the medicines likely to be encountered in a particular setting; and
- has undertaken an assessment and is satisfied as to the individual's knowledge and competence to perform the task; and
- is prepared to accept the responsibility for any errors that are consequential upon using a second level practitioner beyond the role for which they have been trained.

Before selecting the medicine to be administered the nurse must:-

- check that there is a valid prescription (see section 2)
- check the NAME of the patient against the details on the prescription and recording sheet and check the drug allergy box which should never be left blank.

- READ the prescription carefully; and make sure that the medicine is to be administered
- ascertain that the DOSE has not already been administered and that the total dose (where stated) will not be exceeded.
- check the DOSE prescribed and the ROUTE of administration
- Check that the dose prescribed is appropriate especially where the dosage of medication is related to body weight (this is particularly important in relation to neonates and children)

Before administering the medicine the nurse must:-

- verify the identity of the patient, by checking, for example, verbally the name, and the name and unique patient registration number on his/her identity bracelet. The date of birth must always be checked
- select the medicine required, check its STRENGTH, and CHECK THAT THE MEDICINE NAME ON THE CONTAINER LABEL MATCHES THAT ON THE PRESCRIPTION SHEET
- check that the medicine is in date and is not obviously defective in any way.

On the medicine round it is the nurse's responsibility to see that the medicines are actually taken.

Because of the more obvious risk of overdosage, particular care should be taken in the administration of all medicines to neonates and children. It is vital to ensure that the prescribed dose is an appropriate paediatric dose, and that any necessary calculations are correct and have been checked by a second person. For oral liquids a 5ml medicines spoon or measuring cup can be used to measure oral doses which are in multiples of 5ml. An appropriate oral syringe should be used for all other doses. IV syringes should not be used to measure and administer oral liquid medicines. Paediatric formulations should be supplied to wards and departments where children receive treatment. Similar care should be taken in the administration of medicines to elderly patients.

Registered Doctors

The safety of patients comes first at all times. The duties and responsibilities of a registered doctor are outlined in Good Medical Practice[11]. These include responsibilities in respect

of diagnoses, investigation and treatment of patients including those relating to the prescribing and administration of medicines and treatments and the reporting of adverse drug reactions.

Doctors who have special responsibilities for teaching and training must have the skills, attitudes and practices of a competent teacher. They must also ensure that students and junior colleagues are properly supervised. A doctor who delegates treatment or care eg to another doctor, nurse or medical student must ensure that the individual is competent to provide the therapy or carry out the procedure.

Medical Students and Pre-registration House officers

'Tomorrow's Doctor'[12] sets out the clinical and practical skills which graduates must be able to do safely and effectively. These include skills necessary to the prescribing and administration of medicines including:

- working out the drug dosage and recording the outcome accurately;
- writing safe prescriptions for different types of drugs;
- carrying out the following procedures involving veins:
  venepuncture
  inserting a cannula into peripheral veins
  giving intravenous injections
- giving intramuscular and subcutaneous injections
- using a nebuliser correctly
- administering oxygen therapy

In addition, the Student Logbook for Pre-registration House Officer Workshadowing sets out key tasks and skills which a medical student of Queen's University must achieve under the supervision of a PRHO or other junior staff. This emphasises that no drug or intravenous fluid should be prescribed by a medical student. All such medication must be prescribed by a qualified doctor. The log book sets out key tasks/skills to promote safe prescribing and practical procedures which should be achieved and written up including:

writing up a fluid balance chart;
writing a drug prescription chart;
prescribing anticoagulation based on INR chart;
prescribing insulin based on diabetic chart;

giving summary of local antibiotic policy
compiling a list of 10 drugs most commonly used at the Unit, documenting specific details;
practical procedures, under a named supervising staff member, including IV cannula insertion, erection of IV infusions and SC/IM/IV injections

Intravenous Infusions

Medicines given via any form of intravenous infusion should be administered in accordance with the clearly written directions of the prescriber and as laid down in local procedures established by Boards under Circular HSS(OS3)6/79 "Addition of Drugs to Intravenous Infusion Fluids". Aseptic dispensing must be carried out in compliance with published standards[13] as advised in circular HSSE (OCE) 1/97

Intrathecal Administration

Due to the serious consequences resulting from maladministered spinal injections, it is essential that the National Guidance on the Safe Administration of Intrathecal Chemotherapy[14] is observed.

Potassium Chloride Solutions

Systems should be in place to avoid incidents where patients accidentally receive an overdose of intravenous potassium. Particular attention should be given to the guidance issued by the National Patient Safety Agency (NPSA) and endorsed by the Department[15].

Cytotoxic Drugs and Radioactive Substances

By their nature, cytotoxic drugs and radioactive substances constitute a hazard to healthy cells, both in the patient and those who prepare and administer them. Cytotoxic products should, preferably, be prepared in the pharmacy department by trained and experienced pharmacy staff and not at ward level.

Good practice guidelines on the safe handling and administration of cytotoxic[16] and radiopharmaceutical preparations[17] should be observed

Prescribing, supply and administration of specialist medicines[18]

As care for patients becomes more complicated, specialised medicines are increasingly being used. 'Specialist

medicines' have been defined by Departmental guidance and have been designated as 'Red' or 'Amber' List medicines.

It is recommended that the prescribing responsibility for a Red List medicine should remain with the initiating consultant and it should be supplied via a hospital pharmacy. The administration of such medicines may be undertaken by a nurse under the written direction from a doctor/consultant currently registered with the General Medical Council. A formal document should be supplied from the consultant which must state the patient's name, address, condition being treated, the dose and route of administration of the medicine. It must be signed by the consultant responsible for the treatment of the patient and the nurse once the medicine has been administered. A copy of this document should be sent to the patient's GP. The authorisation to administer must then be filed in the patient's notes. Amber List medicines may be prescribed and supplied in primary care. Prescription and supply should be done under a shared care protocol which should be agreed by the hospital and primary care prescriber.

Other Health Professionals

Administration of medicines to patients by other authorised health professionals must be in accordance with the written directions of an appropriate prescriber or in accordance with a PGD. These directions (see sections 2 and 4) must be recorded on the patient's prescription sheet(s) together with a further record of the administration of the medicine (see section 12) signed by the health professional involved.

11 Self-administration of medicines

Self-administration may be defined as a system which allows persons in health service or private care facilities to have possession of some or all of their prescribed medication and to take responsibility for administering it correctly. It is recognised that various medicines often are self-administered eg glyceryl trinitrate, aerosol bronchodilators, and that these medicines are held by the individual concerned during his stay in such establishments.

There is a case for extending this method of administration to a variety of health care situations. This relates particularly to encouraging people to take greater responsibility for their own treatment and also to improving

the continuity of care from hospital to the community where, in the latter situation, patients almost exclusively administer their own medicines. The difficulties inherent in such a system of medicine administration in hospitals are recognised. It is essential, therefore, that where self-administration is introduced, arrangements are in place for the safe and secure storage of the medication, access to which is limited to the specific patient. In addition, records of such self-administration should be maintained appropriate to the environment in which the patient is being cared for.

Given existing practices and the possibility of the development of self-administration programmes, provision should be made for those who are judged to be competent and confident to administer their own medicines, to have a lockable drawer or cupboard in which to store them. In cases involving self administration of controlled drugs subject to Safe Custody requirements, advice should be sought from the Department's Misuse of Drugs Inspector. In addition, each preparation must be clearly labelled with the name of the patient, the name and strength of the medicine, the directions for use, and date of dispensing and the amount dispensed.

Any developments in the area of self-administration of medicines should be along multidisciplinary lines with agreed written protocols of the procedures to be followed.

12 Recording

A record of administration should be made on the medicines recording sheet, at the time the medicine is given to the patient, and initialled by the person (normally the nurse) who administered the medicine. If the medicine has not been taken, this fact should be recorded on the prescription sheet and the prescriber informed. A local system should also be developed whereby any suspected adverse drug reaction is recorded and the appropriate practitioner(s) alerted. Pharmacists could play a useful role in co-ordinating such a scheme. In addition, all suspected adverse drug reactions should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) using the Yellow Card Scheme. Pre-paid Yellow Cards for reporting such reactions are bound within the inside back cover of the BNF.

Schedule 2 Controlled Drugs

In addition to the above, the details relating to the administration of Schedule 2 Controlled Drugs shall be entered in the ward controlled drugs register or other separate record kept specifically for that purpose. Such register/record must be signed by a First Level Registered Nurse and a witness who should also be **present at the administration of the drug**. Where two nurses are involved, one of them must always be a First Level Registered Nurse.

There is no legal requirement to keep a register for Schedule 3 Controlled Drugs, for example, temazepam. However, many hospitals, as a matter of good practice, maintain a register for selected Schedule 3 preparations.

Details concerning Controlled Drugs accidentally or deliberately wasted shall be similarly witnessed and recorded in the ward controlled drugs register/record. A documented CD audit should be carried out by the pharmacist at least three-monthly.

13 Supply of Medicines to Wards and Departments

It is recognised that a number of different methods are used to effect the supply of medicines to wards. However, pharmacists are responsible for the supervision of the dispensing of medicines and for ensuring that systems are established for the safe, secure, effective and economic supply of medicines.

Ordering

Medicines other than Controlled Drugs: All orders must be made in an approved manner and each requisition must indicate the date, ward, department or other healthcare facility and the name, quantity, strength and form of medicines required. Where a 'topping-up' system of supply is in use the requisition may be in the form of a list prepared by pharmacy staff. The Nurse in Charge is the person with responsibility for approving requisitions. In other departments, eg physiotherapy and podiatry, it is the responsibility of the senior professional to requisition designated medicines.

Controlled Drugs: The Misuse of Drugs Regulations (Northern Ireland) 2002 specifies five schedules of medicinal substances which are subject to various forms of control. For most practical purposes hospitals and other healthcare facilities need only be concerned with the specific control requirements of Schedules 2 and 3. However, significant possibilities exist for the illegal diversion of drugs in Schedules 4 and 5 and local procedures should be commensurate with the perceived or actual risk.

- **Schedule 2 Controlled Drugs:** Orders for these medicines, which are mainly opiates, **must** be made on a separate duplicate requisition specifically designated for these preparations and signed by the Sister/Acting Sister in charge of the ward or department or other healthcare facility.
- **Schedule 3 Controlled Drugs:** Schedule 3 drugs include among others dihydrocodeine, temazepam and buprenorphine. They must be ordered on a duplicate requisition signed by the Sister/Acting Sister in charge of the ward or department.

Delivery

It is the responsibility of the pharmacy department to establish safe systems of delivery, incorporating appropriate documentation so as to allow both the issuing department and the receiving unit to effect proper audit.

Staff involved directly in the transport of medicines should be limited to a minimum practical number of identified people, ensuring, of course, a back up of available staff to maintain continuity of service. Ideally transport and portering staff should be part of the pharmacy establishment. Those transporting medicines shall be responsible for their security until delivered to an authorised person and the delivery acknowledged.

Where, in emergencies, non-Trust transport is employed to transport medicines it is the responsibility of the pharmacy department to ensure that adequate security arrangements are in place.

Medicines other than Controlled Drugs: The delivery of medicines to wards, departments etc must be carried out in a manner that ensures that the medicines reach their destination without undue risk of being stolen, damaged or tampered with in any way. Where medicine delivery is undertaken between hospitals all containers must be locked and/or fitted with tamper-evident seals.

Controlled Drugs (Schedule 2): Where Controlled Drugs delivery is undertaken from a pharmacy department within a hospital, delivery (in a sealed package) must be effected in person by a responsible individual. That person must sign for the delivery of the Controlled Drugs before leaving the pharmacy department. At ward level the medicines must be handed to the Sister/Acting Sister who will check the medicines received against the requisition and sign for their receipt.

Where Controlled Drugs have to be delivered between hospitals they must be in a locked container or be fitted with a tamper-evident seal. Where this receptacle contains other medicines the Controlled Drugs must be sealed in a separate package. A signed record of receipt for the Controlled Drugs must be made by the Sister/Acting Sister and returned to the issuing pharmacy department.

Delivery of Medicines to Patients' Homes

Delivery of medicines to patient's homes should be undertaken in accordance with the guidance articulated in the Code of Ethics issued by the Pharmaceutical Society of Northern Ireland

14 Medicines for Staff Personal Use

Medicines for the personal use of staff will not normally be provided from hospital stocks. However, where Boards agree to such provision, where appropriate, charges for the medicines supplied should be made.

15 Storage and Custody

Storage of medicines involves both environmental and security factors. Medicines must be stored under optimum environmental conditions (temperature, lighting etc) in accordance with the manufacturers' instructions. Robust systems must be in place to ensure that unauthorised access to medicines is prevented.

Guidance on security matters may be sought from the Department's Pharmaceutical Inspectorate and PSNI Crime Prevention Officers.

Medicines for use in wards should be stored in approved standard modular cupboards conforming to British Standards where applicable. These include the following categories:-

- Controlled Drugs Cabinet
- Internal Medicines Cupboard
- External Medicines Cupboard
- Cupboard for Disinfectants/Antiseptics used in ward cleaning
- All medicines should be stored according to manufacturers' recommendations in respect of temperature. Where products requiring refrigeration are stored the refrigerator used should be equipped with a means of ensuring that the specific temperature range specified for the product has been maintained. A daily record of such monitoring should be made.
- Cupboard for Diagnostic Reagents, including Urine Testing Cabinet
- Dedicated clinical area for Intravenous Fluids and Sterile Topical Fluids.
- Appropriately secured emergency trolley.

Where there is a perceived extra risk of theft, for example due to the nature of certain preparations, their location, or lack of 24 hour staff presence, additional safeguards should be applied as appropriate.

The area in which cupboards are located must be well lighted by day and at night. Medicines in current use, with the exception of Controlled Drugs, may be kept in a locked approved medicine trolley and not returned to the cupboard after each administration. Medicine trolleys must be parked when not in use either in a lockable cupboard or attached by lock and chain to the wall or floor. They must never be left unattended when opened.

Schedule 2 controlled drugs must always be stored in a Controlled Drugs Cabinet providing, in its construction, a level of security at least comparable to that laid down in the Misuse of Drugs (Safe Custody) Regulations 1973. In theatre suites these should be located in each anaesthetic room and/or recovery room which serves one or more theatres.

Areas where controlled drugs are stored which are regularly and routinely unmanned should, where possible, be monitored by alarm systems or CCTV. Locks securing

doors leading to areas where controlled drugs are stored must be adequate to act as a deterrent to theft.

Keys of controlled drugs cabinet must be carried on the person of the Sister/Acting Sister/Nurse in Charge and be handed over personally to the nurse responsible for taking over the custody of the cupboards. Keys to all other medicine cupboards must be held by either the Sister or a First Level Registered Nurse. Loss of keys must be reported immediately for appropriate action by the Nurse in Charge, who will also inform the pharmacy.

In clinical areas where medicines are frequently required for emergency use, local guidelines should ensure maximum security compatible with functional requirements.

In situations where controlled drugs are in daily use the stock balance should be reconciled on each occasion when responsibility for safe custody is transferred. However where controlled drugs are used less often the frequency of this check may be varied for local operational reasons at the discretion of the Sister/Acting Sister/Nurse in Charge, in consultation with the Pharmacist. This check must be carried out by two qualified nurses one of whom should be on the First Level Register, recorded and signed.

The security of ward stocks must be checked by pharmacy staff periodically, normally every three months, in accordance with locally agreed procedures. They must carry out inspections of ward stocks, with reconciliation where necessary.

Where there has been unauthorised access to, or theft of, ward medicine stock this must be reported immediately to the Nurse in Charge who will conduct an initial investigation and subsequently inform the pharmacy department. It then becomes the responsibility of the pharmacy department to investigate the matter, enlisting the support of other disciplines and liaising with the police as appropriate.

16 Labels

Medicines dispensed from pharmacy must be clearly labelled in accordance with legal requirements. If any of the details on the label on any container are defaced or obliterated, eg name, expiry date or strength, the container must be returned to the pharmacy for replacement.

Alterations to labels must not be made under any circumstances except to indicate the addition of prescribed drug to a container of intravenous or irrigation fluid, or to indicate when any particular pack (eg eye drops) was first used.

17 Transfer of Medicines between Containers

The transfer of any medicine from one container to another, other than by pharmacy staff, is forbidden. Any loose medicines present on a ward must not be used or returned to the container but sent to the pharmacy for disposal.

18 Transfer of Medicines between Wards

Only in exceptional circumstances should medicines supplied from ward stock be used on another ward. In such cases, the smallest original pack should be supplied. Local arrangements should ensure that such transfers are fully documented. The Misuse of Drugs Regulations do not permit the transfer of controlled drugs between wards.

19 Transfer of Patients

Occasionally when a patient is transferred between hospitals insufficient information regarding treatment is given to the hospital to which the patient is transferred. It is appreciated that in some instances hospitals prefer to retain their own records and that an abbreviated summary is often more convenient for the receiving hospital, but the lack of sufficient information could have an adverse effect on the patient's treatment.

A written record of the patient's diagnosis and current treatment, including medication regimen together with any information on known drug allergies and, where appropriate, a 24 hour supply of medication, should accompany the patient on transfer to another hospital. The time when the patient received the last medication must also be given.

These principles should also be applied for the information of the appropriate General Practitioner when a patient is discharged to the Community (see also section 8) and for the information of the nursing home when a patient is discharged to a home.

20 "Out of Hours" Pharmacy Arrangements

Local arrangements for HPSS establishments should ensure the provision of a pharmacy "out of hours" service. Consideration should be given to the provision of an emergency medicines cupboard, the contents of which should be decided by the Pharmacy Department in consultation with senior medical and nursing staff. Access should be restricted to named individuals and records kept of any stock used.

21 Hospital Pharmacy Security

Responsibility

Each pharmacy department must have a pharmacist with delegated responsibility for all aspects of the safe and secure handling of medicines. The pharmacist will define suitable systems of work and storage within the department, taking account of statutory requirements and professional guidance.

Access

Access to the pharmacy stocks must be restricted to personnel authorised by the pharmacist in charge. Medicines can only be supplied in accordance with written procedures approved by the pharmacist in charge.

Emergency pharmaceutical cover should be available for occasions when access to the pharmacy is necessary when the department is closed. Hospital emergency cupboards may provide a source of emergency "out of hours" medicines (see section 20).

Physical Security

Security precautions in general should comply with recommendations made by local Health and Safety Officers, PSNI Crime Prevention Officers and Departmental Officers. There should be a suitable intruder alarm installed in each Department linked to the hospital switchboard or local police station. Such alarms should be regularly tested. Staff must be well informed of the procedures to be followed in the event of a breach of security. Additional security measures including appropriate use of CCTV, panic buttons, toughened glass and restricted access areas are now recommended for all hospital pharmacies.

Storage of Controlled Drugs

Controlled Drugs must be stored in cabinets, safes or rooms which must at least conform to the standards laid down in the Misuse of Drugs (Safe Custody) Regulations 1973. Stock levels should be kept to a minimum compatible with hospital demand and the logistics of replenishment.

Stock Control/Recording and Reconciliation

The purchase and receipt of medicines by the pharmacy should be conducted, and recorded, according to written and approved standard operating procedures (SOPs). These must include a means of identifying the member of pharmacy staff involved at each stage of the transaction.

There must be a clear method whereby medicines being received into the pharmacy store from a supplier are co-related with an official order. The person initiating the order should not, as far as possible, be the person verifying its receipt.

Permanent records of medicines purchased must be maintained and records kept of all medicines coming into and out of the pharmacy. The date of each transaction and the identities of those involved must be recorded.

SOPs should include provision for checks enabling the tracing of medicines, for example, where defects/hazards are reported. Regular stock reconciliation spot checks should be carried out and any discrepancies investigated.

All medicines dispensed from the pharmacy must have been ordered in writing by an appropriate person and a record of the transaction must be maintained together with the signature of the authorised member of the pharmacy staff or other means of his/her identification.

Controlled Stationery

Controlled stationery is any stationery which, in the wrong hands, could be used to obtain medicines fraudulently. Stocks of controlled stationery must be received, held secure and distributed by the pharmacy department.

In normal circumstances only one book/pad of forms should be held by each ward/unit/department at any given time and replacement stationery should only be issued on the evidence that existing forms have been used. Loss or theft of any controlled stationery must be reported immediately to the person in charge of the ward/unit/department and to the pharmacy for investigation.

Inspection

The rights of access and inspection by the Department's Pharmaceutical Inspectorate apply to all health service facilities.

22 Pharmaceutical Waste

The disposal of medicines and controlled drugs should be carried out in accordance with local policies based on *Guidance on the Handling and Disposal of Pharmaceutical Clinical Waste* (Health Estates 2002)[19].

23 Residential and Nursing Homes

The principles relating to prescribing, administration and storage of medicines given in previous paragraphs should also apply to the handling of medicines in residential homes and private nursing homes. In a residential home setting, it is the responsibility of the owner/employing authority to ensure that medicines management is, as far as possible, in line with the standards and guidance given in this document. Boards should establish detailed procedures to be followed in all such homes subject to their control and inspection. The procedures should take into account the specific guidance given in the following paragraphs.

With the exception of approved "household" remedies, all medicines must be prescribed on an individual "named person" basis. Medicines must also be dispensed on an individual "named person" basis and therefore must be administered only to that person.

All prescriptions must clearly indicate the dosage, frequency and route of administration of the medicine. General instructions such as "as directed" are not acceptable.

Each facility should employ a prescription sheet that fulfils all the requirements listed in section 2 whereon a complete record of each resident's prescription(s), administration of medicine(s) etc is maintained. General Practitioners should be encouraged to verify and sign the prescription record sheet as a matter of good professional practice so as to ensure that the residents' prescribing records are at all times up to date and accurate.

Procedures should include instructions, drawn up in consultation with pharmacy, medical, nursing and social services staff as appropriate, for the Manager in relation to approved home remedies for minor ailments and the

recording of their use. Such procedures should conform to published Regional Guidelines.

Where a resident needs a supply of medicine during a temporary absence from the Home, or on discharge, provision must be made for an adequate, suitably labelled supply to be given to the resident, or responsible adult/relative, for administration as prescribed.

All medicines which are unused and/or unfit for use should be returned to a community pharmacy for disposal.

In specialist units eg Hospice care, where specific arrangements for the procurement of medicines have been agreed with the Department of Health, Social Services and Public Safety, their control and use in those units should follow the guidelines laid down in this document for hospital wards.

24 Community Nurses and Health Visitors

Community Nurses and Health Visitors should not normally carry medicines. It is, however, acknowledged that Community Nurses may carry some medicines for emergency use eg adrenaline injection.

Except when carried on the person of the authorised nurse, medicines must be kept out of sight in the nurse's locked vehicle during domiciliary visits. When they are kept overnight in the nurse's own home, they must be securely locked away. Nurses who carry medicines must also carry an identification document, signed by a Senior Nurse, stating their authority to do so.

Each medicine carried must be related to the written prescription of a registered prescriber.

It should be remembered that medicines supplied on prescription to persons in the community are the property of the person for whom they are prescribed.

Nurses have a responsibility for assisting in the education of the public regarding the safe custody and administration of their medicines. Patients should also be warned that medicines require careful storage and that prescribed medicines must not be made available to, or given to, persons other than the patient for whom they were prescribed.

In the administration and recording of medicines by community nurses, the principles of good practice as set out in section 10 must be applied. In addition to the nurse's own records, a record of each administration must be completed for retention by the patient.

Nurses should advise patients and/or their relative(s) and representative(s) that any medicine no longer required should be returned to a pharmacy for disposal.

If at any time the availability of medicine(s) in a patient's home gives cause for concern in relation to the safety of the patient or the custody of the medicine(s), the nurse must exercise his/her professional judgement regarding the removal of medicines. A record of the action taken must be made (including reasons as appropriate) and the patient's doctor fully informed.

25 Midwives

Midwives must observe the rules set out in the Midwives Rules (NMC) and Code of Practice and follow relevant legislation and any local policy and/or procedures specified by the Supervisor of Midwives.

In the Community

Supply and Administration of Controlled Drugs

The Misuse of Drugs Act 1971 provides for the supply of pethidine and pentazocine to midwives using a 'supply order' in accordance with Regulation 11 of the Misuse of Drugs Regulations (Northern Ireland) 2002. In these circumstances full records must be maintained for pethidine in a Controlled Drugs Register which must be made available for inspection, if required, by the Department's Misuse of Drugs inspector. Any controlled drugs prescribed by a general practitioner remain the property of the woman and midwives should ensure that they are stored securely in the woman's home.

Possession and administration of Controlled Drugs by midwives must be in accordance with locally agreed procedures and Regulation 11 of the Misuse of Drugs Regulations 2002. Midwives must record full details of the administration of pethidine or other drugs in the patient's records. All records must be made available for inspection as required by the Supervisor of Midwives.

Supply and Administration of Other Medicines

A list of prescription only medicines which may be supplied to, and used, by midwives is included in the Prescription

Only Medicines (Human Use) Order 1997. The medicines which are to be used by midwives must be decided by the Supervisor of Midwives in accordance with local policy. Supplies should be arranged as above.

Midwives must keep a record of supply, administration and disposal of all prescription-only medicines issued to them.

When in the custody of the midwife, the security of medicines is the midwife's responsibility.

Return/Disposal of Medicines

As indicated above, Controlled Drugs obtained by a woman on prescription from her doctor, for use in her home confinement, are her own property. Even when no longer required they should not be removed by the midwife, but the woman should be encouraged to return the drugs to the pharmacy from which they were supplied so that they may be safely destroyed.

Where a midwife is in possession of medicines, other than Controlled Drugs, which are no longer required, but are still usable, they may be returned to the pharmacy from which they were supplied. In the case of prescription only medicines, a receipt should be obtained and a record of their return made in the midwife's records. A record must also be made of all prescription only medicines disposed of by the midwife.

Audit of Records

Supervisors of Midwives must, as part of their duties, periodically audit the records of medicines kept by each midwife. Any discrepancies must be investigated.

In Hospitals

Midwives Working in Hospitals

Administration of Controlled Drugs and other medicines by midwives working in hospitals must be in accordance with relevant legislation, locally agreed policies and the guidance given in section 10.

26 Primary Care including GP Practices, Health Centres and Community Clinics

Security and storage of prescriptions: There should be an appropriate prescription security system in place to ensure the safe ordering, receipt and storage of prescriptions. It is recommended that practices should have a written policy and documented procedure. Unused prescriptions should be stored in a locked cabinet. It is advised that a register should be kept which should include the following information as a minimum:

- The date and procedure for ordering;
- The date of receipt of prescriptions from courier;
- The prescription serial numbers, the date and to whom prescriptions were issued from the central supply;
- The register should also record the quantity and date of supply to locums, and record the date of return of unused scripts

Prescriptions pads should not be left unattended at any time. It is recommended that a minimum number of prescriptions should be carried when working outside the practice environment. The responsibility for security of prescription pads rests solely with the prescriber to whom the pads were issued.

It is recommended that stock order forms should be used in accordance with Departmental guidance. The principles of security and storage, as outlined above, should also apply to stock order forms.

Blank computerised prescription sheets should be kept secure and the written policy on prescription security should also incorporate best practice on the issuing and use of computerised prescriptions. Detailed advice has been produced by Health and Social Services Boards and further advice may be obtained from the HSS Family Practitioner Units.

Medicines stored and used under the personal control of a doctor: In most cases supplies of medicines are carried personally by doctors. Responsibility for the safe custody of such medicines, including professional samples, rests solely with the doctor concerned and must not be delegated. There should be a practice policy and procedure in place for regularly checking the expiry date and replacement of essential medicines and consequent diposal in accordance with Special Waste Regulations..

Essential medicines (excluding Controlled Drugs) stored in treatment rooms or other clinical areas for daily use by nursing or other professional staff eg for immunisation, podiatry, dentistry, physiotherapy and family planning: The amount stored should be kept to a minimum and need not be under the direct

control of the General Practitioner. Emergency packs of medicines should be clearly marked "For Emergency Use" and be easily accessible to staff during the hours when patients attend. All medicines should be stored according to manufacturers' recommendations in respect of temperature. Where products requiring refrigeration are stored the refrigerator used should be equipped with a means of ensuring that the specific temperature range specified for the product has been maintained . A daily record of such monitoring should be made.

Controlled Drugs: General Practitioners are obliged to store their controlled drugs in accordance with the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 which requires the use of a locked receptacle. General Practitioners are advised to use a custom made Controlled Drugs cabinet which is affixed properly in an appropriate area in the practice.

Doctors may carry their personal stock in a locked bag but are advised to ensure personal control of this at all times and should avoid storage in an unattended vehicle where it would be susceptible to theft.

It should be noted that the use of the Controlled Drugs Register is mandatory. An appropriate Register may be obtained from the Central Services Agency and guidance on good practice in respect of prescription, supply, administration and destruction of controlled drugs, which has been approved by the Department, is contained in the Register.

Prescription Pads: The importance of safe storage and custody of prescription pads (HS21 Rev) is emphasised. Responsibility for the security of these pads rests solely with the prescriber.

Out of Hours (OOH) GP Services

Providers of OOH services should note and follow the principles outlined above for the safe prescription and use of medicines. It is recommended that OOH services **should not** maintain a central supply of controlled drugs but rather ensure that doctors carry a small supply for clinical use.

In certain circumstances small amounts of immediately necessary treatment is issued by practitioners via OOH services. It is essential that these are appropriately labelled with the names of the patient and of the medicine, the quantity supplied and clear instructions for use. The law also requires that a patient information leaflet be supplied to patients.

GP Dispensing Practices

Dispensing GP practices should operate to the same standards as community pharmacy practice.

Medicine Administration

Medicines must not be administered by nursing staff in health centres/GP practices without the written prescription of a registered prescriber or under the authority of an approved PGD.

Supply of Medicines to Community Clinics

Medicines for use in community clinics are normally supplied via Trust hospital pharmacies. The range of medicines for use in these facilities must be agreed by the practitioners involved and the hospital Trust pharmacist.

Orders for medicines must be in writing and on a supply form provided by the pharmacy. Each order must bear the signature of the person authorised to have possession of the medicines.

Primary Care Dental Practitioners

Primary care dental practitioners should familiarise themselves and put into practice those sections of the guidance which are relevant to their own clinical situation.

27 Ambulance Service

The Medicines Act 1968 restricts the administration of parenteral medicines. All medicines for parenteral administration are prescription only and unless self administered, they may be administered only by or under the directions of a doctor or dentist. Under the Prescription Only Medicines (Human Use) Order 1997 (the POM Order), exemptions from these restrictions are provided for specified persons in respect of specified medicines.

Arrangements for ambulance paramedics

Paramedics holding a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State or persons who are state registered paramedics are authorised to administer a range of parenteral medicines[20] for the immediate, necessary treatment of sick or injured persons.

Glossary

Medicinal Product Article 1 of Directive 2001/83 EC defines a medicinal product as 'any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product'.

Administer means administer to a human being or an animal whether orally, by injection or by introduction into the body in any other way, or by external application, a substance or article either in its existing state or after it has been dissolved or dispensed in, or diluted or mixed with, some other substance used as a vehicle (Medicines Act 1968).

Medicine is used in this guidance to refer to all medicinal products.

Controlled Drugs (CD) are substances which are subject to the Misuse of Drugs Act 1971 and Regulations made under that Act. As medicinal products they are also subject to the Medicines Act and its Regulations.

Attention is drawn to the Misuse of Drugs Regulations (Northern Ireland) 2002 (No 1) specifying 5 schedules of Controlled Drugs, to which separate controls apply.

Register means the Single Professional register kept by the Nursing and Midwifery Council (NMC).

Parts of the Register

Part 1 First Level nurses trained in general nursing.
Part 2 Second level nurses trained in general nursing (England and Wales).
Part 3 First level nurses trained in the nursing of persons suffering from mental illness.
Part 4 Second level nurses trained in the nursing of persons suffering from mental illness (England and Wales).
Part 5 First level nurses trained in the nursing of persons with learning disabilities.
Part 6 Second level nurses trained in the nursing of persons with learning disabilities (England and Wales).
Part 7 Second level nurses (Scotland and Northern Ireland)
Part 8 Nurses trained in the nursing of sick children.
Part 9 Nurses trained in the nursing of persons suffering from fever.
Part 10 Midwives.
Part 11 Health visitors.
Part 12 First level nurses trained in adult nursing (Project 2000)
Part 13 First level nurses trained in mental health nursing (Project 2000)
Part 14 First level nurses trained in learning disabilities nursing (Project 2000)
Part 15 First level nurses trained in children's nursing (Project 2000)

Nursing and Midwifery students are persons who are undergoing pre-registration training for admission to the appropriate parts of the Register.

Sister/Acting Sister/Ward Manager is a nurse for the time being in charge of a ward, theatre or other department in a hospital or nursing home or, a caseload holder in a community setting. It includes any male nurse occupying a similar position.

Authorised Medical Officer is a doctor who is for the time being authorised in writing by the local Board's Chief Administrative Medical Officer for the purposes of Regulation 11 - Exemption for Midwives - of the Misuse of Drugs (Northern Ireland) Regulations 2002 or (for signing Midwives' Supply Orders **only**) a Supervisor of Midwives who is so authorised for the purposes of Regulation 11(2) of those Regulations.

Prescriber is a person authorised under the Medicines Act 1968 to order in writing the supply of a prescription only medicine for a named patient

Authorised person is a person authorised by the Department for the purposes of Regulation 27 of the Misuse of Drugs Regulations (Northern Ireland) 2002(destruction of controlled drugs).

Approved name of a medicine is its designated generic name devised and selected by the British Pharmacopoeia Commission and published in accordance with the Medicines Act 1968.

In this guidance all references to staff and patients should be taken as including either sex.

References

[1] *Guidelines for the administration of medicines*, Nursing and Midwifery Council, 2002
[2] *Good Practice in Consent*, issued under cover of HSS(MD)7/2003 on 13th March 2003
[3] *British National Formulary*, incorporating the Nurse Prescribers' Formulary, BMA and RPSGB
[4] A helpful flowchart for determining the appropriateness or otherwise of a PGD is provided at http://www.groupprotocols.org.uk
[5] *Misuse of Drugs Regulations (Northern Ireland) 2002*
[6] The relevant provisions are contained in *The Prescription Only Medicines (Human Use) Amendment Order 2000* (SI 2000 No 1917)
[7] By virtue of *The Prescription Only Medicines (Human Use) Amendment Order 2003* (SI 2003 No 696) the use of PGDs has been extended to the private sector.
[8] *Research Governance Framework for Health and Social Care*, DHSS&PS, November 2002
[9] http://www.emea.eu.int/pdfs/human/ich/013595en.pdf
[10] *Guidance Procedures when a Patient in a Hospital or Clinic Setting is found in possession of Unauthorised Drugs or other Suspicious Substances*, issued under cover of HSS(MD)11/95 on 14th August 1995.
[11] *Good Medical Practice*, General Medical Council, 2001
[12] *Tomorrow's doctors; Recommendations on undergraduate medical education*, General Medical Council, July 2002
[13] *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2002*, The Stationery Office, 2002
[14] *National Guidance on the Safe Administration of Intrathecal Chemotherapy*, Department of Health, London, 2001 (http://www.doh.gov.uk/intrathecalchemotherapy/guidance.pdf); issued in Northern Ireland under cover of HSS(MD)31/01 on 16th November 2001. See also letter on Frequently Asked Questions isued 3rd May 2002 and HSS(MD)2/2003 issued on 9th January 2003.
[15] *Patient Safety Alert - Potassium Chloride*, National Patient Safety Agency (NPSA), 2002 (http://www.npsa.org.uk/admin/publications/docs/riskalertpsa01.pdf); issued under cover of letter CPh2/02 on 23rd July 2002
[16] *Recommendations on Facilities, Staffing and Procedures related to Chemotherapy Administration within the Northern Ireland Cancer Treatment Service*, Regional Advisory Committee on Cancer (RACC), 1999
[17] *Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources*, Administration of Radioactive Substances Advisory Committee (ARSAC) 1998
[18] *The Regional Group on Specialist Drugs - Implementation of Red/Amber Lists* issued under cover of HSS(MD)16/2003 on 2nd April 2003
[19] *Pharmaceutical Clinical Waste - A Guide*, Health Estates, 2002; issued under cover of Health Estates Circular PEL (02) 10
[20] Diazepam 5 mg per ml emulsion for injection;
Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion;
Medicines containing the substances ergometrine maleate 500mcg/ml with oxytocin 5iu/ml but no other active ingredient;
Prescription Only Medicines containing one or more of the following substances but no other active ingredient-

Adrenaline Acid Tartrate	Lignocaine Hydrochloride
Anhydrous Glucose	Metoclopramide
Benzylpenicillin	Morphine Sulphate
Bretylium Tosylate	Nalbuphine Hydrochloride
Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution)	Naloxone Hydrochloride
	Polygeline
Ergometrine Maleate	Sodium Bicarbonate
Frusemide	Sodium Chloride
Glucose	Streptokinase
Heparin Sodium	Syntometrine

In addition, ambulance paramedics are included within the classes of persons permitted to supply or administer medicines under Patient Group Directions (see under section 4 above).

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Department of
Health, Social Services
and Public Safety

An Roinn
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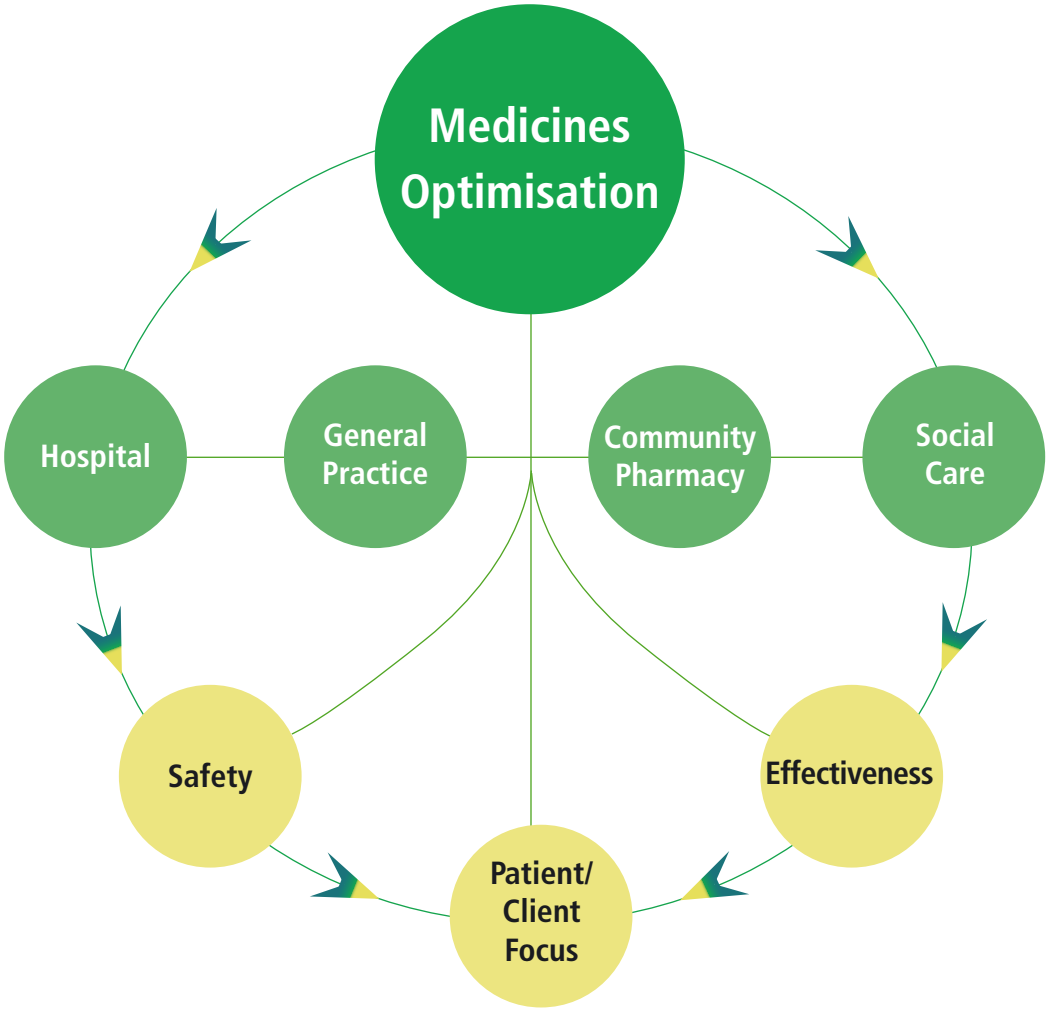
Northern Ireland Medicines Optimisation Quality Framework



March 2016

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FOREWORD

Minister for Health, Social Services and Public Safety

As Minister for Health, Social Services and Public Safety, my mission is to improve the health and well-being of all people of Northern Ireland. Whilst healthier lifestyle choices may be all that is required for some people to maintain health, most will need medicines at some stage to treat or prevent illness.

Medicines are the most common medical intervention used in the health service with an annual expenditure of over £550m. In comparison with other UK countries the volume and cost of medicines used per head of population in Northern Ireland is high. With an aging population and a rising number of people with long term conditions, demand is expected to increase.

Unfortunately evidence shows variance in best practices relating to the appropriate, safe and effective use of medicines and many people do not take their medicines as prescribed resulting in sub optimal health outcomes, wasted medicines and pressure on acute health and social care services.

The Medicines Optimisation Quality Framework aims to support better health outcomes for our population by focusing attention on gaining the best possible outcome from medicines every time that they are prescribed, dispensed or administered.

The Framework supports quality improvement through the consistent delivery of recognised best practice and supports the development and implementation of new, evidence based best practice. Implementation will involve an innovation and change programme involving multi-disciplinary professionals working together and with patients.

Much has been done in recent years to improve the way medicines are used and Northern Ireland is recognised as one of the leading regions in Europe in addressing the health and social care needs of the older population through innovation in medicines management. However, more action is needed to gain optimal outcomes from medicines and provide a sustainable approach to clinical and cost-effectiveness whilst reducing avoidable adverse events and waste.

Everyone has a responsibility to improve medicines use and patients need to become more involved in decisions about their treatment and better informed about the role of medicines in their care. By encouraging dialogue and listening to patients' concerns about their medicines, we can empower them to make informed decisions to improve health outcomes.

The Framework promotes multidisciplinary working and recognises the role of pharmacists in integrated teams within primary and secondary care. I welcome this and would like to see an increased utilisation of pharmacists' clinical skills working collaboratively with other health and social care professionals optimising patients' medicines use.

The development of the Framework has been overseen by a multi-disciplinary and multi-agency Steering Group established by the Department of Health, Social Services and Public Safety. Members of the Steering Group included representatives from the Health and Social Care Board, Public Health Agency, Business Services Organisation, Royal College of General Practitioners, the Pharmaceutical Industry, Community and Hospital Pharmacy, Nursing, Social Care, Patient Client Council, RQIA, Local Commissioning Groups, and the Community Development Health Network.

I wish to thank the contribution made by all those individuals involved in its development. It establishes a solid foundation from which the application of good practice and continuous improvement and innovation in medicines use will ensure the best outcomes for the citizens of Northern Ireland.

SIMON HAMILTON MLA
Minister for Health, Social Services and Public Safety

EXECUTIVE SUMMARY

Introduction

In continuing to provide a world class Health Service, the Department is committed to supporting innovative ways of ensuring that services are safe, that they improve the health and wellbeing of our population and at the same time make the best use of available resources. As medicines are a critical element of what the health service delivers to help patients[1], the Department has developed this Medicines Optimisation Quality Framework so that patients and health care professionals can work together to make the most of their medicines.

This Medicines Optimisation Quality Framework provides strategic direction for actions to improve the use of medicines for the benefit of the health and wellbeing of people in Northern Ireland. The framework builds on existing quality systems and infrastructure to deliver improvements through evidence based services and technologies and seeks to consolidate good practice and support consistency and quality improvement across Health and Social Care (HSC).

Some people maintain a healthy lifestyle without using medicines but for others, medicines play an important part in maintaining their health and treating or preventing illness. However, there is evidence that patients do not always gain the optimal benefit from their medicines and a new approach is needed that focuses on optimising health outcomes when medicines are prescribed, dispensed or administered. Medicines Optimisation is defined by the National Institute of Health and Care Excellence (NICE) as "a person centred approach to safe and effective medicines use to ensure that people gain the best possible outcomes from their medicines."

The overall aim of this Framework is to maximise health gain for patients through the appropriate, safe and optimum use of their medicines. It is split into five main sections.

Section 1: The Quality Framework – summarising what the framework is designed to do, who it is aimed at, what it seeks to deliver and lists its key recommendations. The Framework supports a patient focused approach in which patients are involved in decisions about their medicines and are supported by multidisciplinary[2] professionals working together to deliver best practice.

Section 2: The NI Regional Medicines Optimisation Model – outlining what should be done at each stage of the patient pathway in each of four different settings (hospital, general practice, community pharmacy, social care) to help gain the best outcomes from medicines.

Section 3: 10 Quality Standards – addressing the priority issues for medicines optimisation in Northern Ireland within the three overarching quality domains of safety, effectiveness and patient/client focus. The Quality Standards describe the best practices that should be delivered in each setting, identify gaps in best practices and the actions needed to address them.

1 Throughout the Quality Framework when patients are referred to this also refers to their families and carers.

2 Multidisciplinary includes all health and social care professionals involved in the prescribing, dispensing and administration of medicines. This includes specialist and generalist roles in medicine, nursing, pharmacy, allied health and social care.

Section 4: Implementation through an Integrated Innovation and Change Programme – applying a strategic approach to support and drive continuous improvement through the development and implementation of best practices in medicines optimisation with four components:

- a regional action plan for medicines optimisation;
- a medicines optimisation innovation centre;
- a medicines optimisation network; and
- a regional database to monitor improvement.

Section 5: Contains a summary of the nine overarching key recommendations to introduce and support the Regional Model for Medicines Optimisation.

1. A Regional Model for Medicines Optimisation should be introduced which outlines what patients can expect when medicines are included in their treatment as they access services in HSC settings.
2. The model should be delivered by a mutli-disciplinary medicines optimisation workforce trained and competent in medicines optimisation, with the involvement of pharmacists in all settings.
3. The medicines optimisation workforce should deliver regional services and roles which are commissioned and co-ordinated across all HSC organisations and related agencies involved in the prescribing, dispensing and administering of medicines.
4. The services and roles should aim to consistently deliver regional best practices in compliance with new Quality Standards for Medicines Optimisation.
5. Regional best practices should always be co-designed with patients, following the principles of Personal and Public Involvement (PPI).
6. An innovation and change programme should be implemented, linked to HSC commissioning plans, to support the development, testing and scaling up of technology and service solutions to deliver consistent best practices related to the Quality Standards.
7. Regional systems should be implemented supporting HSC connectivity, electronic transmission of prescriptions and access to the Electronic Care Record, prescribing support, Northern Ireland Formulary and enhanced data analysis.
8. Within the HSC a regional organisational infrastructure for medicines optimisation should be maintained that incorporates the Medicines Governance Team, Pharmacy and Medicines Management Team, Regional Pharmaceutical Procurement Service, Medicines Information service, Medicines Optimisation Innovation Centre (MOIC)[3].
9. A new regional database for medicines optimisation should be developed to monitor progress and enable comparisons regionally and with other UK countries.

3 www.themoic.com

JOINT INTRODUCTION

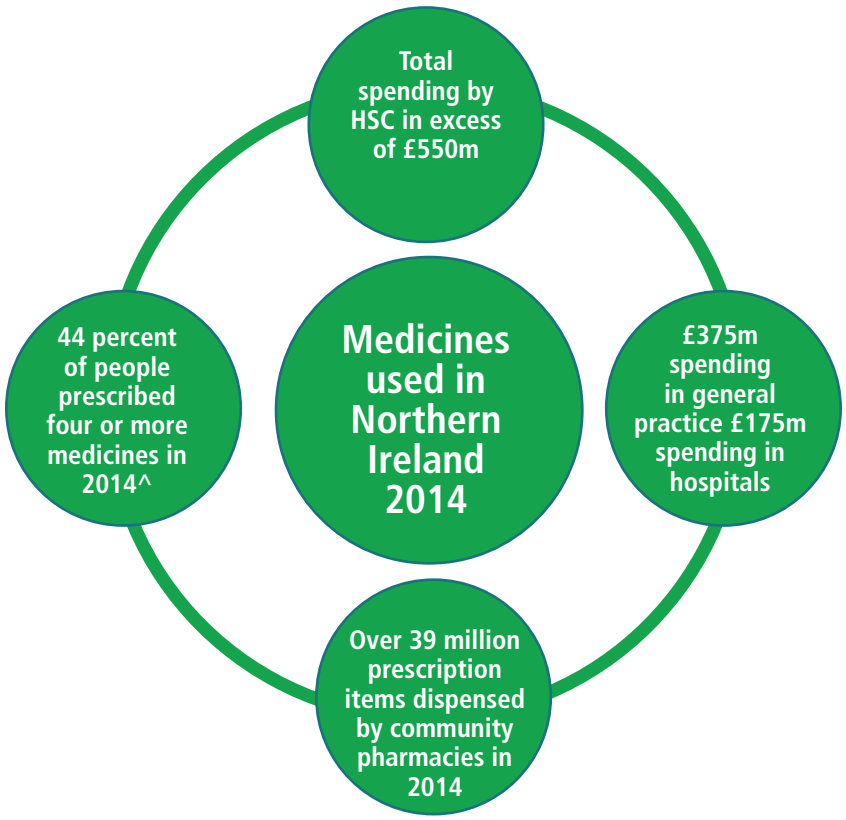
Chief Medical Officer and Chief Pharmaceutical Officer

1. Medicines play an important role in maintaining wellbeing, preventing illness and managing disease. Most people will take a medicine at some point in their lives. This could be a short term curative treatment, for example, a course of antibiotics for an infection or long term treatment for high blood pressure to prevent heart disease.

2. Medicines are the most common medical intervention within our population and at any one time 70% of the population[4] is taking prescribed or over the counter medicines to treat or prevent ill-health.

3. From a financial aspect, medicines expenditure equates to over £550m/annum in Northern Ireland, representing 14% of the total HSC budget and is the second largest cost after salaries.

Figure 1: Medicines Use in Northern Ireland 2014



4 Office of National Statistics Health Statistics 1997
^ Figure based on the definition of a medicine as having a unique number used in the dictionary of medicines and devices (DM+D)

4. As the population ages and the prevalence of chronic disease increases the need for medicines is expected to rise. This will place direct pressure on prescribing budgets and lead to an increased demand across HSC services, particularly those involved with the prescribing, dispensing and administration of medicines.

5. To date, health policy has sought to address these challenges by supporting regional best practice relating to Pharmaceutical Care[5] and Medicines Management[6]. This has introduced a range of services and systems[7] for the safe and effective use of medicines, often associated with the 'five rights'.

Table 1: The Five Rights of Medicines Administration[8]

• The Right Patient
• The Right Medication
• The Right Dose
• The Right Time and Frequency of Administration
• The Right Route

6. With over 14 years of expertise in developing good practice in the area of Pharmaceutical Care and Medicines Management, Northern Ireland was recognised in 2013 as one of the leading regions in Europe with 3 star reference site status for medicines management[9].

7. However, evidence shows that medicines use remains sub-optimal, with patients failing to gain the expected benefits of treatment and services coming under increasing pressure as their care needs escalate. For example:

5 Hepler CD & Strand LM. Opportunities and responsibilities in pharmaceutical care. American Journal of Health Systems Pharmacy 1990; 47: 533-543

6 Medicines management has been defined as "encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care.

7 See Annex A, Table 12 – Examples of regional best practice in medicines management.

8 Jones and Bartlett, Nurse's Drug Handbook, 2009

9 European Innovation Programme- https://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/rs_catalogue.pdf

Table 2: Examples of Sub-optimal Medicines Use

Ten days after starting a new medicine, 61% of patients feel they are lacking information and only 16% of patients who are prescribed a new medicine are taking it as prescribed, experiencing no problems and receiving as much information as they believe they need[10].
One in 15 hospital admissions are medication related, with two-thirds of these being preventable[11].
One in 20 prescriptions in General Practice contains an error, with a higher prevalence associated with prescriptions for the elderly and those taking 10 or more medications[12].
Prescribing errors in hospital in-patients affect 7% of medication orders, 2% of patient days and 50% of hospital admissions[13].
An estimated £18m of medicines are wasted annually in Northern Ireland[14].

8. To address these challenges and the demands of an aging population with increasingly complex medicines needs, a new approach is needed which shifts the focus to Medicines Optimisation. This will ensure that patient facing medicines services are provided in support of improving care and to enable transformation of HSC services through closer cooperation between multidisciplinary professionals and HSC organisations.

9. **Medicines optimisation** is defined by the National Institute for Health and Care Excellence (NICE) as "a person centred approach to safe and effective medicines use to ensure that people obtain the best possible outcomes from their medicines". This has evolved from the four principles of medicines optimisation developed by the Royal Pharmaceutical Society in 2013.

10 Barber et al. Patients' problems with new medication for chronic conditions. Quality and safety in healthcare 2004.

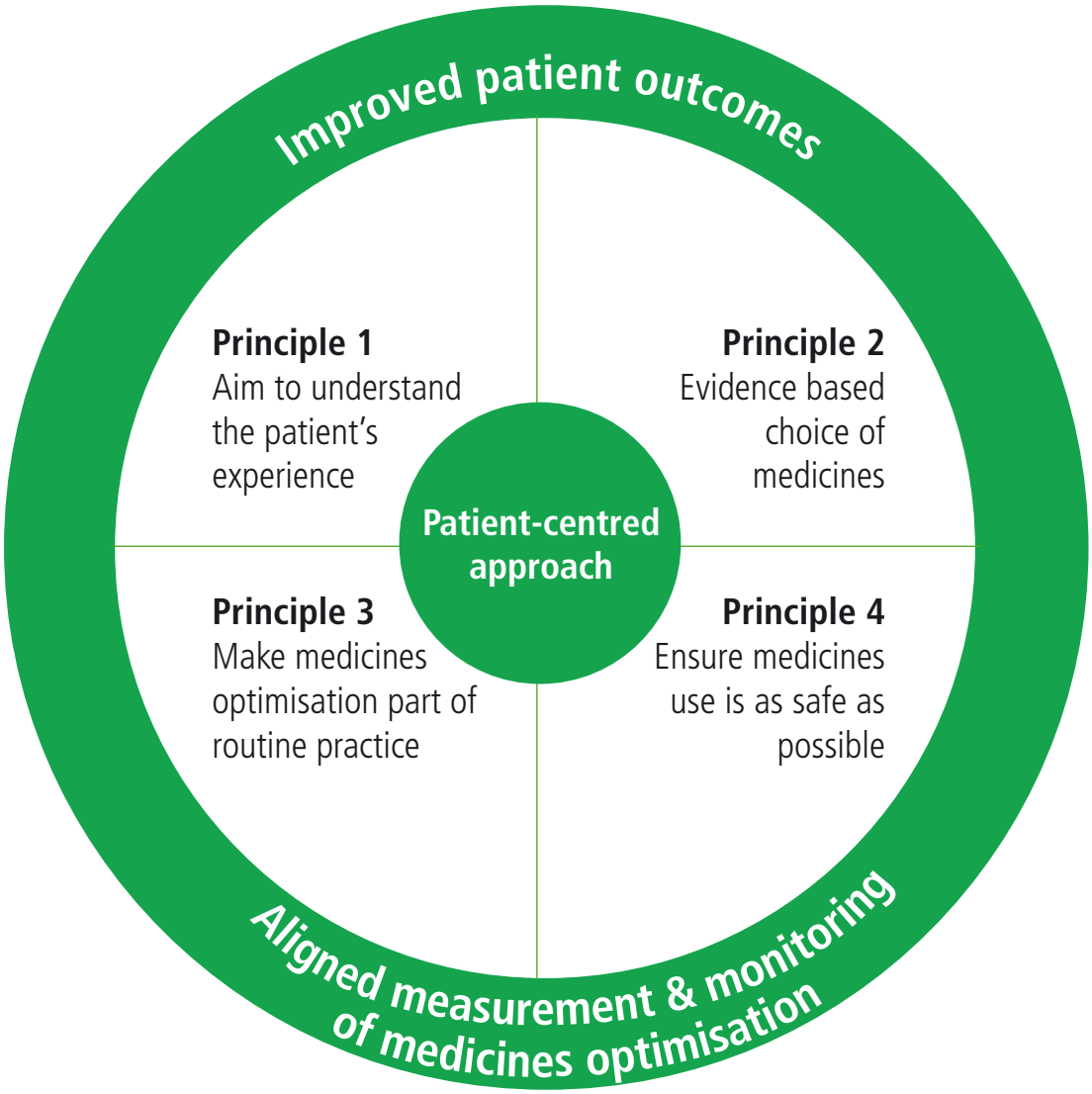
11 Garfield S, Barber N, Walley P, Willson A, Eliasson L. Quality of medication use in primary care--mapping the problem, working to a solution: a systematic review of the literature. BMC Medicine 2009; 7:50.

12 http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf

13 Lewis PJ, Dornan T, Taylor D, Tully MP, Wass V, Ashcroft DM. Prevalence, incidence and nature of prescribing errors in hospital inpatients: a systematic review. Drug Saf 2009; 32(5):379-389.

14 Evaluation of the Scale, Causes and Costs of Waste Medicines, University of London and York 2010.

Figure 2: Patient Centred Approach Model[15]



10. In Northern Ireland the shift to medicines optimisation has started with the implementation of NICE Guideline NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes[16] and the recommendations of the Regulation and Quality Improvement Authority (RQIA) Review of Medicines Optimisation in Primary Care[17].

11. However, to deliver sustainable and measurable improvements at a regional level a strategic approach is needed and the Medicines Optimisation Quality Framework has been developed to provide the necessary direction to support this.

15 https://www.rpharms.com/promoting-pharmacy-pdfs/helping-patients-make-the-most-of-their-medicines.pdf

16 https://www.nice.org.uk/guidance/ng5

17 http://www.rqia.org.uk/cms_resources/RQIA%20Medicines%20Optimisation%20in%20Primary%20Care%20Review%20July%202015.pdf

SECTION 1

THE QUALITY FRAMEWORK

1.1 The Medicines Optimisation Quality Framework provides a roadmap for improving how medicines are used across the HSC system (HSC). Building on existing quality systems and infrastructure, it seeks to deliver improvements in care through evidence based services and technologies that lead to better health outcomes for patients.

1.2 Primarily aimed at those with responsibility for, and influence on, commissioning decisions and front line service delivery in Northern Ireland, the Framework is underpinned by existing HSC responsibilities for ensuring the efficient use of resources and facilitating integration.

1.3 The Framework aims to support both patient care and the transformation of the HSC system by helping to deliver:

- better health outcomes for patients through the appropriate use of medicines, taken as prescribed;
- better informed patients who are engaged and involved in decisions about their medicines;
- improved medicines safety at transitions of care;
- an active medicines safety culture within HSC organisations;
- reduced variance in medicines use through the consistent delivery of medicines management best practices;
- improved intra and inter professional collaboration and a HSC workforce who recognise their role in medicines optimisation and are trained and competent to deliver it as part of routine practice;
- better use of resources through the consistent, evidence based and cost effective prescribing of medicines; and
- the development and implementation of best practice solutions in medicines optimisation across the HSC.

1.4 The Framework introduces a Regional[18] Model for Medicines Optimisation to engage health and social care professionals across the HSC in delivering best practices, supported by quality standards and an integrated innovation and change programme.

1.5 The Framework makes nine key recommendations to introduce and support the Regional Model for Medicines Optimisation.

18 Regional relates to the whole of Northern Ireland

Table 3: Recommendations

1. A Regional Model for Medicines Optimisation should be introduced which outlines what patients can expect when medicines are included in their treatment as they access services in HSC settings.
2. The model should be delivered by a multi-disciplinary medicines optimisation workforce trained and competent in medicines optimisation, with the involvement of pharmacists in all settings.
3. The medicines optimisation workforce should deliver regional services and roles which are commissioned and coordinated across all HSC organisations and related agencies involved in the prescribing, dispensing and administration of medicines.
4. The services and roles should aim to consistently deliver regional best practices in compliance with new Quality Standards for Medicines Optimisation.
5. Regional best practices should always be co-designed with patients, following the principles of Personal and Public Involvement (PPI).
6. An innovation and change programme should be implemented, linked to HSC commissioning plans, to support the development, testing and scaling up of technology and service solutions to deliver consistent best practices related to the Quality Standards.
7. Regional systems should be implemented supporting HSC connectivity, electronic transmission of prescriptions and access to the Electronic Care Record, prescribing support, Northern Ireland Formulary and enhanced data analysis.
8. Within the HSC a regional organisational infrastructure for medicines optimisation should be maintained that incorporates, the Medicines Governance Team, Pharmacy and Medicines Management Team, Regional Pharmaceutical Procurement Service, Medicines Information Service, Medicines Optimisation Innovation Centre (MOIC).
9. A new regional database for medicines optimisation should be developed to monitor progress and enable comparisons regionally and with other UK countries.

1.6 The Framework complements existing health policy, Transforming Your Care[19] principles, recommendations in the Donaldson report[20] and is specifically aligned with the Quality 2020[21] strategic themes of safety, effectiveness and patient/client focus.

1.7 It promotes multidisciplinary approaches which include all health and social care professionals

19 https://www.dhsspsni.gov.uk/topics/health-policy/transforming-your-care

20 https://www.dhsspsni.gov.uk/topics/health-policy/donaldson-report

21 https://www.dhsspsni.gov.uk/publications/quality-2020-ten-year-strategy-protect-and-improve-quality-health-and-social-care

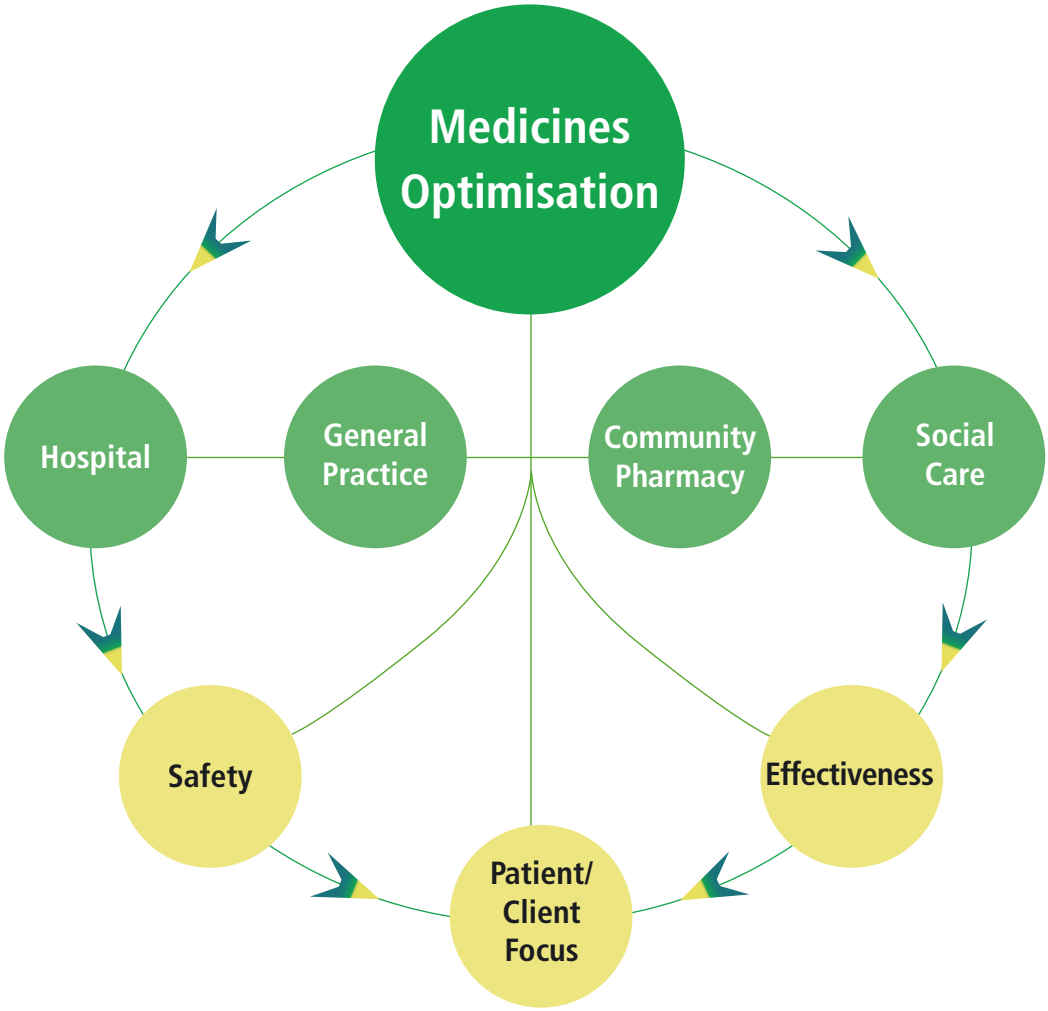
involved in the prescribing, dispensing and administration of medicines. This includes specialist and generalist roles in medicine, nursing, pharmacy, allied health and social care. NICE Guideline NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes recommends that organisations consider a multidisciplinary team approach to improve patient outcomes with the integration of pharmacists. Historically this has not always been the case and the Framework addresses gaps in pharmacist to patient facing interventions in HSC settings.

1.8 The Framework seeks to build on the experience of the past, using existing medicines management services across the HSC as the foundation for improvement where possible. These services and the history of medicines management in Northern Ireland in the period 2000 - 2014 is described in detail in Annex A.

1.9 It has been developed in anticipation of demographic and financial challenges facing the HSC which require a renewed focus on gaining the best possible outcomes for patients from medicines at an affordable cost for the HSC. A detailed description of these challenges is included in Annex B.

SECTION 2

The Northern Ireland Medicines Optimisation Model



2.1 When medicines are prescribed patients should be involved in decisions about their use, know why the medicine is needed, understand the expected outcome, the duration of treatment and be informed of any risks or side effects.

2.2 When medicines are supplied, pharmacists should ensure that they are dispensed safely, that patients receive appropriate information to enable safe and effective use and are offered support to help them take their medicines as prescribed and on time, if needed. Pharmacists are also well placed to advise patients when the presentation of their medicine changes and provide reassurance of continued efficacy.

2.3 During treatment, patients should have their medicines reviewed on a regular basis and if a GP or other authorised health professional involved in assessing the patient makes a clinical decision that there is no health benefit or clinical need for the patient to continue taking the medication, the medication should be stopped.

2.4 When medicines for long term conditions are started, stopped or changed, patients should have their treatment regimen checked to ensure it remains safe and effective.

2.5 In day to day practice, medicines optimisation relies on partnerships between patients and health and social care professionals and aims to help more patients to self manage, to take their medicines correctly, reduce harm, avoid taking unnecessary medicines, cut down on waste and improve medicines safety. Ultimately it can help encourage patients to take increased ownership of their treatment and support care closer to home.

2.6 Within the HSC, success in medicines optimisation is reliant on multidisciplinary teams with the correct skill mix working collaboratively, delivering best practices, supported by quality systems and the necessary regional organisational infrastructure as illustrated by the diagram at the beginning of section 1.

2.7 The model is based on the principles of the Integrated Medicines Management[22] (IMM) service in secondary care which targets the work of pharmacists at specific points in the patient journey on admission, during the hospital stay and at discharge.

2.8 The model seeks to deliver IMM consistently across secondary care and expand the pharmacist role into the interface and intermediate care[23], to general practice, community pharmacy and social care.

22 https://www.dhsspsni.gov.uk/sites/default/files/publications/dhssps/northern-ireland-clinical-pharmacy-standards-2013.pdf

23 Intermediate care means step up/step down beds

2.9 It supports the integration of pharmacists in multidisciplinary teams, providing support with medicines at key points of the patient's journey based on an assessment of need, for example, when a new treatment is started, after discharge from hospital or during a medication review.

2.10 At the interface the model includes roles for consultant pharmacists[24] and specialist outreach pharmacists[25] working with intermediate care, nursing home settings and GP practices, with links to community pharmacy.

2.11 The model introduces a new role for pharmacists working in General Practice. 'Practice-based' pharmacists integrated with and working collaboratively with pharmacists in community pharmacy and secondary care will utilise more fully the clinical skills of the profession to improve patient outcomes.

2.12 In community pharmacy the model includes enhanced roles for pharmacists that will support better outcomes from medicines by working with patients to provide appropriate information and advice when medicines are dispensed and to support adherence and safer transitions through services such as Medicines Use Reviews[26] [27].

2.13 The model recognises the role of nurses and care workers in helping people with their medicines in residential, nursing and domiciliary care settings and the need for regional best practices that support role clarification, accredited training and support systems for staff.

2.14 The model recommends the optimal delivery of existing roles and commissioned services which are already supported by HSC contractual or service level agreements and funding streams as well as the need for new roles and services.

2.15 To deliver the model consistently in all settings additional recurrent funding will need to be targeted to support new roles and infrastructure which demonstrate clinical and cost effectiveness outcomes.

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24 The term consultant pharmacist refers to a pharmacist who has advanced roles in patient care, research and education in a specific medical speciality or expert area of practice.

25 Specialist outreach pharmacists are pharmacists in secondary care who carry out patient medication reviews and follow up in GP practices and are linked with specialist secondary care clinical teams.

26 www.cpwales.org.uk/Contractors-Area/Pharmacy-Contact---Services/DMR/DMR-Evaluation_Final-Report_13082014.aspx

27 http://www.elht.nhs.uk/Downloads-docs/Departmental/Refer-to-Pharmacy/Electonic%20referral%20from%20hospital%20to%20community%20pharmacy%20NWC%20AHSN%20report.pdf

2.16 To monitor progress a regional medicines optimisation database is proposed, based on NHS England's medicines optimisation dashboard,[28] to identify outcome measurements. This will largely bring together existing data related to medicines use from different sources across the region to monitor trends, enable benchmarking and help drive quality improvements using baselines established in recent years from, for example, health surveys. Categories of outcome measurements will include:

- patient/client satisfaction;
- medicines safety incident reporting;
- cost effective use of medicines;
- impact on acute health services; and
- achievement of expected therapeutic outcomes.

Table 4: Examples of Outcome Measurements

Outcome Measure	Examples of Indicators	Source for baseline data
Patient/client satisfaction	• On admission to hospital did a member of pharmacy staff discuss/ check what medicines you were currently taking?	• Northern Ireland Inpatient Survey 2014 [29]
	• Percentage of people prescribed medicines in the previous 12 months involved as much as they wanted to be in decisions about prescribed medicines	• Northern Ireland Health Survey 2012/13 & 2014/15 [30]
Medicines safety incident reporting	• Levels of reported medication incidents and yellow card reporting	• Northern Ireland Medicines Governance network [31] • Medicines and Healthcare Products Regulatory Agency (MHRA) [32]
Cost effective use of medicines	• Percentage compliance with the Northern Ireland Medicines Formulary and generic dispensing rates	• DHSSPS Commissioning Plan Direction 2015/16 [33]

28 https://www.england.nhs.uk/ourwork/pe/mo-dash/

29 https://www.dhsspsni.gov.uk/sites/default/files/publications/dhssps/inpatient-patient-experience-survey-2014.pdf

30 https://www.dhsspsni.gov.uk/articles/health-survey-northern-ireland#toc-0

31 http://www.medicinesgovernance.hscni.net

32 https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

33 https://www.dhsspsni.gov.uk/publications/ministerial-priorities

Outcome Measure	Examples of Indicators	Source for baseline data
Impact on acute health services	• Number and proportion of unplanned admissions to hospital for medicines related factors and non-adherence	• DHSSPS Commissioning Plan Direction 2015/16
Achievement of expected therapeutic outcomes	• Percentage underlying achievement for Quality and Outcomes Framework (QOF) clinical indicators	• QOF [34]

2.17 The Northern Ireland Medicines Optimisation Quality Framework is a 'living document' with examples of current best practice medicines optimisation in each of the four settings in Tables 5 to 8. This will provide a necessary short term focus on improving standards and reducing variance and provide a firm foundation on which to build the evidence base and develop services in all settings.

The Medicines Optimisation Model

What patients can expect when medicines are included in their treatment

Tables 5-8 below provide a summary of what patients can expect as routine practice with regards to medicines optimisation in different settings – Hospital, General Practice, Community Pharmacy and Social Care. The activities described are generic and can be applied across different areas of practice in each setting.

34 https://www.dhsspsni.gov.uk/topics/dhssps-statistics-and-research/quality-outcomes-framework-qof

Table 5: What you should expect when you are admitted to hospital as routine practice

Hospital

On Admission

- Patients bring their medicines to hospital so that they can be checked and used where possible.
- Within 24 hours of admission or sooner if clinically necessary, patients have their medicines reconciled by a trained and competent healthcare professional, ideally by a pharmacist. Medicines reconciliation[35] involves collecting information about current medicines, checking for omissions, duplications and other discrepancies and then documenting and communicating any changes. Patients, family members or carers should be involved in this process.
- Within 24 hours of admission, a clinical management plan is developed which includes discharge planning to help prevent delays on discharge.
- If patients move from one ward to another within a hospital, medicines reconciliation may need to occur again.

Following Medical Assessment/Accurate Diagnosis

- Patients are involved in decisions about their current and any new medicines, their needs, preferences and values taken into account and receive appropriate, tailored information about new medicines and the expected health outcomes.
- Patients have the opportunity to speak to a healthcare professional and ask questions about their medicines.
- During the inpatient stay, prescription charts are monitored by a pharmacist and reviewed in conjunction with medical notes and relevant medical laboratory results.
- Patient responses to medication therapy are monitored and best practices relating to 'high risk medicines' are followed.

Administration of medicines

- On some wards patients may be able to administer their own medicines. However, if this is not possible medicines are administered on time following a check that the direction to administer is appropriate and other related factors are taken into consideration.

35 Medicines reconciliation, as defined by the Institute for Healthcare Improvement, is the process of identifying an accurate list of a person's current medicines and comparing them with the current list in use, recognising any discrepancies, and documenting any changes, thereby resulting in a complete list of medicines, accurately communicated. The term 'medicines' also includes over the counter or complementary medicines, and any discrepancies should be resolved. The medicines reconciliation process will vary depending on the care setting that the person has just moved into – for example, from primary care into hospital, or from hospital to a care home.

On discharge

- Prior to discharge the medicines reconciliation process is repeated.
- Patients receive an appropriate supply of their prescribed medicines which may be a combination of inpatient and discharge medicines dispensed as a single supply labelled for discharge. They are provided with accurate, up-to date information about their ongoing treatment where necessary.
- Patients are educated to ensure that they can use their medicines and devices for example inhalers appropriately.
- Patients know who to contact if they have a query about their medicines after discharge.
- Accurate and up-to date information about medicines is shared with healthcare professionals and communicated in the most effective and secure way such as electronically, ideally within 24 hours of discharge.
- Following discharge from hospital, patients are followed up to ensure that they are completely clear about their medicine regimens.

Other Hospital/Trust Services

- Patients attending outpatient clinics should expect:
  - to be involved in decisions about their medicines with their needs, preferences and values taken into account;
  - their response to medicines to be reviewed;
  - to have the opportunity to speak to a healthcare professional and ask questions about their medicines; and
  - to receive appropriate, tailored information about new medicines and the expected health outcomes.
- Patients in Intermediate Care settings (i.e. step up/step down beds) should have the same quality of care as in hospital.
- Patients receiving specialist outreach services and other services at the interface should expect:
  - links to be established between specialist secondary care clinical teams and primary care;
  - to be followed up in primary care; and
  - to have clinical medication reviews carried out.
- Patients in nursing, residential and children's homes (see table 7)

Table 6: What you should expect from general practice as routine practice

General Practice

- Patients registering with the practice for the first time have a medicines reconciliation check.
- During consultations, patients are involved in decisions about their current and any new medicines, their needs, preferences and values taken into account and receive appropriate, tailored information about new medicines and the expected health outcomes.
- Patients taking multiple medicines or taking 'high risk medicines' are identified and, where appropriate, receive additional information and advice to help take their medicines safely and effectively.
- Patients on repeat medications have checks carried out before issue of prescriptions to reduce the risk of waste.
- All patients on repeat medication have an annual clinical medication review with a GP or pharmacist. (This may be more frequent depending on the individual's care plan or type of medication).
- Patient responses to medication therapy are monitored. Medicines that are not beneficial and not evidence based are not continued.
- Patients with problems taking their medicines as prescribed (non-adherent) are referred for an adherence assessment.
- Patients are involved in decisions about their medicines and are encouraged to ask questions about their treatment and to be open about stopping medication.
- Patients discharged from hospital/other care setting have their medicines reconciled by a trained and competent healthcare professional as soon as possible, before a prescription or new supply of medicines is issued and within one week of the GP practice receiving the information. Patients, family members or carers should be involved in this process and any changes documented.
- Prescribers have up to date information to support clinically appropriate and safe prescribing.
- Prescribers have access to a pharmacist for information and advice about polypharmacy patients taking multiple medicines.
- Practices provide information about prescribed medicines to hospitals and other appropriately authorised health and social care professionals to assist medicines safety during transitions of care.

Table 7: What you should expect from your community pharmacy as routine practice

Community Pharmacy

- On presentation of a prescription the pharmacist will carry out a clinical check of the prescription using the patient's medication record before it is dispensed. This will inform the level of information and advice that is needed for the patient to take their medicines safely and effectively.
- High quality medicines are dispensed safely.
- Patients receive appropriate information and advice with the supply of medicines, particularly if a new medicine or a 'high risk medicine' is supplied.
- If the presentation of a repeat medicine changes, the patient is advised of this change and reassured of continued efficacy.
- Patients are offered a medicines use review after a significant change in their medication. For example, following discharge from hospital or after starting a new treatment regimen.
- Patients having problems taking their medicines as prescribed have their adherence needs assessed and appropriate support provided.
- Patients are asked if they need all their repeat medicines before they are supplied to reduce the risk of waste.
- Pharmacists work closely with other health and social care professionals to ensure patients are on the most appropriate medication and have contact with pharmacists working in local GP practices and hospitals.
- To support safe transitions, pharmacies provide information about medicines supplies to the pharmacist or pharmacy technician conducting a medicines reconciliation check after admission to hospital or to appropriately authorised health and social care professionals in a nursing or residential home.
- On discharge from hospital, community pharmacy receives information on the patient's current medication and medication changes to support safe transfer.
- Pharmacies may provide other services such as clinical medication reviews and monitor health outcomes from medicines to support medicines optimisation.

Table 8: What you should expect from social care as routine practice

Nursing homes

- When individuals first move into a nursing home and at each transition of care thereafter their medicines are checked with their GP Practice and Community Pharmacy.
- Adequate supplies of medicines are always available and prescription ordering systems in homes are carefully managed and monitored to avoid over-ordering and waste.
- Individuals with specific medication needs such as Parkinson's Disease or Diabetes or those taking multiple or 'high risk medicines' are identified and receive the appropriate care in line with best practice.
- Individuals who take their own medicines are monitored to ensure they are taking them as prescribed.
- Medicines are administered on time following a check that the direction to administer is appropriate.
- Individuals taking repeat medication have an annual clinical medication review; the frequency of the review may vary depending on the care plan.
- Staff in nursing homes have contact with pharmacists in the community to assist with queries about medication.

Residential homes

- When individuals first move into a residential home and at each transition of care thereafter their medicines are checked with their GP Practice and Community Pharmacy.
- Adequate supplies of medicines are always available and prescription ordering systems in homes are carefully managed and monitored to avoid over-ordering and waste.
- Residential care home staff who manage medicines are trained and competent.
- Residents self-administer their own medicines where the risks have been assessed and the competence of the resident to self-administer is confirmed. Any changes to the risk assessment are recorded and the arrangements for self-administering medicines are kept under review.
- Residential care home staff receive training on 'High Risk Medicines' and have easy access to information about all medicines.
- Staff have contact with pharmacists in the community to assist with queries about medication.

Children's homes

- When a child/young person first moves into a children's home and at each transition of care thereafter their medicines are checked with their GP Practice and Community Pharmacy.
- Adequate supplies of medicines are always available and prescription ordering systems in homes are carefully managed and monitored to avoid over-ordering and waste.
- The management of medicines is undertaken by trained and competent staff and systems are in place to review staff competency.
- Robust systems are in place for the management of self-administered medicines.
- Prior written consent is obtained from a person holding parental responsibility for each child or young person for the administration of any prescribed or non-prescribed medicine.
- Staff receive training on 'High Risk Medicines' and have easy access to information about all medicines.
- Staff have contact with pharmacists in the community to assist with queries about medication.

Domiciliary care

- Nurses and care workers have clearly defined roles in helping with medicines taking.
- Administration of, or assistance with, medication is facilitated when requested in situations where an individual is unable to self-administer.
- Administration or assistance with medication is detailed in a care plan and forms part of a risk assessment.
- Policies and procedures identify the parameters and circumstances for care workers administering or assisting with medication. They identify the limits and tasks that may not be undertaken without additional training.
- Care workers who administer medicines are trained and competent. A record is kept of all medicines management training completed by care workers and retained for inspection
- When necessary, training in specific techniques (e.g. the administration of eye/ear drops or the application of prescribed creams/lotions) is provided for named care workers by a qualified healthcare professional.

- The care worker documents, on each occasion, the administration or assistance with medication.
- Care workers involved in the management of an individual's medication agree the arrangements for the safe storage within the individual's home. Appropriate information is available about the individual's current medication and staff are aware of any changes following a transition of care, such as discharge from hospital.
- Training on 'High Risk Medicines' is provided and staff have easy access to information about all medicines.
- Staff have contact with pharmacists in the community to assist with queries about medication.
- If an individual is having difficulties in managing their medicines, staff can refer them to the community pharmacist for assistance.

SECTION 3

Quality Standards for Medicines Optimisation

Quality Domain	Medicines Optimisation Standards
Patient/Client Focus Patients are involved in decisions about their treatment with medicines.	1. Safer Prescribing with Patient Involvement
	2. Better Information about Medicines
	3. Supporting Adherence and Independence
Safety Preventing and minimising harm related to medicines use.	4. Safer Transitions of Care
	5. Risk Stratification of Medicines
	6. Safety/Reporting and Learning Culture
Effectiveness Right patient, right medicine, right time, right outcome, right cost.	7. Access to Medicines you Need
	8. Clinical and Cost Effective Use of Medicines and Reduced Waste
	9. Clinical Medication Review
	10. Administration

3.1 In support of the Regional Medicines Optimisation Model new minimum quality standards will drive consistency and bring about a common understanding about what service providers are expected to provide and what patients can expect to receive when medicines are included as part of their treatment.

3.2 The ten standards address the priority issues for medicines optimisation in Northern Ireland within the three overarching quality domains of safety, effectiveness and patient/client focus and are compatible with the draft NICE Quality Standard on Medicines Optimisation[36].

3.3 The standards support delivery of best practice which should be developed and implemented in partnership with patients on an ongoing basis, actively seeking their views and listening to their experiences. For example via the Public Health Agency's 10,000 Voices[37] initiative, involving patients in hospital and learning from their experience through projects like ThinkSAFE[38] and through regular health surveys which can be useful in determining behaviours and attitudes.

36 A NICE Quality Standard for Medicines Optimisation is expected in March 2016. NICE quality standards may be used to inform best practice in Northern Ireland but are not currently formally endorsed by DHSSPS or mandatory within the HSC.

37 http://www.publichealth.hscni.net/publications/10000-voices-improving-patient-experience

38 http://www.thinksafe.care/

STANDARDS

Standard 1 - Safer Prescribing with Patient Involvement
Prescribing is carried out in a manner which promotes safety and optimal health outcomes, with patients involved in decisions about their treatment.

Standard 2 – Better Information about Medicines
Patients/carers receive the information they need to take their medicines safely and effectively.

Standard 3 – Supporting Adherence and Independence
People are helped to remain independent and self manage their medicines where possible but receive support with adherence when needed.

Standard 4 – Safer Transitions of Care
Checks occur at each transition of care to ensure that the transfer of medicines and medicines information between patients, carers and health and social care workers is safe, accurate and timely.

Standard 5 – Risk Stratification of Medicines
Patients who may be at risk because of the medicines that they use receive the appropriate help to take their medicines safely.

Standard 6 – Safety/Reporting and Learning Culture
Organisations promote an open and transparent culture with evidence of processes for the reporting, prevention, detection, communication and cascade of learning from medication incidents and adverse drug reactions.

Standard 7 – Access to Medicines you Need
Patients have appropriate, equitable and timely access to quality assured, evidence-based and cost-effective medicines.

Standard 8 - Clinical and Cost Effective Use of Medicines and Reduced Waste
Within organisations a culture exists promoting a shared responsibility for the appropriate, clinical and cost effective use of medicines supported by systems for avoiding unnecessary waste.

Standard 9 – Clinical Medication Review
Clinical medication reviews are carried out with the patient and occur on a regular basis, at least annually.

Standard 10 – Administration
Following an initial check that the direction to administer a medicine is appropriate, patients who have their medicines administered receive them on time and as prescribed.

Standard 1 - Safer Prescribing with Patient Involvement

Prescribing is carried out in a manner which promotes safety and optimal health outcomes, with patients involved in decisions about their treatment.

Why is the standard needed?

UK studies have highlighted the prevalence of prescribing errors in primary and secondary care showing that medication errors are common and are associated with considerable risk of potentially avoidable patient harm[39] [40]. Studies have also shown that the prevalence of error and potentially inappropriate prescribing are greater for people taking multiple medicines (polypharmacy); generally older people and those living in residential and nursing homes[41] [42]. A range of safer prescribing initiatives are in place to address these issues and a number of tools are available and in development for prescribing support. For example, the pharmacy-led technology intervention (PINCER)[43] has been demonstrated as an effective method for reducing the range of medication errors in general practice. In secondary care, computerised prescriber order entry and decision support have also been shown to improve safety[44].

Modern prescribing practice recognises the importance of involving patients in decisions about their treatment and medication. In this area prescribers are guided by the 2009 NICE Clinical Guideline 76, '*Involving patients in decisions about prescribed medicines and supporting adherence*' which recommends improving communication and increasing patient involvement in decisions about prescribed medicines; a better understanding of the patient's perspective and the provision of more information for patients[45]. This guideline now overlaps with the NICE Guideline NG5 Medicines optimisation. Patients having problems because of

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39 Investigating the prevalence and cause of prescribing errors in general practice http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf.

40 Dornan et al. An in depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education. EQIP Study. 2009 A report to the GMC

41 Bradley et al. Potentially Inappropriate Prescribing and cost outcomes for older people: a cross-sectional study using the Northern Ireland Enhanced Prescribing Database. Eur J Clin Pharmacol, 2012

42 Alldred et al. Care homes' use of medicines study: prevalence, causes and potential harm of medication errors in care homes for older people. Quality and Safety in Health Care. 2009

43 Avery et al: A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. Lancet 2012

44 Bates D W. Using information technology to reduce rates of medication errors in hospitals. BMJ 2000 Mar 18; 320(7237): 788-791

45 https://www.nice.org.uk/guidance/cg76

language barriers need the support of advocates and language formats that they understand to ensure they are involved in decision making. Health and social care professionals who don't have English as their first language may also need support to ensure they have the necessary communication skills.

Doctors also comply with the GMC Good Practice in Prescribing Medicines and Devices 2013 which provides comprehensive advice on the prescribing of medicines to serve the patient's needs with agreement for the treatment proposed. In addition, the Service Frameworks for older people, mental health, learning disability and children all include standards for patient choice and shared decision making. However, time pressures for doctors may make this difficult to achieve and support from other healthcare professionals in supporting patients in decision making is needed.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Patients are involved in decisions about their treatment. • To support clinically appropriate and safe prescribing, prescribers have access to end to end paperless prescribing and administration systems.	• Sufficient time to enable an informed discussion with the patient/carer can be an issue. • An ePrescribing & Medicines Administration (EPMA) system should be developed.
General Practice	• Patients are involved in decisions about their treatment. • Prescribers have access to pharmaceutical advice and up to date information to support clinically appropriate and safe prescribing.	• Routine GP consultation times may be insufficient for some patients. • Pharmacists and electronic prescribing support systems such as PINCER are not available in all GP practices.
Community pharmacy	• Increase in number of pharmacists trained as Independent Prescribers, built on a strong clinical foundation and working in Community Pharmacy settings. • Access to Electronic Care Record (ECR).	• Low numbers of Pharmacist Independent Prescribers working in community pharmacies. • No access currently to ECRs.
Patients	• Patients are involved in decisions about their prescribed medicines.	• Patients do not see themselves as equal partners in decision making.

Actions needed to address the gaps

- In secondary care an ePrescribing & Medicines Administration (EPMA) system and the computerisation of records and processes should be introduced, linked to general practice and community pharmacy (see standard 10).
- GP practices should have pharmacists available to advise on complex medicines and polypharmacy, to conduct clinical medication reviews and to help patients with information and advice to take their medicines safely and effectively.
- In GP practices the role of technology enabled screening tools and clinical decision support systems during prescribing for optimising medicines selection and reducing medication errors should be considered. See NICE Guideline NG5 recommendation 1.7, clinical decision support.
- The Northern Ireland Formulary should be integrated within GP and community pharmacy systems and an EPMA system.
- Greater awareness of the patient's role in decision making should be promoted.
- The use of patient decision aids in consultations involving medicines should be explored. See NICE NG5 recommendation 1.6, patient decision aids.
- Consideration should be given to how patients with low health literacy, where there are language barriers and those patients with mental health incapacity will be more readily included in their treatment decisions where possible.
- Community pharmacists should develop clinically and train as independent prescribers.
- Community pharmacists should have access to ECRs.
- The hybrid independent prescribing model should be expanded where doctors diagnose and routine prescribing is then carried out by non-medical prescribers.
- There should be a greater multi-disciplinary approach to prescribing in the most appropriate setting for the patient to ensure medicines use is optimised.

Standard 2 – Better Information about Medicines

Patients/carers receive the information they need to take their medicines safely and effectively.

Why is the standard needed?

Ten days after starting a new medicine, 61% of patients feel they are lacking information and only 16% of patients who are prescribed a new medicine are taking it as prescribed, experiencing no problems and receiving as much information as they believe they need[46]. Good quality information is essential for greater patient involvement and shared clinical decision making and sufficient high quality information alongside good professional interaction is key to helping clinical decision making[47]. In December 2009 NICE was certified as a quality provider of health and social care information by the Information Standard[48] - a certification scheme for health and social care information aimed at the public. When NICE guidelines are being developed the principles of the Information Standard are followed to ensure key messages of the guideline are summarised in everyday language for users of health and care services, carers and the public. The regional public health strategy Making Life Better states that we need to empower people to make informed decisions about their health by improving health literacy which includes providing appropriate and accessible health information (making greater use of modern communication technology) and advice to all, which is evidence informed and tailored to meet specific needs[49].

Information needs to be accessible to all and communicated effectively at a level that will help patients to manage their condition effectively as opposed to just providing information. Limited health literacy capabilities have implications regarding medicines use and not having English as a first language can also impact significantly on the ability to assimilate and use information related to medicines.

The timing and method of communicating information to enable patients to understand their medicines needs to be considered and the medicines optimisation model allows clarification of the roles of health and social care professionals at particular points in the patient journey.

46 Barber et al. Patients' problems with new medication for chronic conditions. Quality and safety in healthcare 2004.

47 Coulter et al. Assessing the quality of information to support people in making decisions about their health and healthcare. Picker Institute, 2006.

48 https://www.england.nhs.uk/tis/

49 https://www.dhsspsni.gov.uk/articles/making-life-better-strategic-framework-public-health

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Patients receive appropriate, tailored, reliable information about their medicines and support during pre admission clinics and pre discharge counseling. • Patients on specialist medicines have access to a healthcare professional for appropriate advice and tailored, reliable information and support.	• Sufficient time to enable healthcare professionals provide patients with appropriate, tailored, reliable information and support can be an issue • There is no regionally agreed support system for patients post discharge.
General Practice	• Patients receive appropriate, tailored, reliable information and support about medicines when first prescribed and during clinical medication reviews. • Better integration of existing services for example GP referral to Community Pharmacy for medicines use reviews (MURs)/managing your medicines service	• GP consultation times may not be sufficient to provide appropriate, tailored, reliable information and support about medicines required by the patient.
Community pharmacy	• Patients receive appropriate, tailored, reliable advice, information and support when medicines are supplied. • MURs are provided to improve patient knowledge, adherence and use of their medicines. • It is a legal requirement that all medicines are supplied with a Patient Information Leaflet (PIL) provided by the pharmaceutical manufacturer.	• The provision of appropriate, tailored advice, information and support with medicines supplies is inconsistent. • MURs available in community pharmacies while offered by over 90% of community pharmacies, are currently capped in number and limited by patient condition. • The content of the PIL can be both difficult to read and comprehend and supplies with split packs can be problematic.
Social Care	• Nursing and social care staff have access to appropriate up to date information sources for medicines.	• Access to accessible and appropriate up to date information about medicines is limited especially for domiciliary care workers.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Patients	• Patients are aware of where to access the recommended, reliable sources of information on medicines. • Patients have access to information about medicines via the patient zone on the Northern Ireland Formulary website, a patient portal on the NIDirect website and other websites, for example NHS choices. Patients with mental illness have access to information about their medicines via the Choice and Medication website. • Patient helpline available for advice and information.	• Patient awareness of recommended, reliable sources of information is low. • There isn't a regional patient helpline however a helpline pilot is underway in BHSCT and WHSCT.

Actions needed to address the gaps

- A regional system should be agreed to support patients with their medicines after discharge from hospital.
- In GP practices, pharmacists should be available so that patients can be referred to them for appropriate, tailored, reliable information, advice and support to help them take their medicines safely and effectively.
- Community pharmacies should follow a Standard Operating Procedure (SOP) for the risk stratified provision of appropriate support, information and advice with supply of medicines. Information sources for patients should be promoted [patient portal].
- Increased use of technology to direct patients to information resources.
- If the pilot demonstrates benefits a regional patient helpline should be available for advice and information with appropriate signposting to existing national help lines.
- There should be increased availability of the current MUR service in community pharmacy and it should be developed further to include other conditions in particular for those patients prescribed new medications or recently discharged from hospital.
- Health and social care professionals should be trained on how to communicate information effectively to patients.
- Any information provided on internet sites for patients should be in a style accredited by the Plain English Campaign[50] or the Information Standard.

50 http://www.plainenglish.co.uk/

Standard 3 – Supporting Adherence and Independence

People are helped to remain independent and self manage their medicines where possible but receive support with adherence when needed.

Why is the standard needed?

UK evidence shows that 30-50% of long term conditions sufferers do not take their medicines as prescribed[51]. Consequences of non-adherence include poorer than expected clinical outcomes; reduced quality of life; deterioration of health and unplanned admissions to hospital. In the UK the NHS costs of hospital admissions resulting from people not taking medicines as recommended were estimated at £36-196 m in 2006-7[52]. A Cochrane review 'Interventions for enhancing medication adherence' concluded that improving medicines-taking may have a far greater impact on clinical outcomes than improvements in treatments[53].

It is important that people are helped to remain independent and self-manage their medicines for as long as they are able, with the confidence that they will be supported if the time comes when they need more help. Self management should provide people with the knowledge and skills they need to manage their own condition more confidently and to make daily decisions which can maintain or enhance their health and well-being as well as their clinical, emotional and social outcomes[54]. The King's fund paper, 'supporting people to manage their health – an introduction to patient activation describes the patient activation measure (PAM) which measures an individual's knowledge, skill and confidence for self-management. It is stated that patient activation is a better predictor of health outcomes than known socio-demographic factors such as ethnicity and age[55]. Good communication and effective systems can help support people, particularly as they age, to stay in control of ordering, collecting and taking their prescribed medicines.

51 Horne R, Weinman J, Barber N, Elliott R, Morgan M. Concordance, adherence and compliance in medicine-taking. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D. 2005.

52 NICE Costing Statement: Medicines Adherence: involving patients in decisions about prescribed medicines

53 Cochrane review: Interventions for enhancing medication adherence, 2008

54 DHSSPS Living with Long Term Conditions Strategy, 2012

55 Supporting People to Manage Their Health – An Introduction to Patient Activation. The King's Fund, 2014

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• On admission to hospital, patients with sub-optimal adherence are identified through the NI Single Assessment Tool (NISAT) and/or IMM Medicines Reconciliation. Their needs are assessed and appropriate post-discharge support is arranged prior to discharge. • Improved clinical coding of the incidence of unplanned admissions to hospital associated with non-concordance.	• There is no common approach to using NISAT, identifying and assessing non-adherence and to the provision of solutions or support at discharge. • The IMM service is currently only available for 50% of beds. • The clinical coding of medicines related admissions including non-concordance is under reported.
General Practice	• Patients who are experiencing problems adhering to their medicines are identified and referred for assessment.	• There is no common regional approach to identifying and assessing non-adherence and to the provision of solutions.
Community pharmacy	• Patients with sub-optimal adherence are identified through the targeted medication use review (MUR) service which is offered by over 90% of community pharmacies and the Manage Your Medicines Service. • Adjustments are made to medicines packs and adherence aids provided to assist patients to take their medicines more effectively. • On the request of GPs community pharmacies can supply medicines weekly for high risk patients when it is essential to protect the patient and prevent life-threatening non-compliance.	• The targeted MUR Service is limited to patients with respiratory disease and/or diabetes and MURs are currently capped in number. • The Manage Your Medicines Service has low uptake. • There is no common regional approach to identifying and assessing non-adherence and to the provision of solutions. However a Medicines Adherence Support Service (MASS) pilot has been carried out and is currently being evaluated.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Social Care	• Patients should have the necessary support to remain independent and manage their medicines for as long as possible without the need for interventions such as Monitored Dosage Systems (MDS).	• Although healthcare professionals undertake many specialist clinics and invest significantly in supporting patients in medicine adherence and independence including for example inhaler techniques and discussions regarding adverse drug reactions (ADRs) there is still a heavy reliance on a one size fits all approach through MDS.
Patients	• Patients have access to a wide range of patient education/self management and training programmes provided within the HSC and by voluntary and community organisations to help provide the skills and tools they need to self-care/manage for example the Pain Toolkit[56] and Beating the Blues[57] • Patients have self-management plans to support self management of their chronic or long term condition using medicines	• There is low awareness of the resources available. • There is no regional approach to self-management plans to empower patients to be more involved in managing their chronic or long term condition(s).
Other	• Patients have access to tele-monitoring services which enable them to monitor e.g. BP at home, avoiding visits to GP or A&E with their readings being monitored remotely and help available if required.	• Tele-monitoring services are still under development.

56 http://www.paintoolkit.org/

57 http://www.beatingtheblues.co.uk/

Actions needed to address the gaps

- An integrated regional system for identifying and assessing non-adherence and providing solutions should be agreed with defined roles for secondary care, general practice, community pharmacy services and social care.
- Appropriate clinical pharmacy staffing levels particularly in emergency departments to identify and help manage adherence/ adverse drug reaction related admissions.
- Guidance for health and social care professionals on the availability of adherence solutions other than MDS.
- The roles of nurses and care staff in medicines optimisation in domiciliary care settings should be reviewed, clarified and agreed regionally with accredited training and competency based assessments for care staff.
- A range of low and high tech solutions to support adherence should be developed with patient involvement and commissioned.
- The MUR service should be developed for patients with multi-morbidities and polypharmacy.
- Development of new referral mechanisms to community pharmacists for patients who require adherence support..
- A regional system for improving the quality of coding for medicines related factors to identify admissions due to poor adherence should be developed and implemented.
- The availability of self help information relating to medicines and adherence should be promoted.
- Self-management plans should be developed to support patients with a chronic or long term condition(s). See NICE Guideline NG5 recommendation 1.5, self-management plans.

Standard 4 – Safer Transitions of Care

Checks occur at each transition of care to ensure that the transfer of medicines and medicines information between patients, carers and health and social care workers is safe, accurate and timely.

Why is the standard needed?

When patients move between care settings it is important that their medicines and information about their medicines transfers safely and accurately with them, to avoid harm. Over half of all hospital medication errors occur at interfaces of care, most commonly on admission to hospital[58]. A report for the General Medical Council in 2012 investigating the prevalence of prescribing errors in general practice highlighted risks at the primary/secondary care interface with significant problems concerning correspondence about medications particularly at the time of hospital discharge[59]. Older people, those taking multiple and higher risk medicines are most at risk. Risks also exist at transitions of care with intermediate care, community settings including residential, nursing or children's homes, transfers between GP practices and entering or leaving prison. The Donaldson Report highlighted the role that pharmacy can offer at transitions between hospital and the community.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Integrated Medicines Management (IMM) Service providing electronic medicines reconciliation at transitions; post-discharge communication with GPs, community pharmacies and other health and social care workers.	• The IMM service is limited to around 50% of hospital beds mainly during weekdays from 8:00am to 6:00 pm and delivery of the service varies between HSC Trusts. • Electronic medicines reconciliation is not available in all Trusts.

58 Garfield S, Barber N, Walley P, Willson A, Eliasson L. Quality of medication use in primary care--mapping the problem, working to a solution: a systematic review of the literature. BMC Medicine 2009; 7:50.

59 Investigating the prevalence and cause of prescribing errors in general practice http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital contd	• Consultant pharmacists led services/Senior Clinical Pharmacists supporting appropriate polypharmacy in older people in intermediate care and nursing/ residential homes. • Regional Guidelines for the Supply of 'Take Home Medication' from Northern Ireland Emergency Departments [60] developed by GAIN • Regional Guidelines for Immediate Discharge Documentation for Patients Being Discharged from Secondary into Primary Care[61] developed by GAIN, 2011	• Consultant Pharmacist-led services for older people are not available in all Trusts.
General Practice	• GP practices provide information relating to prescribed medicines to secondary care and to appropriately authorised health and social care professionals looking after patients in care homes[62] or their own homes. • GPs receive timely notification electronically when their patients are admitted to hospital and receive timely and accurate information about medication changes on discharge.	• There is no agreed approach to the timely provision of this information. • GPs do not always receive timely notification that their patients have been admitted to hospital and post discharge medicines information is not always reconciled to the GP list before a prescription or new supply of medicines are issued and within 1 week of the GP practice receiving the information. • No process currently in place to ensure that GP practices are advised if any of their patients are admitted to prison.

60 http://www.gain-ni.org/images/Uploads/Guidelines/Regional_Guidelines_for_the_supply_of_Take_Home_Medication_from_Northern_Ireland_Emergency_Departments_DEC_2014.pdf

61 http://www.gain-ni.org/images/Uploads/Guidelines/Immediate-Discharge-secondary-into-primary.pdf

62 Where reference is made to' care homes 'this means Nursing Home, Residential Home and Children's Homes.

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice contd	• People discharged from an acute care setting to primary care have their medicines documented in the discharge summary and reconciled in the GP list as soon as is practically possible, before a prescription or new supply of medicines is issued and within 1 week of the GP practice receiving the information. • GP practices are notified if a patient is admitted to prison and on release. Prescribing information from the Prison health GP IT EMIS system should be uploaded onto, and available on, the ECR.	• Prison health can see ECR when prisoner arrives in prison, but cannot add to it, so that no information about prescribing during the prison stay is available to the patient's GP on release of the patient.
Community pharmacy	• With patient agreement a nominated community pharmacy receives post discharge medicines information from secondary care electronically. • The Royal Pharmaceutical Society Innovators' Forum has produced a toolkit[63] to support safer transition from secondary care to community pharmacy. • Information relating to medicines supplied is provided on request to secondary care and to appropriately authorised health and social care professionals in care homes. • There is a defined role for community pharmacy to support safer transitions at discharge.	• HSC Trusts do not routinely provide information to community pharmacies post discharge. • There is no specific role or service for community pharmacy to support safer transitions for patients at discharge. • The ECR is not yet accessible to community pharmacies.

63 http://www.rpharms.com/support-pdfs/3649---rps---hospital-toolkit-brochure-web.pdf

Provider	What best practice should be delivered	Gaps in delivery of best practice
Social Care	• Nursing staff conduct medicines checks for new patients in nursing homes and independent healthcare settings. • Medicines checks are completed by social care workers when children move into a children's home or change day care setting[64]. • Domiciliary care staff are made aware of changes to patients' medicines following transitions of care. • Community nurses and appropriately authorised health and social care staff have visibility of medicines prescribed through access to ECR.	• Community Nurses can contact GPs to discuss a patient's medication on transfers of care however the ECR is not accessible to them. • The ECR is not accessible to appropriately authorised health and social care professionals in care homes. • When patients are discharged from hospital or return home from a care setting there is no system to make domiciliary care workers, who assist them with their medicines aware of changes to their medication.
Patients	• Patients bring their current medication and related information with them to hospital and all Trusts have policies for using patients own drugs where possible. • Patients are responsible for knowing what medicines they are currently prescribed and why. • Patients have access wherever possible to ECR and/ or a patient passport and are aware of who else has what information, under what circumstances and with what safeguards.	• The patient's role in managing their own medicines and medicines information during transitions of care is not well understood. • Patients are not involved in decisions about their medicines as much as they should be to enable them to take responsibility for knowing what they are prescribed and why. • Patient view allows patients internet access to their own records but access to the ECR is needed to improve co-ordination of care

64 https://www.dhsspsni.gov.uk/articles/care-standards

Actions needed to address the gaps

- An Integrated Medicines Management Service with electronic medicines reconciliation should be delivered consistently across HSC Trusts which includes hospital attendance without admission for example at outpatient clinics. See also NICE Guideline NG5 recommendation 1.3, medicines reconciliation.
- A regional consultant pharmacist led service should be commissioned for managing polypharmacy in older people in intermediate care, nursing and residential care settings.
- There should be 'one single source of truth' for example ECR regarding patient's medications which is up to date and can be accessed by patients and shared by all healthcare professionals. See also NICE Guideline NG5 recommendation 1.2, medicines-related communications systems when patients move from one care setting to another.
- A regional protocol for safe transitions in the community should be developed to ensure that medicines checks occur at each transition of care with defined roles for GPs, Community Pharmacists, and health and social care workers in care settings, facilitated by appropriate access to the ECR.
- Electronic communication between hospitals and GPs should be improved to notify when patients are admitted to hospital and provide timely and accurate medicines information on discharge
- A process should be established to ensure that GP practices are advised if a patient is admitted to prison.
- Information about prescribing during a prison stay should be uploaded onto the ECR for the patient's GP to see on release of the patient.
- The patient's role in managing their own medicines and related information during transitions of care should be promoted.

Standard 5 – Risk Stratification of Medicines

Patients who may be at risk because of the medicines that they use receive the appropriate help to take their medicines safely.

Why is the standard needed?

Although the use of all medicines is associated with a level of risk, some medicines are known to carry a greater risk of side effects, adverse events and/or admission to hospital than others. A systematic review of medicines related admissions to hospital found that four groups of drugs account for more than 50% of the drug groups associated with preventable drug-related hospital admissions - antiplatelets, diuretics, NSAIDs and anticoagulants[65]. In addition, a review was carried out of medication incidents reported to the National Reporting and Learning System in England and Wales over a 6 year period. The top 5 medicines for which the clinical outcome was death or severe harm were opioids, antibiotics, warfarin, low molecular weight heparins and insulin[66]. Antimicrobial resistance is among the civil emergencies listed in the Cabinet Office's National Risk Register of Civil Emergencies[67]. In Northern Ireland, antimicrobial prescribing is high and the prevalence of systemic antimicrobial prescribing in residential homes was found to be relatively high compared with care homes (particularly nursing homes) in other countries[68]. By measuring and addressing performance indicators, the quality of antibiotic prescribing could be improved[69]. The misuse of prescription and over the counter drugs is a significant public health and social issue in Northern Ireland, resulting in negative impacts on physical and mental health, and there have been an increasing number of deaths related to the misuse of a range of prescription drugs. There are particular issues in relation to poly-drug use, especially when combined with alcohol and the use of hypnotics which are associated with increased mortality, even in patients taking fewer than 18 Doses/Year[70]. Other medicines also require caution in use including some specialist 'red and amber list' medicines which may need ongoing patient monitoring. These are initiated by a hospital prescriber and may be delivered directly to a patient's home with associated services (homecare services). Risks of harm are higher for some patient groups, for example, older people, those taking multiple medicines (polypharmacy), and for whom careful adherence is critical for example in the treatment of diabetes, Parkinson's Disease and some mental health conditions. A useful tool, SPARRA[71] (Scottish Patients at Risk of Readmission and Admission) has been developed by the Information Services Department, Scotland which can be used to predict an individual's risk of being admitted to hospital as an emergency inpatient within the next year.

65 Which drugs cause preventable admissions to hospital? A systematic review. www.ncbi.nlm.nih.gov/pubmed/16803468

66 Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years. Br J Clin Pharmacol; 2012 Oct; 74(4):597-604

67 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419549/20150331_2015-NRR-WA_Final.pdf

68 McClean et al. Antimicrobial prescribing in residential homes. J Antimicrob Chemother, 2012.

69 Maripu H et al. An audit of antimicrobial treatment of lower respiratory and urinary tract infections in a hospital setting. Eur J Hosp Pharm 2014;21:139-144

70 Kripke DF et al. Hypnotics' association with mortality or cancer: a matched cohort study. Pharmacology and therapeutics, 2012

71 http://www.isdscotland.org/Health-Topics/Health-and-Social-Community-Care/SPARRA/

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• There is an agreed approach across Trusts for the management of patients taking high risk or specialist medicines which includes specialist pharmacists with a strategic responsibility for high risk medicines across Trusts. • Clinicians record medicines related issues as causative factors for admission/ re-admission in patients' notes, supporting accurate clinical coding and monitoring trends across Trusts. • A regional electronic antimicrobial surveillance system is in operation which includes resistance tracking, alert functionality and antimicrobial stewardship. • The pharmacy management system (JAC) has high risk medicines flagged	• The interface pharmacist network provides pharmaceutical care for some groups of patients on specialist medicines. This varies depending on service delivery and capacity and would not encompass all medicines on the red amber list. Other specialist pharmacists also play a significant role. There is inconsistency in the level of information provided to patients, carers and social care workers when high risk medicines are prescribed and dispensed. • There is low awareness among medical staff of medicines related issues as causative factors for admission/ re-admission leading to under reporting in patient's notes, incomplete clinical coding and lack of data for monitoring trends. • A system for surveillance and monitoring of antimicrobial resistance and antimicrobial stewardship with alert functionality is not available in all Trusts. • High risk medicines are not highlighted on JAC, the pharmacy management system.

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• Patient safety tools are in use for example PINCER, STOPP/START and the GRASP suite of tools • Proactive case management and targeting care to those most at risk through a primary care enhanced service for risk stratification is included in the work of ICPs. • All patients on high risk medicines receive appropriate help to take their medicines safely. • A regional electronic antimicrobial surveillance system is in operation which includes resistance tracking, alert functionality and antimicrobial stewardship which collects data from GP practices across the region. • Patients' records including the ECR highlight the use of high risk and specialist medicines. • A local enhanced service (LES) for those patients in nursing and residential homes supports those who may have more complex needs supported by pharmacist prescribers and case management nurses in primary care.	• There is no regional multi-disciplinary approach to the management of patients on high risk medicines. • A surveillance system to capture microbiological data in general practice is not available across the region. • Examples of high risk medicines are available on a poster for practices however there is no agreed system for highlighting high risk and specialist medicines on patient records and ECR. • The LES for nursing and residential homes does not currently specify management of patients on high risk medicines.
Community pharmacy	• Risk stratified provision of appropriate support, information and advice with supply of medicines. • Community pharmacies have access to up to date information relating to patient medication including high risk and specialist medicines.	• Examples of high risk medicines are available on a poster for community pharmacies however there is no protocol which they use to stratify risk. • Community pharmacies do not currently have access to the ECR.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Social Care	• Patients in nursing and residential homes taking high risk medicines are identified and receive appropriate care. • In domiciliary care there is compliance aid support for at risk patients based on a person's physical capability/cognitive ability/mental health difficulties. • The roles of nurses and care staff support patients on high risk medicines in domiciliary care settings agreed regionally with accredited training and competency based assessments for care staff. • Consistent provision to social care workers of information regarding patients on high risk medicines. • A regional electronic antimicrobial surveillance system is in operation which includes resistance tracking, alert functionality and antimicrobial stewardship which collects data from nursing and residential homes across the region.	• The roles of nurses and care staff supporting patients on high risk medicines in domiciliary care settings is unclear. • A surveillance system to capture microbiological data in nursing/residential homes is not available across the region.
Patients	• Patients with a greater awareness of high risk medicines and empowered to seek support, information and advice in the use of these medicines.	• There is a lack of knowledge among patients regarding high risk medicines to enable them to manage them appropriately.

Actions needed to address the gaps

- A regional risk stratification tool should be developed and implemented in primary and secondary care which includes outpatients to identify patients who may be at risk because of the medicines they use.
- Patients and carers should be made aware when high risk medicines are prescribed and dispensed and receive the necessary support and information to assist safe and effective use.
- An ePrescribing & Medicines Administration (EPMA) system and JAC in hospitals should highlight when high risk medicines are being used.
- Increased use of patient safety tools for example PINCER, STOPP/START and the GRASP suite of tools.
- The ECR should highlight when high risk and specialist medicines are being used.
- Information to patients and their GPs regarding specialist medicines should be consistently provided.
- A regional plan to improve reporting/clinical coding of the incidence of unplanned admissions to hospital associated with medicines should be developed and implemented.
- GP and community pharmacy computer systems should have high risk and specialist medicines highlighted.
- High risk patients should be prioritised for regular clinical medication reviews (See Standard 9).
- Roles and responsibilities relating to risk stratification and medicines optimisation should be included in ICP patient pathways for at risk patient groups.
- A regional antimicrobial prescribing and surveillance system should be established which includes resistance tracking, an alert functionality and antimicrobial stewardship.
- The roles of nurses and care staff in medicines optimisation in domiciliary care settings should be reviewed, clarified and agreed regionally with accredited training and competency based assessments for care staff.
- For high risk drugs there should be shared care guidelines not only with the GP but also with the patients chosen community pharmacist.

Standard 6 – Safety/Reporting and Learning Culture

Organisations promote an open and transparent culture with evidence of processes for the reporting, prevention, detection, communication and cascade of learning from medication incidents and adverse drug reactions.

Why is the standard needed?

The medicines governance teams in primary and secondary care are well established in promoting medication incident reporting, developing risk management processes, implementing regional best practice policies and risk education. However there is variance in the degree to which medicines incidents are reported across the HSC and reluctance from community pharmacies to report due to current legislative penalties for errors. One of the recommendations of the Donaldson Report was a need to make incident reports really count.

The MHRA has received over 700,000 UK spontaneous adverse drug reactions (ADRs) since the scheme was first started and typically they receive around 25,000 reports per year. In the 5 years prior to June 2013, there have been 2,110 ADR reports reported to MHRA from Northern Ireland. We need to improve our reporting of medicines incidents including ADRs across the HSC and raise public awareness of patient reporting of ADRs.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• All medicines incidents and ADRs are reported via the appropriate mechanisms • All near miss information from pharmacist interventions are captured electronically to enable learning. • A modified risk assessment tool based on the national quality assurance and fit for purpose and medicines error potential tools is used in the procurement process. However, there is a need for other tools to identify medication safety risks.	• The rates of medicines incident reporting and yellow card reporting are low and vary between Trusts, professionals and clinical areas/specialities • The Electronic Pharmacist Intervention Clinical System (EPICS) software to capture pharmacist interventions is not in use in all Trusts. • Although Datix is used to report adverse incidents (AIs) and serious adverse incidents (SAIs), and can be used to help identify medicines safety risks, there are currently no tools, for example, global trigger tool/ medication safety thermometer tool.

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• A software system is in place to allow the recording of medicines incidents by GPs in their general practice (e.g. Datix) and to analyse medicines incidents. • All ADRs are reported via the yellow card scheme through the GP IT clinical system. • Tools are available to identify medication safety risks.	• The rates of medicines incident reporting are low. • The rates of yellow card reporting are low. • There are currently no approved tools for example global trigger tool/medication safety thermometer tool.
Community pharmacy	• A software system is in place to allow the recording of medicines incidents by community pharmacists in their pharmacy practice (e.g. Datix) and to analyse medicines incidents. • Community pharmacists actively report ADRs via the yellow card scheme and can do so through their pharmacy IT system.	• The rates of medicines incident reporting are low. • The rates of yellow card reporting are low.
Social Care	• Systems are in place to report ADRs and incident reporting systems for medicines. • Medication incidents are reported from all registered facilities to RQIA.	• The rates of incident and yellow card reporting are low.
Patients	• Systems are in place to allow patients to report medication incidents. • Patients report ADRs via the yellow card scheme.	• Patients are not currently encouraged to report medication incidents. • The rates of yellow card reporting are low.

Actions needed to address the gaps

- An open and fair culture to encourage timely reporting of medicines incidents and ADRs should be established across the HSC.
- A regional programme should be launched to increase yellow card reporting by health care professionals and patients with consideration of introducing contractual requirements to support implementation.
- A regional system should be introduced to allow electronic reporting, monitoring and analysis of medicines incidents by GPs, Community Pharmacies and Social Care Workers.
- A regional system should be introduced to identify and review incident data, identify and develop learning and explore new ways of how to deliver learning and share knowledge. See NICE Guideline NG5 recommendation 1.1
- Formal links should be established with other UK countries with respect to medication incident reporting and learning.
- Process reviews along with engineering and technological solutions should be developed which aim to minimise system failures that underpin medication errors.
- The use of Institute for Healthcare Improvement (IHI) methodology and other improvement science tools should be increased to improve medicines safety.
- A Never Event approach should be introduced as recommended in the Donaldson report for medication errors.

Quality Theme – Effectiveness

Standard 7 – Access to Medicines you Need

Patients have appropriate, equitable and timely access to quality assured, evidence-based and cost-effective medicines.

Why is the standard needed?

Improved access to medicines has contributed to an increase in life expectancy, helping people to stay healthy for longer and many previously debilitating or fatal conditions are now prevented or managed, often on a long term basis, through regular medicines use. The population of Northern Ireland uses a high volume of medicines per head of population. Robust systems are in place to ensure that medicines are prescribed to patients across the region in line with evidence and best practices in a cost effective manner. Furthermore, regional and local procurement practices in Trusts ensure the availability of quality assured medicines in hospitals. Equally, community pharmacies comply with professional standards for the sale and supply of medicines in the community and go to great lengths to ensure that patients have access to the medicines they have been prescribed, whether these are one-off prescriptions or ongoing medicines for long-term conditions. However, Northern Ireland is part of a wider UK and global medicines market and shortages can and do arise within the medicines supply chain which are frequently beyond their control. The consistent delivery of safe, high quality and cost effective prescribing and procurement is essential to facilitate continued access to medicines for the population. For new medicines, a regional managed entry process exists which aims to ensure timely and equitable access for patients to those medicines for which there is an evidence base on efficacy and cost-effectiveness. However, there is a perception that there are differences in access across the region and compared to other UK countries particularly in respect to cancer and specialist medicines.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Hospital pharmacies ensure timely access to safe, quality assured medicines so as to avoid delays in administration. • All Health and Social Care Professionals are aware of the HSCB Regional Managed Entry [72] process which supports timely and appropriate access to new medicines for which there is an evidence base on efficacy and cost-effectiveness. • Timely and appropriate access to new medicines for patients for which there is an evidence base on efficacy and cost-effectiveness. • Compliance with regional guidelines for managing medicines shortages in hospitals. • All Individual Funding Request (IFR) applications subject to regionally consistent clinical input and peer review. • Improved support regarding access to unlicensed or off-label medicines in areas of unmet medical need, thus enhancing the landscape for developing, licensing and procuring innovative medicines.	• The funding mechanisms and the process of applying for funding for new, unlicensed and specialist medicines is not well understood. • Unlicensed and off-label medicines are not part of the established regional IFR process. • There is inconsistency across Trusts regarding Non-NICE medicines approval however work is progressing on the implementation of the DHSSPS IFR consultation recommendations.

72 http://niformulary.hscni.net/ManagedEntry/Pages/default.aspx

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• All Health and Social Care Professionals are aware of the HSCB Regional Managed Entry process which supports timely and appropriate access to new medicines for which there is an evidence base on efficacy and cost-effectiveness.. • Compliance with regional guidelines for managing medicines shortages in primary care.	• The funding mechanisms for new, unlicensed and specialist medicines is not well understood. • There are no regional guidelines for managing medicines shortages in primary care.
Community pharmacy	• All community pharmacists are aware of the HSCB Regional Managed Entry process which supports timely and appropriate access to new medicines for which there is an evidence base on efficacy and cost-effectiveness. • Community pharmacies ensure timely access to safe, quality assured medicines so as to avoid delays in administration However if there are shortages outwith their control, they cannot be held accountable. • Compliance with regional guidelines for managing medicines shortages in primary care. • All patients have their repeat medicines dispensed on time to avoid clinical consequences.	• The funding mechanisms for new, unlicensed and specialist medicines is not well understood. • There are no regional guidelines for managing medicines shortages in primary care.
Patients	• Patients are aware of the HSCB Regional Managed Entry process which supports timely and appropriate access to new medicines for which there is an evidence base on efficacy and cost-effectiveness. • Timely and appropriate access to new medicines for patients for which there is an evidence base on efficacy and cost-effectiveness.	• There is public perception of variance in the managed entry of new, unlicensed and specialist medicines.

Actions needed to address the gaps

- Regional guidance should be developed to improve public and healthcare professional awareness and understanding of the processes for managed entry and access to new, unlicensed and specialist medicines in Northern Ireland. This should include accessible, accurate and up to date information for the public to view and include a schematic that shows how to access medicines in the HSC.

- Regional guidelines on handling medicines shortages in primary care should be developed. This would include the provision of advice by community pharmacists to prescribers of stock shortages and making recommendations for alternative products. If shortages arise within the medicines supply chain which are outwith the control of community pharmacists, they cannot be held to account.

- The recommendations of the DHSSPS IFR consultation should be implemented.

Standard 8 - Clinical and Cost Effective Use of Medicines and Reduced Waste

Within organisations a culture exists promoting a shared responsibility for the appropriate, clinical and cost effective use of medicines supported by systems for avoiding unnecessary waste.

Why is the standard needed?

Within HSC organisations it is important that systems for the procurement, prescribing, ordering and supply of prescribed medicines provide cost effective use of medicines providing optimal health outcomes, safety and avoiding waste.

A regional focus on evidence based and cost effective prescribing has resulted in significant improvements in the quality of prescribing in recent years with evidence of change in terms of drug costs, volumes and levels of compliance with the Northern Ireland Formulary. Advertising campaigns have sought to raise public awareness of the need to reduce medicines waste by only re-ordering repeat medicines that are needed and highlighting actions for community pharmacies, GP practices and care homes. However, evidence shows that around 11% of UK households have one or more medicines that are no longer being used[73] and estimates, based upon a study conducted by the University of York, put the cost of wasted medicines in Northern Ireland at £18m per year[74]. The highest levels of wasted medicines are associated with repeat medicines that are ordered, prescribed, dispensed, collected by the patient/carer but never used and subsequently wasted. Waste in nursing and residential homes is recognised as a particular challenge.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Prescribing is informed by the Northern Ireland Formulary. • All Trusts have policies promoting the use of patient's own drugs (PODs) where possible on admission to hospital.	• Prescribing data by clinical indication in secondary care is not available. • There are differences between Trusts in how the process of using PODs is adopted.

73 Woolf, M. Residual medicines: a report on OPCS Omnibus Survey data

74 Evaluation of the Scale, Causes and Costs of Waste Medicines, University of London and York 2010

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• Prescribing is informed by the Northern Ireland Formulary. • HSC Board medicines management advisors, prescribing support pharmacists and practice-based pharmacists support effective prescribing in GP practices. • Repeat prescribing policies and processes aim to restrict over-ordering and reduce errors in ordering.	• The Northern Ireland Formulary is not linked to GP ICT systems. • Not all GP surgeries have prescribing support. • The current repeat dispensing service is paper based, inefficient and underused. • Unwanted items previously prescribed may be re-ordered in error.
Community pharmacy	• Systems are in place to check that items ordered on repeat prescription are required before supply is made. • Medicines waste returned to pharmacies for disposal is safely handled and levels of waste are monitored. • Pharmacies follow HSC Board guidance relating to ordering and collection of medicines.	• There is no requirement for pharmacies not to dispense prescribed items and unwanted items ordered in error may still be supplied. • The level of waste returned for disposal is not monitored. • Full compliance with the HSC Board guidance relating to ordering and collection of medicines is not assured.
Social Care	• Systems are in place to manage the ordering of prescribed medicines to ensure adequate supplies and prevent wastage. The RQIA encourages and promotes good stock control.	• Stock control is an ongoing problem. • Over ordering and waste returned for disposal from nursing and residential homes is not monitored.
Patients	• Systems are in place to allow patients to order their medicines when needed and prevent inappropriate ordering.	• Inappropriate ordering (over ordering, ordering unwanted items and under ordering) may still occur.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Other	• An ongoing regional medicines waste advertising campaign which seeks to influence patient behaviour and prescription ordering processes in GPs, Community Pharmacies and care homes. This should also encourage patients to bring their medicines into hospital with them to avoid unnecessary waste	

Actions needed to address the gaps

- A regional prescribing database should be available for secondary care with the Dictionary of Medicines and Devices (DM&D) as the dictionary to enable merging with primary care data.
- Prescribers should have access to an electronic Northern Ireland Formulary which is linked to GP ICT systems to inform prescribing.
- Consistent prescribing compliance with the Northern Ireland Formulary should be achieved.
- Levels of waste returned from pharmacies and care homes should be monitored and the impact of interventions on waste reduction measurement.
- Consideration should be given to a role for minimising medicines waste to be included in GP and community pharmacy contracts.
- The repeat dispensing service should be reviewed and re-launched in electronic form.
- To influence patient behaviour regarding medicines waste, the medicines waste advertising campaign should be ongoing.
- New approaches to minimising wasted medicines should be explored including collaboration with the pharmaceutical and technology industry.

Standard 9 – Clinical Medication Review

Clinical medication reviews are carried out with the patient and occur on a regular basis, at least annually.

Why is the standard needed?

The importance of medication reviews is recognised and a number of health policies and service frameworks recommend regular reviews for specific patient groups including: older patients, people with diabetes, respiratory disease and cardiovascular disease.

Medication reviews in this context are clinical reviews conducted with the patient and with full access to patient medication records. They are not medicines reconciliation checks, medicines use reviews (MURs), Manage Your Medicines service reviews or desk top patient medication record checks.

Currently medication reviews may occur at various stages in the patient journey carried out by a range of healthcare professionals with varying levels of clinical autonomy and expertise in medicines. There is a level of inconsistency in approach in terms of what the review involves, the optimal time and frequency for completion and who is best to conduct it.

An increasing challenge for medication reviews is the prevalence of multi-morbidities and polypharmacy as the population ages. Another issue is that patients may have medicines prescribed concomitantly by a number of different doctors and non-medical prescribers involved in their care.

These issues reinforce the need for a robust regional approach to clinical medication reviews.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• 95% of people admitted to hospital receive a clinical medication review during their stay which is documented. • Clinical medication reviews to optimise medicines use in outpatient clinics for example diabetes, anti-coagulant and rheumatology.	• There is inconsistency in clinical medication reviews carried out in secondary care as the IMM service is currently only available for 50% of beds and there is variance in the quality of delivery of the service between Trusts.

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• Within the core GMS contract is an expectation that patients on chronic medication have an annual clinical medication review. The appropriate frequency should be tailored to the individual and their care plan and may need to be carried out more frequently than annually • High risk patients are prioritised for 'regular' medication reviews as agreed in patient's care plans.	• Detailed clinical medication reviews are not being undertaken with patients on a consistent basis. • There is no regionally agreed best practice approach to clinical medication reviews resulting in duplication between reviews offered in secondary care, primary care and community pharmacy.
Community pharmacy	• Suitably trained Pharmacist Independent Prescribers (PIPs) with remote access to patient records from general practice have a role in the provision of clinical medication reviews.	• There is no defined role or service for community pharmacy in the provision of clinical medication reviews. • The number of PIPs working in community pharmacy is currently low.
Social Care	• Consultant pharmacist led care in intermediate care, nursing and residential homes supporting appropriate polypharmacy through clinical medication reviews. • GP Local Enhanced Service (LES) 2014/15 PIPs conduct clinical medication reviews of registered patients in nursing and residential homes.	• There is currently no agreed regional service available to provide clinical medication reviews for older people in intermediate care, nursing and residential homes settings.
Patients	• Patients are aware of what a full clinical medication review involves, when it should be carried out and by whom. • Clinical medication reviews should be carried out in a setting and time convenient to the patient where possible.	• Lack of understanding of what a full clinical medication review involves and when it is required.

Actions needed to address the gaps

- A regional model for clinical medication reviews should be developed which describes what should be included in the review, when it should be conducted and by whom. See NICE Guideline NG5 recommendation 1.4, medication review
- In primary care the frequency of clinical medication reviews for patients should be agreed within individual care plans and the requirement for completion of reviews included in GP contracts.
- In Trusts the availability of the IMM service should be increased and the service delivered to a consistent quality involving a clinical medication review conducted by a pharmacist.
- Within multi-disciplinary teams in primary care, secondary care and as outreach from Trusts, pharmacists should conduct clinical medication reviews and a role should be developed for community pharmacists
- The clinical medication review standard should be included as a generic standard in all service frameworks relating to patients with long term conditions, multi-morbidity and polypharmacy.

Standard 10 – Administration

Following an initial check that the direction to administer a medicine is appropriate, patients who have their medicines administered receive them on time and as prescribed.

Why is the standard needed?

A review of all medication incidents reported to the National Reporting and Learning System (NRLS) and England in Wales between 1st January 2005 and 31st December 2010 was undertaken. Incidents involving medicine administration (50%) and prescribing (18%) were the process steps with the largest number of reports. Omitted and delayed medicine (16%) and wrong dose (15%) represented the largest error categories[75]. A Rapid Response Report from the National Patient Safety Agency on 'Reducing harm from omitted and delayed medicines in hospital' highlighted that medicine doses are often omitted or delayed in hospital for a variety of reasons[76]. This can lead to serious harm or death for some critical conditions, for example patients with sepsis or pulmonary embolism where there is a delay/omission of intravenous medicines[77]. Parkinson's UK - Get it On Time campaign[78] outlines the importance of people getting their Parkinson's medication on time, every time in hospitals and care homes. A GAIN audit carried out in 2013 - The Importance of Timing in Parkinsons Medication[79] found that 59% of patients did not receive their medication on time during their hospital stay. A study which investigated the prevalence of medication errors in care homes in the UK found that 22.3% of 256 residents were observed to receive an administration error. The commonest administration errors were omissions because the drug was not available, so omissions need to be monitored and ordering, particularly of "as required" medicines, needs to be improved[80]. In a 2011 study of medicine administration errors in older persons in hospital wards in the UK, the number and severity of medication administration errors was found to be higher than previous studies. During 65 medicine rounds 38.4% of doses were administered incorrectly[81]. In domiciliary care settings nurses and care workers are involved in activities which range from administration to prompting patients to take their medicines. More older people are being cared for in their own homes often with complex and multiple medicines regimens and there is the need for regional best practices that support role clarification, accredited training and support systems for staff.

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75 Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years. Br J Clin Pharmacol; 2012 Oct;74(4):597-604

76 National Patient Safety Agency. Patient Safety Observatory Report 4: Safety in doses; 2007.

77 National Patient Safety Agency. Rapid Response Report, 2010.

78 http://www.parkinsons.org.uk/content/get-it-time-campaign

79 http://www.gain-ni.org/images/Uploads/Audit/GAIN_-_FINAL_GIOT_REPORT_-_19_April_2013.pdf

80 Alldred DP, Barber N, Carpenter J, Dean-Franklin B, Dickinson R, Garfield S, Jesson B, Lim R, Raynor DK, Savage I, Standage C Wadsworth P, Woloshynowych M, Zermansky AG. Care homes use of medicines study (CHUMS). Report to the Patient safety {Portfolio, department of Health). 2009.

81 Kelly J and Wright D. Medicine administration errors and their severity in secondary care older persons' ward: a multi-centre observational study J Clin Nursing. 2011

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• All patients should receive their medicines on time following a check that the direction to administer is appropriate and other related factors taken into consideration for example insulin dose close to meal time and meals are not delayed. • Patients self-administer their own medicines, where the risks have been assessed and the competence of the patient to self-administer is confirmed. • 'One-stop' dispensing[82] and the use of patient bedside medicines lockers to improve access and reduce medicines administration errors. The move from a 'trolley-based' system for administering medicines to a 'one-stop' dispensing system using patient's own drugs and custom-designed patient bedside medicine lockers has resulted in safer and faster medicine administration rounds[83] [84].	• Doses of medication are being omitted and delayed as shown in an audit carried out in the five Trusts in Northern Ireland in 2013.12.7% of doses were omitted and delayed. (NB however work is ongoing to ascertain how many were true omissions/failure to record). • Self-administration occurs to varying degrees in Northern Ireland hospitals. • One-stop dispensing occurs in varying degrees in Northern Ireland hospitals.

82 'One-stop' dispensing refers to the practice of combining inpatient and discharge dispensing into a single supply labelled for discharge. Patients are encouraged to bring their own medicines into hospital on admission and medicines are assessed by pharmacy as suitable for use are used for the patient during their hospital stay. A 28-day supply is given of any medicines deemed unsuitable for us, when the quantity of a particular medicine is depleted and when new medicines are commenced http://www.hospitalpharmacyeurope.com/featured-articles/one-stop-dispensing-and-discharge-prescription-time

83 Anon. Giving medicines from patient lockers reduces errors. Pharmaceut J 2002;268:274

84 Hogg et al. Do patient bedside medicine lockers result in a safer and faster medicine administration round? Eur J Hosp Pharm, July 2012 http://ejhp.bmj.com/content/19/6/525.abstract

Provider	What best practice should be delivered	Gaps in delivery of best practice
Community Pharmacy	• All patients required to take their medicines under supervision are treated in a confidential, non-judgmental manner in a private area within the pharmacy. • Community pharmacists helping to facilitate administration through new systems or additional support provided to care homes. • In domiciliary care community pharmacists supporting self administration of medicines through the provision of a variety of medicines adherence support solutions.	• Patients requiring medicines to be taken under supervision may not always feel that they are treated in a confidential, non-judgemental manner. • There is a limited evidence base for support systems for care homes and domiciliary care and no common regional approach to identifying and assessing non adherence and to the provision of solutions. However Medicines Adherence Support Service (MASS) pilot has been carried out and is currently being evaluated.
Social care	• All residents in care homes who have their medicines administered should receive their medicines on time following a check that the direction to administer is appropriate. • Patients self-administer their own medicines, where the risks have been assessed and the competence of the patient to self-administer is confirmed. • Community nursing core services associated with medicines administration of high risk and specialist medicines as well as other medicines such as vaccines in patients own home. • Domiciliary care workers are appropriately trained and supported to contribute to medicines optimisation.	• Evidence of administration errors in care homes due to omissions. • The roles of nurses and domiciliary care workers in medicines optimisation need to be reviewed and clarified.
Patients	• All patients living at home with predictable conditions are supported to self-administer their medicines and to remain independent for as long as possible.	• There are limited solutions available for supporting independence with medicines taking.

Actions needed to address the gaps

- In secondary care an ePrescribing & Medicines Administration (EPMA) system and the computerisation of records and processes should be introduced, linked to general practice and community pharmacy (see standard 1).
- An increase in the number of wards in hospital providing a 'one-stop' dispensing service should be considered.
- There should be an appropriate skill mix within clinical settings to ensure safe administration of 'critical' medicines.
- Self-administration schemes should be rolled out in secondary care and intermediate care where the risks have been assessed and the competence of the patient to self-administer is confirmed.
- Community pharmacies providing a substitution treatment service should have a private area where supervised administration can be undertaken which serves to normalise the process for patients.
- Consideration should be given as to how community pharmacists could provide additional support in relation to administration to patients living both in their own home and in a care home environment.
- The roles of nurses and care staff in medicines optimisation in domiciliary care settings should be reviewed, clarified and agreed regionally with accredited training and competency based assessments for care staff.
- There should be a regionally agreed process to support community nursing teams and care staff to administer medicines on time.

Integrated Innovation and Change Programme

Smarter Medicines Better Outcomes

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SECTION 4

Integrated Innovation and Change Programme

Supporting Continuous Improvement and Innovation in Medicines Use

4.1 The Quality Standards have identified a number of gaps in medicines management systems which impact on the delivery of the Regional Medicines Optimisation Model. Many of the actions needed to address these gaps require regional systems which may involve an element of whole system change with interdependencies across the HSC.

4.2 Traditionally a range of organisations have had active programmes of research and service development relevant to medicines optimisation with funding coming from a variety of sources.

4.3 The ultimate success of these programmes is for their outputs to inform practice throughout the HSC through changes to medicines policy or commissioned services. However, this does not always occur and in many instances outputs are not recognised or valued by commissioners and policy makers or practices are not successfully translated across the HSC leaving fragmented or disjointed services. Outputs need to be demonstrably transferrable across the wider HSC and monitored to ensure the programmes continue to be a success following roll-out.

4.4 A new strategic approach to pharmaceutical innovation is proposed to support and drive continuous improvement through the development and implementation of best practice in medicines optimisation in Northern Ireland exploiting new funding opportunities whilst using existing funding streams and resources efficiently and following the core values and principles of Personal and Public Involvement (PPI).

4.5 This will require a dedicated oversight group to drive the development and implementation of evidence based best practice associated with each medicines quality standard.

4.6 The strategic approach has four components:

- a regional action plan for medicines optimisation;
- a medicines optimisation innovation centre;
- a medicines optimisation network; and
- a regional database to monitor improvement.

Regional Action Plan for Medicines Optimisation

4.7 The Regional Action Plan for medicines optimisation will prioritise activities in a regional change programme of research, service development and translation with clear outputs and timelines for developing, testing and implementing solutions.

4.8 Methodology to develop the plan will include:

- a baseline assessment of all activities underway or in development across the HSC relating to each quality standard;
- stratification of the activities to identify those capable of informing regional versus local best practice;
- agreement with commissioners of the priority and timescales related to the regional activities; and
- analysis of the regional activities to identify the different actions needed, timeframes and costs as follows:

Table 9: Regional Action Plan Analysis of Activities

Type of Activity	Action needed	Timeframe and costs
Activities involving best practices that are or have the potential to be regionally commissioned through existing services or contractual agreements and performance managed thereafter.	• Promote the best practice regionally to all relevant providers and set quality expectations • Amend contractual agreements and/or job descriptions of service providers to include responsibility for delivery • Manage performance	• Immediate to Short term. • No cost.

Type of Activity	Action needed	Timeframe and costs
Activities involving best practices that are available in some but not all areas regionally which need support to scale up and roll out.	• Develop a business case for scale up and roll out • Utilise change management principles to implement consistently across HSC • Amend contractual agreements and/or job descriptions to include responsibility for delivery • Manage performance	• Medium term • Costs associated with regional roll out
Activities addressing gaps in best practice which involve the development, feasibility testing and evaluation of new solutions.	• Agree a prioritised innovation programme of research and service development to develop and test new solutions • Engage the Medicines Optimisation Innovation Centre to manage the programme • Consider the evidence base and type of solution needed • Test and evaluate the solution within the HSC • Develop a business case for scale up and roll out • Utilise change management principles to implement consistently across HSC • Amend contractual agreements and/or job descriptions to include responsibility for delivery • Manage performance	• Longer term • Costs associated with R&D and pilots for service development.

4.9 Methodology to deliver the plan will include:

- an agreement across HSC organisations to adopt regional best practices;
- a system for the timely translation of best practice across the HSC including support for organisations and staff involved in change, utilising evidence based change methodology;
- a prioritised innovation programme of research and service development to develop and test new solutions;
- an agreed process for involving patients in research and service development in medicines optimisation;
- a training and development plan for staff involved in new medicines optimisation roles; and
- a financial plan outlining revenue and capital investment, invest to save approaches and the utilisation of HSC, UK and EU funding streams and resources to deliver the work plan objectives.

Medicines Optimisation and Innovation Centre

4.10 An element of the regional action plan will involve projects seeking new solutions, to address gaps in best practices for the quality standards, which are developed and tested within the HSC prior to commissioning for scale up and implementation regionally. These projects will be undertaken in collaboration with the Medicines Optimisation and Innovation Centre (MOIC).

4.11 The MOIC centre provides a locus for developing a systematic approach to finding and testing solutions for the HSC with the following functions.

- Project manage an innovation programme of research and service development projects.
- Develop, test and evaluate solutions to pre-commissioning stage.
- Support successful translation into HSC service delivery and commissioning.
- Help projects to access and utilise available funding streams.
- Provide a regional centre of expertise for research and service development in medicines optimisation and post-implementation review of service delivery.
- Build local expertise and competence in developing and translating research into practice.
- Facilitate a continuous cycle of improvement within the HSC in the area of medicines optimisation.

4.12 The centre also has wider benefits combining pharmaceutical and R&D skills with technology and business acumen to:

- provide evidence based solutions for medicines optimisation which could be developed commercially, marketed and sold to other countries with the HSC as a beneficiary;
- promote Northern Ireland as a leading area for medicines optimisation research and development and strengthen Northern Ireland's 4 star EU reference status bid;
- attract inward investment into a Northern Ireland Medicines Optimisation Innovation Fund/ Programme; and
- increase collaborative work with other established research networks in UK, Europe and internationally.

Medicines Optimisation Network

4.13 The work of the MOIC will lead to the development of a medicines optimisation network linking the HSC with other health and life science networks and innovation centres in Northern Ireland, UK and internationally. It will also support knowledge sharing both within the HSC and with wider networks and the development of collaborative working partnerships and joint working arrangements between participants that may include the following.

- Commissioning organisations (HSC Board, Trusts, PHA, BSO)
- Policy (DHSSPS)
- Patients and their representative bodies
- Independent contractors (GPs and community pharmacists)
- Independent Domiciliary Care Providers
- Academia (UU and QUB)
- Pharmaceutical and Technology Industries
- Voluntary sector
- Charities
- Expert(s) with research skills
- NIMDTA, NICPLD, NIPEC
- Other Innovation Centres and translational research groups
- Health and Social Care professionals
- Experts from across the UK and international

Regional Database to Monitor Improvement

4.14 To allow commissioners and policy leads to monitor progress and enable comparisons regionally and with other UK countries a new regional database is proposed. This will largely bring together existing data related to medicines use from different sources across the region to monitor trends, enable benchmarking and help drive quality improvements. It will also provide an understanding of how well patients are supported across the region to use their medicines safely and effectively to improve health outcomes. Outcome measurements include:

- patient/client satisfaction;
- medicines safety incident reporting;
- cost effective use of medicines;
- impact on acute health services; and
- achievement of expected therapeutic outcomes.

4.15 Methodology to develop a regional database to monitor improvements will include:

- agreement of core outcome measurements for medicines optimisation in Northern Ireland;
- alignment with a Medicines Optimisation dashboard based on NHS England's dashboard which was developed in collaboration with Clinical Commissioning Groups, Trusts and the pharmaceutical industry; and
- the inclusion of questions relating to patient's experience of medicines in relevant Northern Ireland Health Surveys.

4.16 Implementation of the Medicines Optimisation Quality Framework will be monitored by DHSSPS through existing arrangements for HSC commissioning plans.

4.17 The Medicines Optimisation Quality Framework will be reviewed in 2021.

SECTION 5

Summary of Recommendations

Table 10: Recommendations

1. A Regional Model for Medicines Optimisation should be introduced which outlines what patients can expect when medicines are included in their treatment as they access services in health and social care settings.

2. The model should be delivered by a multi-disciplinary medicines optimisation workforce trained and competent in medicines optimisation, with the involvement of pharmacists in all settings.

3. The medicines optimisation workforce should deliver regional services and roles which are commissioned and coordinated across all HSC organisations and related agencies involved in the prescribing, dispensing and administration of medicines.

4. The services and roles should aim to consistently deliver regional best practices in compliance with new Quality Standards for Medicines Optimisation.

5. Regional best practices should always be co-designed with patients, following the principles of Personal and Public Involvement (PPI).

6. An innovation and change programme should be implemented, linked to HSC commissioning plans, to support the development, testing and scaling up of technology and service solutions to deliver consistent best practices related to the Quality Standards.

7. Regional systems should be implemented supporting HSC connectivity, electronic transmission of prescriptions and access to the Electronic Care Record, prescribing support, Northern Ireland Formulary and enhanced data analysis.

8. Within the HSC a regional organisational infrastructure for medicines optimisation should be maintained that incorporates, the Medicines Governance Team, Pharmacy and Medicines Management Team, Regional Pharmaceutical Procurement Service, Medicines Information Service, Medicines Optimisation Innovation Centre (MOIC).

9. A new regional database for medicines optimisation should be developed to monitor progress and enable comparisons regionally and with other UK countries.

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ANNEX A

History of Medicines Management in Northern Ireland 2000 - 2014

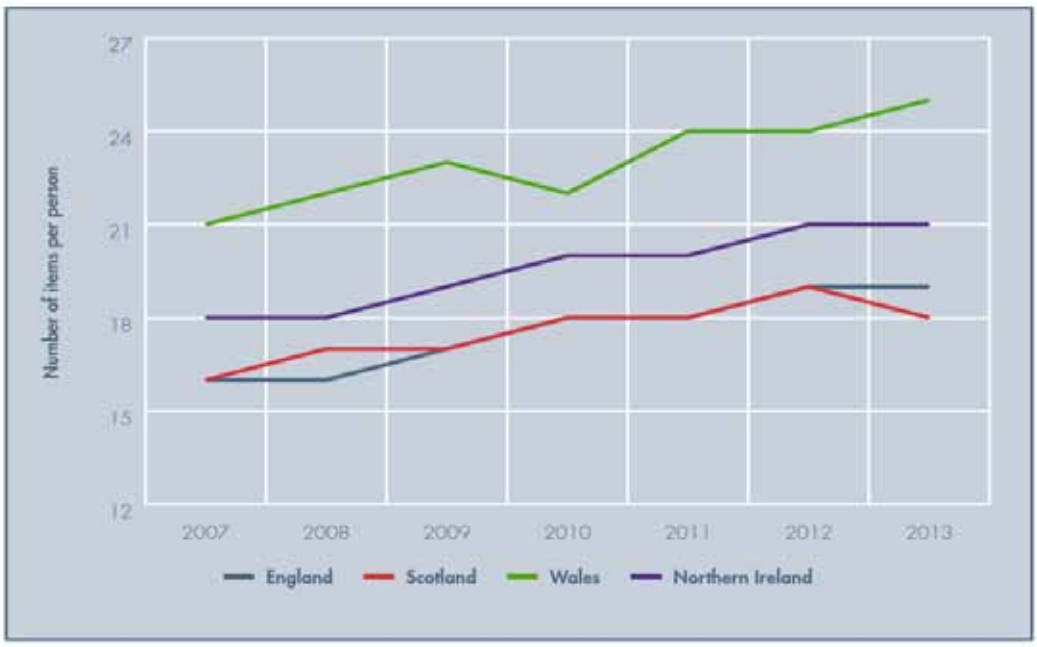
1. Medicines are the most common medical intervention within our population and at any one time 70% of the population[85] is taking prescribed or over the counter medicines to treat or prevent ill-health.

2. From a financial aspect, HSC medicines expenditure equates to £550m/annum in Northern Ireland, representing 14% of the total HSC budget and is the second largest cost after salaries. This does not take into account private transactions.

3. Social deprivation is linked with health and social care needs and levels of need for medicines. In comparison with other UK countries the volume and cost of medicines used per head of population in Northern Ireland is historically high, as detailed in Figures 3 and 4 and Table 11.

Number of items prescribed per head of population in the UK from 2007-2013

Figure 3: Source – NI Audit Office Primary Care Prescribing Report 2014



85 Office of National Statistics Health Statistics 1997.

Prescribing cost per head of population

Figure 4: Source – NI Audit Office Primary Care Prescribing Report 2014

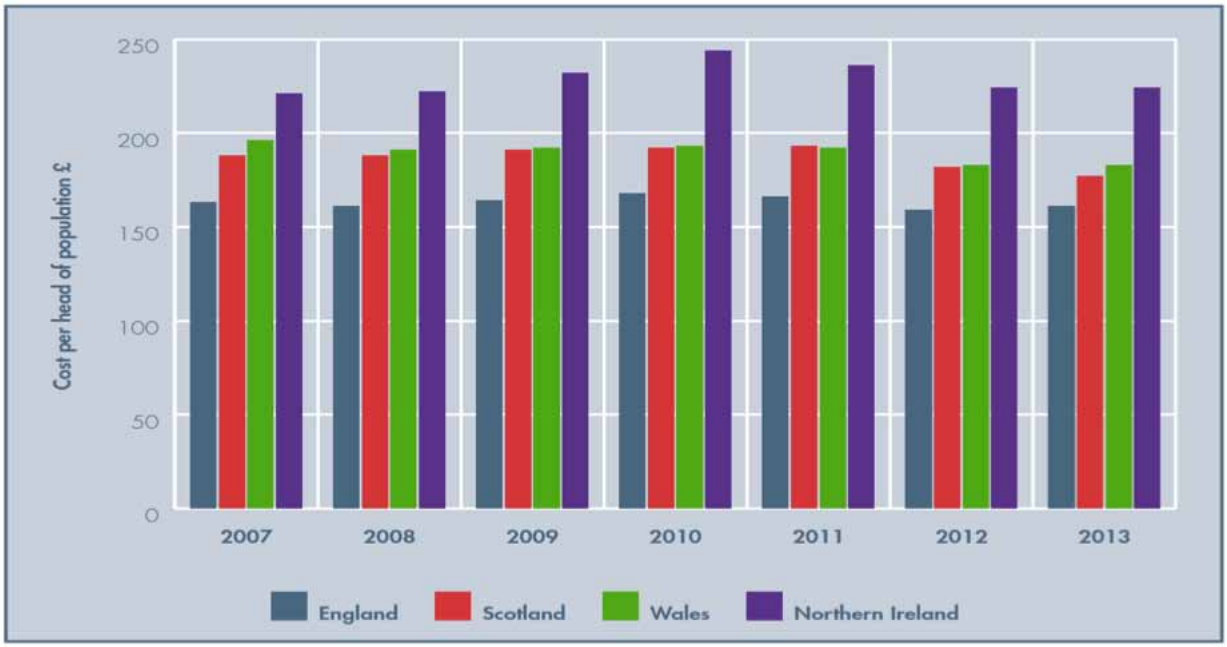


Table 11: Source - Business Services Organisation – Prescription Cost Analysis Reports

		2007	2010	2013
	NI	£221.09	£243.94	£223.54
	England	£162.95	£167.82	£160.12
	Scotland	£187.92	£192.25	£183.73
	Wales	£196.37	£193.05	£182.96

4. The 2014 NI Audit Office Primary Care Prescribing Report[86] highlighted that the volume of items prescribed per head of population per annum has been higher in Northern Ireland than in England and Scotland from 2007 and primary care prescribing costs have been consistently the highest here compared with the other regions in the UK from 2007 to 2013. However, it should be noted that the analysis does not consider the differences in data definitions and prescribing arrangements between the four countries so care is required on interpretation.

86 http://www.niauditoffice.gov.uk/primary_care_prescribing-2.pdf

5. High prescribing costs were first highlighted in 2000 when the limited outcome of the Comprehensive Spending Review required the Department to review spend against all budget areas, including the medicines budget.

6. In response, the Department established a Pharmaceutical Services Improvement Plan (PSIP) which for the first time considered a whole system approach encompassing both primary and secondary care.

7. This work identified and challenged all parts of the medicines journey from procurement through to prescribing, supply and utilisation introducing the concept of "Medicines Management"[87] [88] to HSC practice.

8. Professor John Appleby's Review in 2005 helped inform the next phase of PSIP. The report highlighted the need for new mechanisms to tackle high prescribing costs and to encourage greater use of generic drugs[89].

9. In response the existing PSIP programme was augmented with a new Pharmaceutical Clinical Effectiveness (PCE) Programme comprising a number of initiatives designed to work together to optimise medicines management which delivered savings across the HSC during the period from 2005/06 to 2007/08. Savings of £54m were made against a community drugs budget of approximately £387m. Re-engineering of pharmacy services in secondary care demonstrated savings as described in paragraph 16.

10. The PCE programme was extended into the 2008/09 - 2010/11 period and several new initiatives were added to provide a regional focus to medicines management establishing an infrastructure within the HSC through operational models, systems and policies to deliver:
    a. clinical and cost effective procurement;
    b. clinical and cost effective prescribing;
    c. behavioural change by engaging healthcare professionals in decision making;
    d. Integrated Medicines Management within the HSC; and
    e. extension of the secondary care medicines governance team which was established in 2002 to primary care.

87 Medicines management has been defined as "encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care.

88 Audit Commission (2001) A Spoonful of Sugar – Medicines Management in NHS Hospitals.

89 https://www.dhsspsni.gov.uk/publications/appleby-report

11. In the 2014 NI Audit Office Primary Care Prescribing Report it was noted that in the three year period following the introduction of PCE significant efficiencies had been made and the rate of growth in expenditure on drugs was reduced to less than 5 per cent per annum.

12. Responsibility for the prescribing budget was transferred from DHSSPS to the HSC Board in July 2010 and an annual PCE programme was established which continues today[90].

13. In the four year period from 2010/11 to 2013/14 the PCE programme has delivered a total of £132.2m against a target of £122m, an overachievement of approximately £10m.

14. Although the prescribing budget transferred to the HSC Board in 2010 the Department retained a role in pharmaceutical innovation, leading a regional 'Innovation in Medicines Management Programme' based on an 'invest to save' ethos which continues today. The Innovation Programme has overseen a range of medicines optimisation projects within the HSC including the development of the Northern Ireland Medicines Formulary.

15. The PCE and Innovation programmes have resulted in a range of best practices for medicines management as listed in Table 12, many of which are now embedded within HSC systems, services and patient pathways whilst others are suitable for regional roll out.

90 HSC Board's Pharmaceutical Clinical Effectiveness Programme 2014/15 http://www.hscboard.hscni.net/medicinesmanagement/NMP%20-%20Pharmacist%20Prescribing/03%20Pharmaceutical%20Clinical%20Effectiveness%202014-15.pdf

Table 12: Examples of regional best practice in medicines management

Procurement	The rational selection and therapeutic tendering of medicines, in secondary care, in line with NICE guidance and emerging evidence using the Safe and Therapeutic Evaluation of Pharmaceutical Product Selection (STEPSelect)* model[91 92]
Selection	Northern Ireland Medicines Formulary[93]*
Prescribing	Prescribing Policies • Generic medicines (Generics leaflet)* (Medicines unsuitable for Generic Prescribing)* • Identified therapeutic classes of medicines* (Anticoagulants) (Antipsychotics) (Controlled Drugs) (Diabetes) (Lithium) (Opioid Substance) • Specialist medicines (Interface Pharmacist Network Specialist Medicines, red/amber drugs)* (Trust interface arrangements for patients in the community, eg mental health) • NI Wound Care Formulary* • Prescribing guidance for safe and evidence based prescribing (NICE)[Y] • Antimicrobial guidelines[94] for primary care (Primary Care Management of Infection Guidelines)* and secondary care • Independent Pharmacist, Nurse and other Non-Medical Prescribers (DHSSPS Non-Medical Prescribing)*
Supply	• Extended supplies on hospital discharge (PCE Programme)* • Repeat Dispensing (Repeat Dispensing Guidance)* • Minor Ailments scheme (Minor Ailments)*

* regional initiatives

Y UK-wide guidance

91 Scott MG ,McElnay JC Janknegt R et al Safe Therapeutic Economic Pharmaceutical Selection (STEPSelect) :development .introduction and use in Northern Ireland European Journal of Hospital Pharmacy Practice 2010 ;16:81-3

92 Scott MG Pharmaceutical Clinical Effectiveness Programme (PCEP) –STEPSelect (Safe Therapeutic Economic Pharmaceutical Selection) British Journal of Pharmaceutical Procurement 2012; 3(1):23-6

93 The Formulary provides guidance on first and second line drug choices and covers the majority of prescribing choices and is focused on non-specialist prescribing choices in Northern Ireland. Whilst the Formulary will aim to standardise practice and ensure a level of consistency, it is recognised that individual patients may require medicines which lie outside such guidance.

94 Antimicrobial Guidelines for Primary Care can be accessed in digital format, including through smartphone apps and in secondary care settings, antimicrobial prescribing guidelines are accessible on Trusts' websites, and in some Trusts are also available to download as an app.

Adherence	• NI Single Assessment Tool* (NISAT) • Targeted Medicines Use Reviews (MURs) (Guidance for conducting Medicines Use Reviews)* • Managing Your Medicines Service (Managing Your Medicines)*
Safe transitions of care and Medicines Reconciliation	• The Integrated Medicines Management Service NI clinical pharmacy standards* • Regional Guidelines for the Supply of 'Take Home Medication' from Northern Ireland Emergency Departments* • Regional Guidelines for http://www.gain-ni.org/images/Uploads/Guidelines/Immediate-Discharge-secondary-into-primary.pdf*
Appropriate polypharmacy and optimal outcomes in the elderly	• Pharmaceutical Care Model for Older People within intermediate care, residential and nursing homes[95] [96] [a] • Consultant led Pharmacist clinical medication reviews in nursing homes[97] [a] • Application of PINCER[98] • Application of STOPP/START tool[99]
Governance	• Medicines Governance Networks in Primary and Secondary Care Medicines Governance*
Cost effectiveness	• Pharmaceutical Clinical Effectiveness (PCE) programme (PCE Programme)*
Medicines Information Services	• Regional Medicines and Poisons Information Service* http://www.belfasttrust.hscni.net/Pharmacy.htm

* regional initiatives

a Local Pilot

95 Darcy C, Miller R, Friel A, Scott M. Consultant pharmacist case management of elderly patients in intermediate care. British Geriatrics Society for better health in old age, Book of Abstracts, Spring Meeting 2014; p78 http://www.bgs.org.uk/pdf_cms/admin_archive/2014_spring_abstracts.pdf

96 Miller R, Darcy C, Friel A, Scott M, Toner S. The introduction of a new consultant pharmacist case management service on the care of elderly patients in the intermediate care setting. Int J of Phar Prac, 2014; 22 (Suppl 2): 106-107. Available at: http://onlinelibrary.wiley.com/doi/10.1111/ijpp.12146/pdf

97 McKee H A, Scott M G ,Cuthbertson J and Miller R. Do consultant led pharmacist medication reviews lead to improved prescribing? British Geriatrics Society Autumn Meeting 2014 Page 26 http://www.bgs.org.uk/pdf_cms/admin_archive/2014_autumn_abstracts.pdf

98 Avery et al: A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. Lancet 2012

99 Gallagher et al: STOPP (Screening Tool of Older Person's Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment). Consensus validation. Int J Clin Pharmacol Ther. 2008 Feb; 46(2):72-83

Integrated Medicines Management Service (IMM)

16. One example of best practice is the Integrated Medicines Management Service (IMM) which has strategically re-engineered clinical pharmacy services in HSC Trusts. By targeting the work of pharmacists and pharmacy technicians on admission, during the patient's inpatient journey and at discharge, the service has demonstrated significant improvements in patient care validated by two randomised controlled trials. These included reduced length of stay, lower re-admission rates, reduced medication errors and increased medicines appropriateness and revealed that each £1 invested equated to £5-8 in non cash-releasing efficiencies[100] [101]. It was demonstrated that the IMM programme of care was transferable to routine hospital care in two hospital sites in NI supporting the case for roll out of IMM as routine clinical practice in all NI Trusts by 2008[102]. A more recent study which applied risk predictive algorithms to a sample of patients who received IMM throughout their hospital stay has shown a correlation between the number of ward-based clinical pharmacy services with a reduction in risk-adjusted mortality index (RAMI)[103] [104].

17. Many best practices work synergistically to drive whole system improvements in the use of medicines. For example, innovative methodology for medicines selection has resulted in prescribers within the HSC referring to a Northern Ireland Medicines Formulary. This along with a regional generic prescribing policy has helped support the effective utilisation of medicines resources in line with clinical guidance for the benefit of patients. Prescription data analysis relating to the period April-June 2013 shows a high level of prescribing compliance (83%) in primary care with Northern Ireland Formulary recommendations and a 68% generic dispensing rate. Generic prescribing policies are also in place in secondary care with generic supply from pharmacy, where appropriate.

18. In community pharmacy the MUR Service aims to improve patients' knowledge, adherence and use of medicines and vulnerable or at risk patients are further supported through the Managing Your Medicines service.

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100 Scullin et al. An Innovative approach to integrated medicines management. Journal of evaluation in clinical practice. Vol 13, issue 5. Oct 2007: 781-788.

101 Burnett et al. Effects of an integrated medicines management programme on medication appropriateness in hospitalised patients. American journal of health-system pharmacy. May 1 2009 vol 66, no.9: 854-859

102 Scullin C Hogg A Scott MG et al Integrated Medicines Management-can routine implementation improve quality? Journal of Clinical Evaluation 2012 ;18(4) :807-15

103 Feras et al. Enhanced clinical pharmacy service targeting tools: risk-predictive algorithms. Journal of Evaluation in Clinical Practice. Vol 21, issue 2. April 2015: 187-197

104 RAMI is a predictive tool which was developed to calculate the risk of death during inpatient stay based on a range of variables – age, gender, diagnosis-related group, diagnosis and specific co-morbidities within the population being investigated.

19. These are among the initiatives that helped Northern Ireland to be formally identified as a reference site within the European Innovation Partnership in Active and Healthy Aging (EIP-AHA) in April 2013 and awarded three stars for the level of innovation, scalability and outcomes demonstrated in medicines management[105]. This recognises Northern Ireland as one of the leading regions in Europe in addressing the health and social care needs of the older population through innovation in medicines management.

105 European Innovation Programme- https://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/rs_catalogue.pdf

ANNEX B

Moving to Medicines Optimisation – The Challenges and Need for Change

1. It is clear that a significant amount of work has been undertaken to improve how medicines are managed within the HSC Service. However, Northern Ireland has the fastest growing population in the UK, a rising number of older people with increasing multi-morbidities and a health seeking culture in which people use more medicines with higher associated costs per head per annum than other UK countries. The Regulation and Quality Improvement Authority (RQIA) carried out a Review of Medicines Optimisation in Primary Care in 2015 and concluded that more work needs to be done to achieve optimal medicines optimisation processes, leading to better, measurable outcomes for patients. There are potentially significant challenges ahead which require a renewed focus on using medicines to gain the right outcomes for patients at the right cost for the HSC.

Increasing Need

2. Global innovation in medicines development and improved access to medicines with a good evidence base, for example NICE Guidance[106] have contributed to an increase in life expectancy helping people to stay healthy for longer and many previously debilitating or fatal conditions are now prevented or managed, often on a long term basis, through regular medicines use.

3. Medicines use increases with age and 45% of medicines prescribed in the UK are for older people aged over 65 years and 36% of people aged 75 years and over take four or more prescribed medicines[107].

4. Each year community pharmacies in Northern Ireland dispense in excess of 38 million prescription items, for medicines costing £375m. In addition, some £175m of medicines are dispensed in the hospital setting.

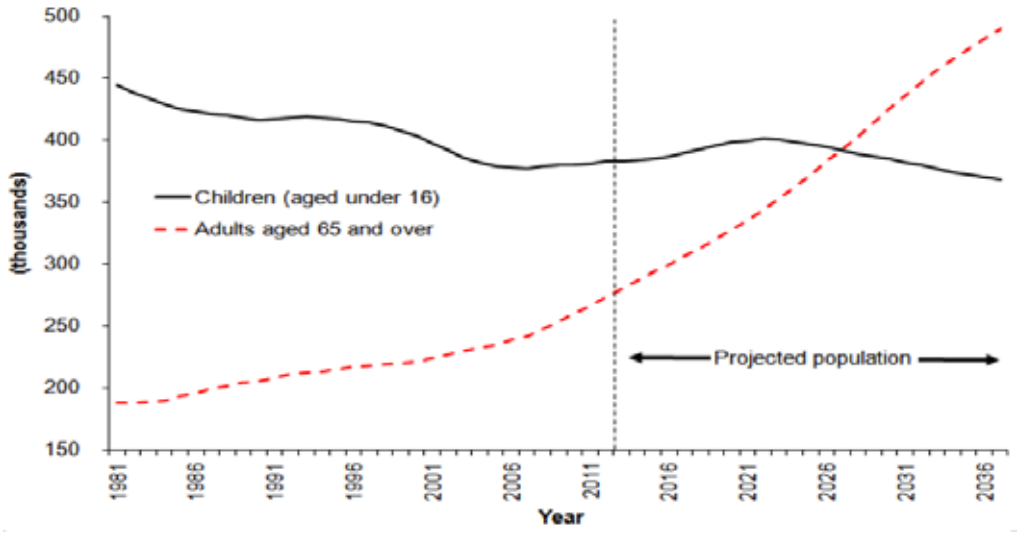
106 https://www.nice.org.uk/guidance

107 Department of Health (2001). Medicines and Older People. Implementing medicines-related aspects of the NSF for Older People. Department of Health. www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4008020

5. Within Northern Ireland the future need for medicines is expected to increase as the population ages and the prevalence of chronic disease increases. Northern Ireland has the fastest growing population in the UK. Currently there are approximately 1.8m people living in Northern Ireland, a figure which is expected to rise to 1.918m by 2022. In 2012, it was estimated that 15% of the population were aged 65 and over. This figure is expected to rise by 26% by 2022 and those aged 85 years and over will increase by 50%[108].

Children aged under 16 and adults aged 65 and over, actual and projected, 1981-2037 (non-zero y-axis)

Figure 5: Source – Northern Ireland Statistics and Research Agency, Statistical Report 2012



6. A report from Public Health Ireland predicts that between 2007 and 2020 the number of adults living with long term health conditions (LTC) in Northern Ireland will rise by 30%[109].

108 Northern Ireland Statistics and Research Agency, Statistical Report 2012 NISRA 2012 Based Population Projections

109 Institute of Public Health in Ireland, 2010 -"Making Chronic Conditions Count"

Table 13: Source – Institute of Public Health - "Making Chronic Conditions Count"

	2007		2015		2020	
	No.	% of population	No.	% of population	No.	% of population
Hypertension	395,529	28.7	448,011	30.3	481,867	31.7
CHD	75,158	5.4	87,848	5.9	97,255	6.4
Stroke	32,941	2.4	38,405	2.6	42,457	2.8
Diabetes (Type 1 & 2)	67,262	5.3	82,970	6.0	94,219	6.6

7. Low health literacy alongside cultural and structural factors have a significant influence on lifestyle decisions. These decisions such as unhealthy diets , smoking and harmful misuse of alcohol also contribute to the overall prevalence of disease in Northern Ireland. Rates of admission to hospital due to alcohol continue to rise year on year and national data indicates that around 70% of weekend emergency department attendances are alcohol-related[110]. From the Northern Ireland health survey 2014/15 - 60% of adults measured were either overweight or obese and 7% of children aged 2-15 years were assessed as being obese. Loss to the local economy as a result of obesity is estimated at £400 m, £100m of these costs being direct healthcare costs[111].

8. As well as the impact on prescribing budgets a rising need for medicines will place increased pressure on primary and secondary care services and community pharmacies. Increased use of medicines by a larger older population will also impact on social care services.

110 http://www.publichealth.hscni.net/sites/default/files/Drug%20and%20Alcohol%20Commissioning%20Framework%20Consultation%20Document.pdf

111 The Cost of Overweight and Obesity on the Island of Ireland – Safefood, November 2011)

Patient Engagement

9. In NI, the involvement of users and carers is a statutory duty for all those employed in statutory HSC organisations[112]. Donaldson highlighted that we are trailing behind with patients and families having a much weaker voice in shaping the delivery and improvement of care than is the case in the best healthcare systems of the world. It is crucial that Personal and Public Involvement (PPI) is supported by all involved in decisions at all levels of care; including at a strategic level and that the values that underpin all PPI work which include dignity and respect, inclusivity, equality and diversity, collaboration and partnership, transparency and openness are promoted. The value and importance of involving individuals in decisions about their care is recognised in the King's Fund paper[113] and in national guidance from NICE [NICE Clinical Guideline 76 which now overlaps with NICE Guideline NG5 Medicines optimisation] although full implementation of its recommendations will require change in existing service models. For example, consultations with patients may need to be longer to provide time to prescribers to listen to any concerns patients may have, provide better information about newly prescribed medicines empowering patients to make informed decisions, anticipated treatment outcomes and to consider patient choice, benefits and acceptability. Furthermore, sufficient time will be needed for regular medication and adherence reviews and patients taking multiple or high risk medicines will require regular scheduled specialist clinical reviews. Patients living with their health condition(s) are often 'experts by experience' and communication with patients about their experience helps inform decisions regarding their medication at review.

Non Adherence

10. The volume and costs of prescribed medicines are increasing but there is evidence that between a half and a third of medicines prescribed for long term conditions are not taken as recommended[114].

11. This is known as non-adherence and can involve people taking either more or less medicines than prescribed or not taking them at all. The factors which contribute to non-adherence fall into two overlapping categories.

    - **Intentional** where the individual decides not to follow the treatment recommendations perhaps because of concerns about the value or effectiveness of medicines, their side-effects, and the inconvenience of taking the drugs at the prescribed times and frequency. Also, patients with a mental health illness for example, schizophrenia, may have altered thinking and beliefs about medicines and their illness which may affect adherence.

112 www.publichealth.hscni.net/sites/default/files/PPI%20Strategy%20-%20March%202012_0.pdf

113 http://www.kingsfund.org.uk/sites/files/kf/Making-shared-decision-making-a-reality-paper-Angela-Coulter-Alf-Collins-July-2011_0.pdf

114 Horne R, Weinman J, Barber N, Elliott R, Morgan M. Concordance, adherence and compliance in medicine-taking. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D. 2005.

- **Unintentional** where the individual wants to follow the treatment recommendations but is prevented from doing so by practical barriers which include cognitive problems, poor organisational skills, polypharmacy and difficulty accessing medicines[115].

12. There are many layers to non-adherence and whatever the cause(s), non-adherence represents a health loss for the individual and an economic loss for society. Consequences include; reduced quality of life; deterioration of health; and unplanned admissions to hospital as people fail to gain the optimal outcomes from their medicines.

Generic Medicines

13. Government policy promotes the use of generic medicines, where appropriate. However, patients concerns regarding inconsistency in the medicines they are supplied with has been highlighted in the Patient Client Council Report 2011[116]. For example, variations in size, colour and shape of their medicines which are made by a range of manufacturers. This is particularly confusing for the elderly who may be on multiple medications leading to an inability to manage their medicines appropriately, risking their independence and impacting on the help they need from carers and families. Lack of support and unexplained changes to how a medication looks can result in patients not taking their medicines. Community pharmacists are well placed to provide advice if the presentation changes but all health and social care professionals and patients should be aware that the presentation of medicines can change and that there is a system to support patients when this occurs.

Medicines Related Harm

14. All medicines are associated with a level of risk and each year millions of people worldwide are hospitalised due to potentially avoidable, medicine-related factors. Medicines used in combination and patients with multiple co-morbidities who are taking multiple medicines are at increased risk. The constant repeating of medicines without regular medication reviews leaves patients susceptible to harm from medicines which they may not need to be taking. Additionally an individual's social circumstances can significantly affect the level of harm related to medicines use. On average, around 3-6% of hospital admissions are due to the adverse effects of medicines[117] [118] [119] and this can increase up to almost 30% in elderly

115 Steinman MA and Hanlon JT. Managing Medications in Clinically Complex Elders "There's Got to Be a Happy Medium". Journal of the American Medical Association. 2010; 304(14):1592-1601. doi: 10.1001/jama.2010.1482

116 http://www.patientclientcouncil.hscni.net/uploads/research/People%E2%80%99s_views_about_prescription_charging_and_products_available_on_prescription_-_June_2011.pdf

117 Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA 1998; 279:1200-5.

118 Pirmohamed et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004;329:15-9

119 Roughead EE. The nature and extent of drug-related hospitalisations in Australia. J Qual Clin Pract 1999;19:19-22

people who are taking more medicines and are more susceptible to their adverse effects[120]. In Northern Ireland, positive steps taken to reduce harm related to medicines include the work of multidisciplinary medicines governance committees in HSC Trusts, the implementation of National Patient Safety Agency (NPSA) alerts and the HSCB/PHA management of serious adverse incidents (SAIs) through the Quality, Safety and Experience (QSE) multidisciplinary group and the Safety, Quality and Alert Team (SQAT). More recently to improve safety, there has been a standardisation of adult medicines kardexes (process for prescribing and recording administration of medicines to patients in hospital).

15. UK evidence shows that one in 15 hospital admissions are medication related, with two-thirds of these being preventable[121]. Evidence also shows that some medicines are associated with a higher risk of harm than others with four groups of drugs accounting for 50% of preventable drug related admissions to hospital[122]. A review carried out of medication incidents reported to the National Reporting and Learning System in England and Wales over a 6 year period showed that the top 5 medicines where the clinical outcome was death or severe harm were opioids, antibiotics, warfarin, low molecular weight heparins and insulin[123]. In Northern Ireland, examples of high risk medicines are available on a poster for GPs and community pharmacies however there is no agreed system for highlighting high risk and specialist medicines on patient records and ECR.

16. Another cause of harm is medication errors which can occur at any stage of the medicines process from prescription, to dispensing to the patient taking the medication. A report for the General Medical Council in 2012 investigating the prevalence of prescribing errors in general practice found that one in 20 prescriptions contained an error with a higher prevalence associated with prescriptions for the elderly and those taking 10 or more medications[124]. Prescribing errors in hospital in-patients are a common occurrence affecting 7% of medication orders, 2% of patient days and 50% of hospital admissions[125]. The NPSA estimated that medication errors in 2007 cost £770m due to the cost of admissions for adverse drug reactions and the cost of harm due to medicines during inpatient stay[126].

120 Chan M, Nicklason F, Vial JH. Adverse drug events as a cause of hospital admission in the elderly.Intern Med J 200; May-Jun;31(4):199-205

121 Garfield S, Barber N, Walley P, Willson A, Eliasson L. Quality of medication use in primary care--mapping the problem, working to a solution: a systematic review of the literature. BMC Medicine 2009; 7:50.

122 Which drugs cause preventable admissions to hospital? A systematic review. www.ncbi.nlm.nih.gov/pubmed/16803468

123 Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years. Br J Clin Pharmacol; 2012 Oct;74(4):597-604

124 http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf

125 Lewis PJ, Dornan T, Taylor D, Tully MP, Wass V, Ashcroft DM. Prevalence, incidence and nature of prescribing errors in hospital inpatients: a systematic review. Drug Saf 2009; 32(5):379-389.

126 NPSA safety in doses:medication safety incidents in the NHS 2007

17. When patients transfer between HSC settings there is a greater risk of medication error and evidence shows that 30% to 70% of patients have an error or unintentional change to their medicines when their care is transferred[127]. In a study carried out in Northern Ireland, it was shown that 33% of patients post discharge had medication related problems[128].

Polypharmacy

18. Polypharmacy, the concurrent use of multiple medications by one individual, is becoming increasingly common. UK data highlight that of those patients with two clinical conditions, 20.8% were receiving four to nine medicines, and 10.1% receiving ten or more medicines; in those patients with six or more co-morbidities, these values were 47.7% and 41.7 %, respectively, and increasing with age[129].

19. The 2013 Kings Fund report on Polypharmacy and Medicines Optimisation[130] proposes that polypharmacy can be classified as appropriate or problematic recognising that it has the potential to be beneficial for some patients, but also harmful if poorly managed. The value of a co-ordinated, multidisciplinary approach to managing polypharmacy has been recognised by other UK countries and the Scottish Government has issued specific guidance on polypharmacy in the elderly.[131]

20. Patients are finding it increasingly difficult to manage the volume of medicines they are prescribed. In particular, older people are most likely to be prescribed multiple medications for multi morbidities (different diseases) and polypharmacy is a growing challenge for individuals, carers and social care workers trying to manage complicated medicines regimens at home. Multi-compartment compliance aids/Monitored dosage systems (MDS) are often used to support patients to manage their medicines and are currently perceived as the only solution for the elderly and those with dementia in particular. However, there are many other ways in which patients can be helped to take their medicines safely, or carers supported to administer medicines correctly, and alternative interventions should be considered as outlined in the Royal Pharmaceutical Society guidance, The Better Use of Multi-compartment Compliance Aids[132].

21. Polypharmacy is also a challenge for prescribers. Prescribing is largely based on single disease evidence-based guidance which does not generally take account of multi-morbidity, now the

127 Campbell et al. A systematic review of the effectiveness and cost-effectiveness of interventions aimed at preventing medication error (medicines reconciliation) at hospital admission. The University of Sheffield, School of Health and Related Research (ScHARR), Sep 2007

128 Brookes K Scott MG McConnell JB The benefits of a hospital based community liaison pharmacist. Pharmacy World and Science 2000; 22(2): 33-8

129 Payne RA, et al. Prevalence of polypharmacy in a Scottish primary care population. Eur J Clin Pharm 2014; in press.

130 The Kings Fund 2013 Polypharmacy and Medicines Optimisation - Making it Safe and Sound

131 Scottish Government 'Polypharmacy Guidance' October 2012

132 http://www.rpharms.com/support-pdfs/rps-mca-july-2013.pdf

norm in those over 65 years[133]. Also, prescribing decisions may be made by different medical and non-medical prescribers involved in the individual's care resulting in combinations of medicines which may not work effectively together and increase the risks of medicines related harm. Deprescribing i.e. the process of tapering, reducing or stopping medication which may be causing harm, may no longer be providing benefit or may be considered inappropriate should be a planned process for patients on multiple medications. There are barriers to deprescribing so guidance and the use of tools such as STOPP/START could help facilitate the process.

Specific Patient Groups

22. Difficulties arise across interfaces when specific patients for example mental health patients who live in the community require secondary care services. The primary/secondary care interface and responsibilities of the various professionals can make it difficult for patients to receive the medication they require. For patients with Parkinson's disease where it is crucial that they get the right medication at the right time, there is a clear need for a consistent service when they move across interfaces and between different healthcare professionals. Those with life-long conditions for example Inflammatory Bowel Disease which most commonly presents in patient's teenage years/early twenties need access to multidisciplinary teams working collaboratively with them and each other and is key to ensuring optimisation of their medicines.

23. Better knowledge and understanding of rare diseases among healthcare professionals is essential to ensure that patients receive a timely and accurate diagnosis. Delays in diagnosis of rare diseases can lead to patients not receiving timely and appropriate medication for their condition. Additionally, misdiagnoses can mean that patients may receive inappropriate treatment and lack of support. A multidisciplinary approach to accurate and safe care plans and shared decision making regarding treatment choices is necessary to delivering effective care to these patients.

133 Barnett K, Mercer SW, Norbury M et al. Epidemiology of multimorbidity and implications for healthcare, research, and medical education: a cross sectional study. The Lancet 2012:380:37-43

Access to Information

24. Access to good quality information about medicines is essential to enable optimal management of clinical conditions. However, there is a vast amount of information on the internet regarding medicines, some of which is reliable and relevant in the UK and some is not. There are some credible websites and proposed plans for the development of a patient portal on the NIDirect website to help direct patients to appropriate information about medicines and how to use this information are welcomed.

Over Use and Misuse of Medicines

25. Increased access to medicines via prescription, internet and over the counter sale introduces new risks. The New Strategic Direction for Alcohol and Drugs Phase 2 highlighted the emerging issue of the misuse of prescription drugs and over-the-counter drugs with benzodiazepines reported as one of the main drugs of misuse[134] in Northern Ireland. Although there has been some success in tackling benzodiazepine use, other challenges with regards to potential for abuse remain with commonly prescribed medicines including opiate painkillers and pregabalin.

26. A Scottish literature review explored the links between poverty, social exclusion and problematic drug use. It supported the view that the extent of drug problems is strongly associated with a range of social and economic inequalities and is complex[135]. A study which looked at the influence of socioeconomic deprivation on multimorbidity at different ages found that higher rates of drug misuse correlated with deprivation across all age groups, but particularly in those under 45 years of age[136].

27. Inappropriate and overuse of antimicrobial medicines is a particular concern and the consequences are that common infections will be harder to treat as the incidence of antimicrobial resistance and healthcare acquired infections increases presenting a major public health challenge[137]. Increasing healthcare professional, patient and public awareness and changing behaviour by applying behavioural science may help address this issue. A recent literature review and behavioural analysis carried out by the Department of Health and Public Health England proposes a range of behavioural science interventions that could be tested in practice[138].

134 DHSSPS (2011) New Strategic Direction for Alcohol and Drugs, Phase 2 2011-2016

135 Drugs and poverty:A literature review. Scottish drugs forum report, March 2007

136 McLean G et al. The influence of socioeconomic deprivation on multimorbidity at different ages: a cross-sectional study. Br J Gen Pract. Jul 2014; 64(624): e440-e447

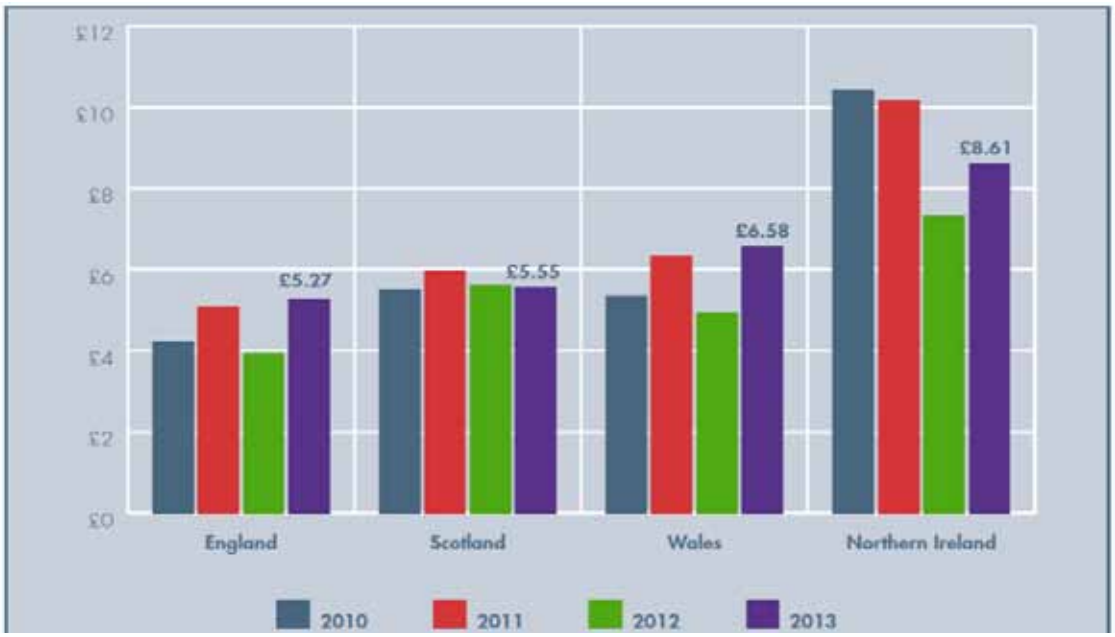
137 DHSSPS Strategy for tackling antimicrobial resistance (STAR) 2012-2017

138 Behaviour change and antibiotic prescribing in healthcare settings, literature review and behavioural analysis. February 2015 https://www.gov.uk/government/publications/antibiotic-prescribing-and-behaviour-change-in-healthcare-settings

28. Antidepressant use in Northern Ireland is high compared to other countries in Western Europe. In comparison to other countries in the UK, Northern Ireland had higher antidepressant costs per head of population from 2010 to 2013.

The cost of anti-depressant prescribing per head of population in the UK over the 4 year period to 2013

Figure 6: NI Audit Office Primary Care Prescribing Report 2014



29. Better access to services, for example counselling, stress and anxiety management is crucial if we are to see a reduction in the use of medicines to manage some mental health conditions. Choice and Medication[139] is a good example of where people can access information regarding alternatives to medicines and when necessary and appropriate, information regarding their medicines to manage their condition.

Waste

30. Wasted medicines are a significant problem in Northern Ireland with large quantities of unused medicines regularly returned to community pharmacies for safe disposal. These medicines are either ordered but no longer required or no longer prescribed for a particular condition. Returned medicines to community pharmacies cannot be re-used and are destroyed because their safety and effectiveness cannot be guaranteed. Not all unused medicines are returned

139 www.choiceandmedication.org/hscni/

to pharmacies and many are kept in patients' homes, sometimes well past their expiry date, or are incorrectly added to household waste. In hospital, medicines that are no longer required are returned to the hospital pharmacy for safe disposal or, where appropriate, recycled and reused to minimise waste. It is difficult to measure the exact value of medicines wasted. Based on research findings elsewhere in the UK the value of medicines wasted in Northern Ireland is estimated to be around £18m per annum[140] although as yet there is no way of accurately validating this figure.

Reform of Health and Social Care Services

31. Ongoing HSC reform supporting care closer to home will mean that in future more people will receive care at home rather than in residential care or hospital. For many people care at home will require support with managing and taking multiple medicines. This will require changing roles for social care workers and an increasing demand for pharmaceutical care in the community and primary care to support safe and effective medicines use[141].

32. As new services develop creating new interfaces for example acute care at home and rapid response respiratory services, issues of prescribing and supply need to be addressed. Drug specific shared care agreements are available already for specialist medicines through the 'Interface Pharmacist Network Specialist Medicines' but are not yet available for non specific prescribing and supply in such new settings.

33. Another issue is the increasing use of third party homecare services. A homecare service in this context is defined as the delivery of medicines and where necessary, associated care, which is initiated by the hospital prescriber, direct to the patient's home with their consent. This is a growing market and the volume and costs of medicines supplied through homecare services in Northern Ireland has increased from £6m in 2008 to almost £22m in 2014. Homecare services bring both benefits and risks for patients and new challenges for the provision of pharmaceutical care by HSC Trusts. A review of homecare medicines supply in England in 2011[142] included having stable contractual arrangements which would enable Trusts to adapt easily and safely to changes in homecare providers and through a quality framework have clear lines of responsibility for dispensing, delivery to patients and nursing care provision when required. Better use of technology could track expenditure and interface with electronic care

140 Evaluation of the Scale, Causes and Costs of Waste Medicines, University of London and York 2010

141 Pharmaceutical Care is defined as "A patient-centred practice in which the practitioner assumes responsibility for a patient's medicines-related needs and is held accountable for this commitment". Cipolle RJ, Strand LM, Morley PC. Pharmaceutical care practice: the clinicians guide. 2nd ed. New York:McGraw-Hill; 2004.

142 Homecare medicines – towards a vision for the future, DH 2011

records would allow information to be available in real time. Communication of the service to all healthcare professionals involved in a patient's care is essential. A regional assessment of the optimal approach to homecare medicines is needed to ensure quality, good governance, accountability and effective use of resources.

34. HSC reform will also support new integrated models of care as exemplified by Integrated Care Partnerships (ICPs). ICPs are collaborative networks of care providers, bringing together doctors, nurses, pharmacists, social workers, hospital specialists, other healthcare professionals and the voluntary and community sectors, as well as service users and carers to design and coordinate local HSC services. These collaborative networks present new opportunities for the integration and co-ordination of care for frail older people and those with long term conditions. ICPs are tasked with focussing on four key aspects for delivery of integrated care; Risk Stratification, Information Sharing, Care Planning and Evaluation (RICE). All 17 ICPs in Northern Ireland are currently delivering person centred proactive care management for a risk stratified cohort of patients through collaborative multidisciplinary working. A more co-ordinated and person centred approach to medicines management has been an important aspect of this work. There are also a number of local ICP service improvements which involve improved integration of community pharmacy services as part of the care pathway. The structure of ICPs which has community pharmacists embedded at a local level to promote the development of collaborative relationships is an effective platform for the delivery of improved medicines management and associated patient outcomes.

35. More recently the Northern Ireland General Practice Committee (NIGPC) has developed a network of GP Federations with the vision of supporting primary care and working at the scale needed to realise the ambitions of Transforming Your Care.

36. In future, patients are likely to have a number of health and social care professionals involved in their overall care at the same time. This will include an increasing number of non-medical prescribers (DHSSPS non-medical prescribing) using existing skills and knowledge to ensure better patient access to advice about medicines, assessment of their condition and help patients receive appropriate medication without delay alongside helping reduce demand on GPs and medical staff in hospitals.

37. The Donaldson Report, Transforming Your Care, Living with Long Term Conditions Framework[143] and the RQIA Review of Medicines Optimisation in Primary Care all recognise the increased role that pharmacists (in particular community pharmacists) have to play in raising a patient's quality of care and improving their health outcomes. The Community Pharmacy Future Project[144] shows that patients derive considerable benefits in terms of health outcomes and quality of life when they receive additional support and advice from community pharmacists alongside the supply of their normal medication. The profession could be further utilised in this setting by using their clinical skills, working in partnership with patients and other health and social care professionals to contribute significantly to medicines optimisation.

38. A recent Royal Pharmaceutical Society (RPS) and Royal College of General Practitioners (RCGP)[145] Joint Statement supports the inclusion of practice based pharmacists within primary care teams to improve patient care. They state that there is considerable evidence to support the benefit of this role and the RPS and RCGP will work together to promote the uptake of practice based pharmacists.

39. As new models of care develop it will be necessary to establish a clear understanding of roles and responsibilities for medicines optimisation for health and social care professionals within the patient's care. This will require clarification of existing roles and the development of new roles within integrated secondary care, general practice and community pharmacy linking to social care supporting safe, appropriate and effective medicines use throughout the patient journey. This is a patient centred model in which multidisciplinary professionals will work collaboratively and share information to meet the needs of patients.

Variance

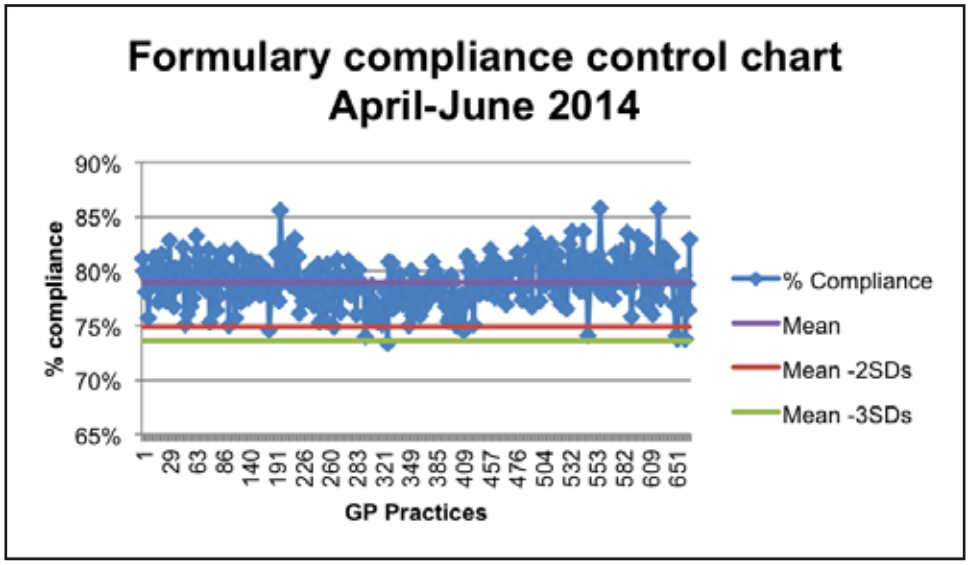
40. There is variation in how medicines are used and managed across the HSC. For example there are differences in; the uptake of NICE approved medicines and implementation of NICE guidance; delivery of the IMM Service and service provision across seven day working within HSC Trusts. The introduction of the Northern Ireland Formulary is supporting a reduction in variance in prescribing in general practice as demonstrated in Figure 7.

143 https://www.dhsspsni.gov.uk/publications/living-long-term-conditions-policy-framework

144 http://www.communitypharmacyfuture.org.uk/pages/sitesearch.cfm

145 http://www.rpharms.com/promoting-pharmacy-pdfs/rcgp-joint-statement-for-pharmacists-in-gp-surgeries-version-2.pdf

Figure 7: % compliance with the Northern Ireland Formulary, quarter 2, 2014



41. A King's Fund report in 2011 concluded that there are wide variations in the quality of care in general practice stating that the delivery of high-quality care requires effective team working for which the skill-mix needs to evolve, so that the GP should no longer be expected to operate as the sole reactive care giver, but should be empowered to take on a more expert advisory role, working closely with other professionals[146].

42. There is a growing awareness of the risks of variance in the quality of service delivery within the health service as exemplified by the Francis Report 2013 which emphasised the need to put patients first at all times and that they must be protected from avoidable harm and the Berwick Report 2013 which recommends 4 guiding principles for improving patient safety including:

- place the quality and safety of patient care above all other aims for the NHS;
- engage, empower and hear patients and carers throughout the entire system and at all times;
- foster wholeheartedly the growth and development of all staff, especially with regard to their ability and opportunity to improve the processes within which they work; and
- insist upon, and model in your own work, thorough and unequivocal transparency, in the service of accountability, trust, and the growth of knowledge.

146 Improving the quality of care in general practice. Report of an independent inquiry commissioned by the King's Fund, 2011. http://www.kingsfund.org.uk/publications/improving-quality-care-general-practice

43. Whilst it is important that variance in practice is reduced where appropriate across the HSC advances in personalised or precision medicines will introduce an approach which is used for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. As we move towards an era of personalised or precision medicine it is clear that more choice and variability will be required to select the most appropriate medicine for a specific patient.

Evidence Based Decision Making

44. Evidence-based medicine (EBM) is the cornerstone of modern medical practice. Defined as the conscientious, explicit, and judicious use of current best evidence, in combination with the physician's clinical expertise and the preferences of the patient in making decisions about the care of individual patients[147], EBM relates to all aspects of medical practice including the prescribing of medicines.

45. With over 13,000 medicines with Marketing Authorisations in the UK[148], prescribers need to be able to keep up to date with the evidence base in order to select the most appropriate, safe, clinically effective and cost effective medicines for their patients.

46. Scientific advances in drug development mean that the clinical use of medicines is becoming more complex and increasing sophistication inevitably leads to higher costs both for the medications themselves and for the clinical management process (e.g. increased monitoring).

47. Not only does this pose challenges in terms of resource implications but it requires increasing diligence as to the appropriateness of the introduction of new medicines. In Northern Ireland, systems exist through NICE (DHSSPS NICE guidance)[149] and the Scottish Medicines Consortium to adjudicate the utility of new medications allied to their provision within the NHS through managed entry arrangements (HSC Board Managed Entry).

48. There is already clear evidence of where the pressures are, for example in the areas of cancer, biologics and mental health and these will continue to be significantly resource intense areas. Similarly, the growth in long term preventative medicine e.g. use of statins and an escalating trend in treatments for lifestyle related disease such as anti-obesity medicines has major cost implications for the pharmacy elements of the health and care system.

147 Dawes M, Summerskill W, Glasziou P, et al. Second International Conference of Evidence-Based Health Care Teachers and Developers. Sicily statement on evidence-based practice. BMC Med Educ. 2005;5(1):1.

148 This figure includes different strengths of the same medicine and generics. Source – Medicines and Healthcare Products Regulatory Agency

149 https://www.dhsspsni.gov.uk/articles/nice-clinical-guidelines

49. In addition, the evidence base for medicines management practices will continue to expand in the coming years. For example, the NICE Guideline NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes was published in March 2015 and other NICE clinical guidelines and quality standards are under development relating to medicines optimisation, domiciliary care, managing medicines in care homes, older people with long term conditions and multi-morbidities.

50. These guidelines and standards are useful and will inform best practice in Northern Ireland but their timely implementation and consistent incorporation into existing services and roles will have to be monitored and managed.

Improvements in Communication, Technology, Data Management

51. The ECR and ongoing ICT development programme will facilitate better sharing of information between healthcare professionals and enable advances such as electronic prescribing. There needs to be 'one source of truth' regarding documentation of patient's medications which can be accessed by the patient and shared by all healthcare professionals. Patients' views need to be taken into consideration when decisions are being made regarding the level of clinical data being shared. The growing use of health analytics (which analyses large, complex data sets with sophisticated software) will help clinicians and managers to utilise various information sources to identify and target interactions of patients with the highest risk. This will further necessitate role clarification among health and social care professionals and standardised approaches to medicines management.

52. However, tracking activities in secondary care requires improvements in informatics and data management systems to provide the level of whole system monitoring of medicines use and service delivery needed to support improved quality and governance across the HSC and allow comparison with other UK countries.

53. Further advances in technology, robotics and tele-health will enable the automation of routine processes and self-monitoring by patients and allow health and social care professionals more time to focus on clinical care and optimising health outcomes. To maximise the benefit of these advances for patient outcomes their integration into patient care plans needs to be planned and managed.

Prevention and Alternatives to Medicines

54. This Framework deliberately focuses on improving the use of medicines. However, it is recognised that over time the aim of health policy is to reduce the population's need for medicines. Current Government strategies like Making Life Better[150] and Making it Better through Pharmacy in the Community[151] support this, encouraging people to be more aware of healthier lifestyle choices and supporting prevention through initiatives to help address the underlying causes of disease. In modern healthcare there is a heavy reliance on medicines and the system needs to change to adopt a more holistic approach where medicines are not seen as the only solution available. This issue is highlighted in the Patient and Client Council's Pain Report[152].

Summary

55. In summary, the future will bring new challenges as the number of older people rises, demand for medicines grows, advances in medicine, therapeutics and technology accelerate and the evidence base for decision making expands.

56. In this era of economic, demographic and technological challenge, optimal use of medicines will help secure better quality, patient outcomes and value from medicines.

150 Making Life Better 2013-2023 https://www.dhsspsni.gov.uk/articles/making-life-better-strategic-framework-public-health

151 Making it Better through Pharmacy in the Community 2015-2019 https://www.dhsspsni.gov.uk/publications/making-it-better-through-pharmacy-community

152 http://www.patientclientcouncil.hscni.net/uploads/research/Pain_Report_-_Final_HARDCOPY_VERSION.pdf

MEDICINES MANAGEMENT STANDARD (SAFE AND SECURE HANDLING OF MEDICINES)

Standard

The organisation handles medicines safely and securely, in accordance with legislative requirements and best practice.

Overview

The Audit Commission (2001) defined medicines management as encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care. Medicines governance more specifically focuses upon the safety and risk management issues concerned with medicines and importantly, systems risks that can lead to error and resultant adverse incidents.

This standard, while addressing many of the components identified above is not designed to cover the more specific clinical aspects of medicines management, although there are evidently intrinsic linkages. This is not to minimise the importance of the clinical and cost effective use of medicines and organisations are expected to work to these goals in the provision of optimal patient care.

The safe and secure handling of medicines in both the hospital and primary care settings requires appropriate policies, procedures and quality assurance systems to be in place. It covers processes throughout the organisation, not just in pharmacy.

This standard outlines legislative and best practice relating to the safe handling of medicines, including controlled drugs. The main legislation addressed within this standard includes:

- The Medicines Act 1968, as amended, which regulates the manufacture, distribution, import, export, sale and supply of medicinal products
- The Misuse of Drugs Act 1971, which controls the availability of drugs liable for misuse
- The Misuse of Drugs (Northern Ireland) Regulations 2002, which enables specified health care professionals to possess, supply, prescribe and/or administer controlled drugs in the sphere of their practice.
- The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted).
- Health Act 2006

Guidance

Each HPSS body (Board, Trust, Agency as it relates to them) needs to ensure the safe and secure handling and storage of medicines. This will require a review of the different locations in which medicines are stored, dispensed and transported and consideration of the various staff groups responsible for these functions.

Within the HPSS body, attention should focus on a review of the risks and control systems covering: procurement, ordering, delivery, storage, distribution, prescribing, dispensing, issue, supply, administration and disposal within and between the various locations (community hospitals, staff working in the community, in GP practices etc). Any such review should also consider continuing professional development as related to pharmacy and medicines management, along with other associated human resource issues (such as COSHH training, skill mix, training in the management of controlled drugs, handling and disposal of drugs in the community, adverse event reporting etc). The HPSS body also needs to ensure that the organisation has effective systems in place for the reporting of adverse events involving medicinal products and can demonstrate a pro-active approach to investigating any incidents locally (as well as responding to DHSSPS or MHRA alerts).

In addition to reviewing its own internal systems in relation to medicines management, the HPSS body should also request evidence from organisations with which the HPSS body holds service level agreements etc. as to the effectiveness of their risk management concerning the handling and storage of medicines (e.g. Ambulance Trusts, Medical Physics Agency, Out-Of-Hours Service Providers) since risks need to be considered across organisational boundaries.

If an organisation undertakes a robust risk assessment against this standard and deems a particular criterion to be non-applicable, it is essential that the rationale for any such decision is documented and evidence is available to support this assessment.

It is also important to consider the linkages between this and other standards (e.g. risk management, governance, purchasing and supply, medical equipment and devices), which seek to ensure that there are controls in place to minimise all risks across the organisation.

Controlled Drugs

The Health Act 2006 introduced three provisions in relation to the Fourth report of the Shipman Inquiry namely,

- the appointment of an Accountable Officer by Designated Bodies with the duties of the Accountable Officer encompassing the development and monitoring of systems to ensure the safe and effective use and

management of controlled within the organisation subject to their oversight.

- a duty to collaborate and share intelligence on controlled drugs by Responsible Bodies. The Duty of Collaboration will place a legal duty on Responsible Bodies to share (within certain constraints) information and intelligence regarding the use of controlled drugs in the health and social care sector.
- A power of entry and inspection for certain Authorised Persons.

The Health Act provides enabling powers for Northern Ireland to take forward it's own subordinate legislation in order to introduce suitable arrangements for the management of controlled drugs. This subordinate legislation is being drafted and there will be guidance and training to support those involved in taking forward these provisions.

Assessment Guidance

HPSS organisations vary significantly in size and in the nature of the services they deliver. It follows that not all controls assurance standards will apply to each organisation. This is implicit in the current Departmental guidance, eg. *The Reference Table on Applicability and Expected Levels of Compliance* which should be referred to before commencing the self-assessment exercise.

Even where a standard is generally applicable to the work of an organisation it is quite possible that not all of the criteria will be materially applicable. Before self-assessing against a standard, therefore, an organisation should consider the relevance of each criterion to its own business and conduct its assessment accordingly. Thus, where a criterion is clearly relevant to an organisation, the score should be based on the **totality of the action taken to address the requirement**. Where there is little or no relevance, the criterion should be considered "not applicable" and ignored for scoring purposes as explained in the guidance on *Reporting Compliance* issued by the Department.

This approach will ensure that the assessment has no unfairly detrimental effect on the organisation's overall score but reflects a proper evaluation of the key areas of risks identified and the actual levels of controls put in place to manage those risks.

Likewise, the *Examples of Verification* set out in the standard are just that – examples, for guidance only. Once again, it is the nature of each organisation's business that determines the type of evidence needed to prove that appropriate controls are in place. In effect, this may mean that only some of the examples listed are relevant to a particular HPSS organisation or, indeed, that there are other more relevant examples which can be adduced as evidence of compliance. It is also the case that some evidence can be deployed to demonstrate compliance with more than one criterion or standard.

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INDEX OF MEDICINES MANAGEMENT

Criterion 1 (*Accountability*)

Board level responsibility for the safe and secure handling of medicines is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board.

Criterion 2 - 12 (*Processes*)

Suitable controls are in place, which ensure that the principles and the guidelines set out in ‘Use and Control of Medicines’ are met.

Medicines are procured, stored and handled in an efficient safe and secure manner.

The organisation conforms to the HPSS Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2008 (as amended)

Unlicensed aseptic dispensing in hospital pharmacies complies with Circular HSSE (OCE) 1/97, and licensable activities are covered by a manufacturing "specials" licence.

Prescription, supply and administration conform to the requirements of relevant legislation. Prescription, supply and administration of medicines is undertaken only by appropriately qualified, competent staff.

The prescribing, supply, administration, safe custody and destruction of controlled drugs complies with the appropriate legislation.

All medicines no longer required are destroyed or otherwise disposed of in accordance with safety, legal and environmental requirements.

The supply of medicines for clinical trials is undertaken in accordance with relevant legislation and best practice guidelines

The organisation reports adverse incidents involving medicinal products and devices to the relevant agency, and appropriately manages any subsequent required action.

Supervision of pharmaceutical dispensing processes is undertaken in accordance with relevant legislation and current professional standards.

The risk management process contained within the risk management standard is applied to the safe and secure handling of medicines.

Criterion 13-15 (*Capability*)

All healthcare staff involved with medicines undertake continuing professional development to ensure that there are safe and secure handling processes in place.

The organisation, through the Chief Pharmacist, has access to up-to-date legislation and guidance relating to the safe and secure handling of medicines.

Adequate resources support the safe, secure and appropriate use of medicines.

Criterion 16 & 17 (*Monitor, review, learn, improve*)

Key indicators capable of showing improvements in the safe and secure handling of medicines and the management of associated risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

The system in place for the safe and secure handling of medicines, including risk management arrangements, is monitored and reviewed by management and the board in order to make improvements to the system.

Criterion 18 (*Independent assurance & Outcomes*)

The board seeks independent assurance that an appropriate and effective system for the safe and secure handling of medicines is in place and that the necessary level of controls and monitoring are being implemented.

CRITERION 1

Board level responsibility for the safe and secure handling of medicines is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board.

Source

- Standards Australia Risk Management AS/NZS 4360:2004
- Best Practice Best Care (2001) - A framework for setting standards, delivering services and improving monitoring and regulation in the HPSS.
- Audit Commission (2001) A Spoonful of Sugar. Medicines management in NHS hospitals. Audit Commission, London.
- Audit Commission (2002) Procurement and Supply. Review of National Findings, Acute Hospital Portfolio, No.5, p.20.
- The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

Guidance

The Chief Executive of the organisation has the overall statutory responsibility for the safe and secure handling of medicines. The Chief Pharmacist has responsibility for ensuring that systems are in place to appropriately address all aspects of the safe and secure handling of medicines and reports directly to the Chief Executive for this purpose across the whole of the organisation. The organisation's commitment to the safe and secure handling of medicines should be clearly signalled.

Clear lines of accountability for the Safe and Secure Handling of Medicines throughout the organisation should be established; these should define the relationships between the Board, board sub-committee(s) responsible for overseeing all aspects of risk management and governance Pharmacy Services and other relevant groups. There must be a Medicines Management Committee to review, analyse and monitor medicines use processes.

Examples of Verification

- Accountability arrangements chart
- Minutes of the board sub-committee(s) responsible for overseeing risk management
- Board minutes
- A strategy for medicines use, within the organisation, has been approved by the board, reviewed and reported annually
- Terms of reference for any medicines management committee required.
- Job description of Chief Pharmacist.

Links with other Standards

MAHI - STM - 097 - 9608

All standards (generic criterion)

CRITERION 2

Suitable controls are in place, which ensure that the principles and the guidelines set out in 'Use and Control of Medicines' are met.

Source

Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS.

Other Reading

- Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005 www.rpsgb.org.uk
- Nursing and Midwifery Council. Standards of proficiency for nurse and midwife prescribers. 2006. (www.nmc-uk.org)
- Nursing and Midwifery Council. Standards for Medicines Management. 2008. (www.nmc-uk.org)
- Royal Pharmaceutical Society of Great Britain. Professional Standards and Guidance for Pharmacist Prescribers. Medicines Ethics and Practice 32:2008. (www.rpsgb.org)
- Department of Health, Social Services and Public Safety. Improving patients' access to medicines: A guide to implementing nurse and pharmacist prescribing in Northern Ireland. (www.dhsspsni.gov.uk)
- Medicines and Healthcare Products Regulatory Agency. MHRA guidelines on the Yellow Card Scheme. (www.mhra.gov.uk)

Guidance

The new guidance on the Use and Control of Medicines Guidelines (2004) takes account of important legislative changes and developments in professional practice and accountability as well as integrating and giving consistency to associated guidelines emanating from professional bodies, agencies and reviews. It addresses a wide range of issues but principally:

- Prescribing
- Administration
- Record keeping
- Storage and security
- Supply, delivery and transfer
- Labelling
- Waste
- Practice environments
- Specific practitioners

The revised Duthie report sets out standards for the handling, administration, storage and custody of medicinal products, in hospitals, community clinics,

residential and nursing homes, community nursing or midwife units and the ambulance service. At each step where a medicine changes hands there should be clear procedures which document:

- Where responsibility lies, whether it may be delegated and how far it extends
- What should be recorded where, by whom and how long records should be kept
- How often stock reconciliation should take place and who should undertake the task

Examples of Verification

- A control system is in place, which meets the principles of the 'Use and Control of Medicines' guidelines
- The organisation audits itself against the principles, and can demonstrate, if necessary, that mechanisms have been put in place to change practice.

Links with other Standards

Health and Safety
Management of Purchasing and Supply
Medical Devices
Records Management
Waste Management

CRITERION 3

Medicines are procured, stored and handled in an efficient, safe and secure manner.

Source

- The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2000. SR No 120
- Medicines Act 1968 (as amended) The Stationery Office, London
- The Misuse of Drugs Regulations (Northern Ireland) 2002 SR No 1 The Stationery Office, London
- The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 The Stationery Office, London
- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (Feb 2008 - 4th reprint), DHSSPS.
- Circular HSS (PPM) 8/2003. Revised Public Procurement Policy for the Public Sector. DHSSPS.
- Circular HSS (PPM) 7/2004. Procurement strategy for Health, Social Services and Public Safety. DHSSPS.
- Pressure Systems Safety Regulations 2000 SI No 128 The Stationery Office, London
- NHS Estates (1994) HTM 2022 Medical gas pipeline system. The Stationery Office, London
- Ethics and Practice. A Guide for Pharmacists in Northern Ireland 2004 Edition Pharmaceutical Society of Northern Ireland.
- The Medicines (Administration of Radioactive Substances) Regulations 1978 SI No 1006 The Stationery Office, London
- The Ionising Radiation (Medical Exposure) Regulations 2000 SI No 1059. The Stationery Office, London
- The Public Contracts Regulations 2006

Other Reading

- Self Administration of medicines by hospital inpatients – Audit Commission
- Hospital Pharmacist (2002) One-stop dispensing, use of patients own drugs and self-administration schemes (article March 2002 vol 9)
- The Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005
- The Shipman Inquiry (2004) Fourth Report. The Regulation of Controlled Drugs in the Community (Cm 6249).The Stationery Office, Norwich
- Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft)
- Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)

Guidance

The Medicines Act 1968 applies to all substances, which are used as medicinal products, or as ingredients in medicinal products.

The act divides medicines into three categories:

- Prescription Only Medicine (POM)
- Pharmacy Medicine (P), which is supplied by a pharmacist, but can be dispensed without a prescription
- General Sale List (GSL), which need not be obtained through a pharmacist

Pharmacy staff should be involved in replenishing, monitoring, and adjusting medicines stock control.

Appropriate procedures must be in place for the ordering, stock control, storage, movement and safe handling of medical gases.

Under the management of Chief Pharmacists, wherever possible, corporate action should be taken to ensure the efficient and effective procurement of all medicines, particularly in the context of the Pharmaceutical Contracting Executive Group, established by Trust Chief Executives and aligned to public procurement policy and strategy.

Particular attention should be paid to all medicine security issues including:

- Storage of medicines, whether in bulk in the pharmacy or in smaller quantities elsewhere
- Methods of ordering medicines
- Means of delivery
- Receipts procedures, including full records
- Methods of distribution both within and between hospitals
- Dispensing of medicines including patients own medicines, dispensing for discharge and self administration
- Administration of medicines
- Disposal of medicines
- Where self-administration schemes are in operation

Physical security measures include:

- Lockable cupboards, freezers and fridges for the storage of medicines, with temperature monitoring as appropriate
- Cabinets which meet the requirements as set out in the revised Duthie report for all medicines
- Lockable medicine trolleys which are immobilised when not in use
- Lockable, bedside medicine storage cupboards, which are not easily portable (where appropriate)
- Lockable, security sealed containers for transporting / moving medicines

- Entrances to pharmacies and other controlled areas should have solid doors, fitted with security locks and intruder alarms
- Stationery including requisition books, order books and blank prescription forms should be kept in a locked cupboard.

COSHH regulations require organisations to ensure that precautions are taken by staff handling medicinal products, which are hazardous to health by any route (inhalation, ingestion, and absorption through the skin or contact with the skin). Contact should either be prevented or, where this is not reasonably practicable, adequately controlled.

Examples of Verification

- There is a local policy in place, which complies with relevant aspects of legislation
- Staff are aware of, and have access to the organisation's policy
- Local procedures comply with the HPSS security manual and the principles of the revised Duthie report
- Pharmacy technician/assistant "top-up" service
- There is a policy in place, which staff are aware of, which states the required action to be taken when there is a breach of security
- COSHH assessments
- Procedures for ordering, stock control, storage, movement and safe handling of medical gases are in place and approved by the quality controller (medical gases)
- There is a policy in place that includes an assessment checklist to support re-use of patient's own drugs (POD's) if applicable
- There is an agreed protocol to assess patients' suitability for self-administration of medicines, which documents informed consent to participate if applicable.
- Compliance with Good Procurement Practice as defined by the Audit Commission (2002)

Links with other Standards

Health and Safety
Management of Purchasing and Supply

CRITERION 4

The organisation conforms to the HPSS Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2008

Source

- HPSS Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) (as amended) 2008 SR No 488 The Stationary Office, London
- HPSS Management Executive (OP1) 2/92 Supply of Medicines and Other Pharmaceutical Products – Responsibility for Prescribing Between Hospitals and Family Practitioner Services
- 28 Day Dispensing on Discharge from Hospital. Letter Circular HSS SC (804) BP411/01

Guidance

Arrangements should be in place for the collection of prescription charges as specified in the source guidance taking into account permitted exemption and remission from charges.

No charge should be made for medication administered or supplied within hospital premises to HPSS patients. There is also no charge liability for discharge medication.

Medication for the treatment of venereal disease (STDs) is dispensed free of charge.

Examples of Verification

- Policy and procedure

Links with other Standards

Financial Management

CRITERION 5

Unlicensed aseptic dispensing in hospital pharmacies complies with HSSE(OCE)1/97, and licensable activities are covered by a manufacturing "specials" licence.

Source

- Ionising Radiations Regulations 1999. Approved Code of Practice and Guidance. The Stationery Office, London. ISBN 071761-7467 HSE Books
- Medicines Act 1968 (as amended) The Stationery Office, London
- The Medicines (Administration of Radioactive Substances) Regulations 1978 SI No 1006 The Stationery Office, London, and relevant amendments
- The Ionising Radiation (Medical Exposure) Regulations 2000 SI No 1059. The Stationery Office, London and relevant amendments
- The Radioactive Substances Act 1993 (c. 12) The Stationery Office, London
- MHRA Guidance Note 14 – The supply of Unlicensed Relevant Medicinal Products for Individual Patients Revised January 2008
- MHRA Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007 – Pharmaceutical Press
- Circular HSSE (OCE) 1/97 Aseptic Dispensing in HPSS Hospitals
- Pharmaceutical Isolators: A guide to their application, design and control. Pharmaceutical Press, 2004 ISBN 0 85369 5733
- Quality Assurance of Aseptic Preparation Services (4th Edition) Pharmaceutical Press, October 2005 ISBN 0 85369 6152
- HC (76) 9 Report of the working party on the additions of drugs to intravenous fluids.
- Chief Pharmaceutical Officer Letter (CPh3/03) Aseptic dispensing in HPSS hospitals. DHSSPS.

Other Reading

- Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources (March 2006). Administration of Radioactive Substances Advisory Committee (ARSAC)
- Medical and Dental Guidance Notes prepared by the Institute of Physics and Engineering in Medicine. ISBN 1903613 09 4
- Quality Assurance of Radio Pharmaceuticals: The radiopharmacy group and the NHS Quality Control Committee Nuclear Medicine Communications 2001; 22:909-916
- Manual for Cancer Services DH 2004
- Chief Pharmaceutical Officer Letter (CPh (1/95) Aseptic Dispensing for NHS Patients Farwell J. Aseptic dispensing for NHS patients [Farwell report]. London: Department of Health; 1995.
- Pharmaceutical Resource for Oncology in Northern Ireland, Report of the RMSC working group (2003)

Guidance

The Medicines Act 1968 allows HPSS hospital pharmacies to carry out aseptic preparation without a manufacturer's licence, if the activity is under the supervision of a pharmacist. HPSS organisations are liable to prosecution, under the Medicines Act 1968, if medicinal products supplied are not of the nature or quality expected.
Unlicensed aseptic dispensing facilities in hospital pharmacies should undergo regular inspections every 24 months. The inspections are carried out by the Regional Pharmaceutical Laboratory Service. The results of the inspections should be made known to the trust Chief Executive and those commissioning health services so that standards are maintained. Licensed activities are subject to regular audit by the MHRA Inspectors. There should also be a programme of regular internal audit.

There should be a programme of capacity planning for equipment and staff.

Aseptic dispensing is an increasing and demanding activity. Extant guidance indicates that it should be carried out under the control of a pharmacist in suitable facilities to avoid the additional risk of microbiological contamination and medication errors sometimes associated with the preparation of parenteral medication at ward level. This is increasingly crucial given the incidence of serious life-threatening infections eg MRSA.

Radiopharmaceutical dispensing activities must take into account the registration of open sources by the Environment Agency, additional training requirements for staff, the radiological implications for staff and a prospective programme for quality assurance of products.

Verification that users of radiopharmaceuticals are authorised to do so must be sought prior to use. Where products are transported to other sites, proper packaging and the services of a safety adviser must be employed. Radiopharmacies should be licensed unless operated under the direct supervision of a pharmacist.

Examples of Verification

- Policy
- Regular internal and external audit reports and progress on follow-up
- Staff skill mix and competence assessed
- Capacity plan
- Error/near miss reporting in place
- Robust systems in place for high risk procedures e.g. vinca alkaloids and intrathecal injections
- Range of products prepared linked to risk assessment of hospital usage of intravenous products
- Records of appropriate training

- Manufacturer's "specials" licence
- Copies of the Radioactive Substances Act regulations authorisation from the Environment Agency for storage and disposal of radioactive materials
- COSHH assessments
- Certification of clinicians under the Medicines (Administration of Radioactive Substances) Regulations 1978 (Commonly referred to as “ARSAC” certificates)

Links with other Standards

Infection Control
Human Resources
Health and Safety
Medical Devices and Equipment

CRITERION 6

Prescription, supply and administration conform to the requirements of relevant legislation. Prescription, supply and administration of medicines is undertaken only by appropriately qualified, competent staff.

Source

- The Misuse of Drugs Regulations (Northern Ireland) 2002 SR No 1 The Stationary Office, London
- EC 92/27 Labelling and Leaflet Directive
- Medicines Act 1968 (as amended) The Stationery Office, London
- Prescription Only Medicines (Human Use) Order 1997 (as amended) The Stationery Office, London
- The Radioactive Material (Road Transport) Regulations 2002 SI No. 1093 (as amended) The Stationery Office, London
- The Radioactive Material (Road Transport) (Northern Ireland) Order 1992 SI No 234(NI 2). The Stationery Office, London
- Circular HSS (MD) 45/2003 Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy
- Circular HSS 09/2000 Patient group directions
- Circular HSS (MD) 39-02 Safe administration of Intrathecal Chemotherapy.
- Ethics and Practice. A Guide for Pharmacists in Northern Ireland 2004 Edition Pharmaceutical Society of Northern Ireland.

Other Reading

- Pharmacy in the Future - Implementing the NHS Plan
- NSF Older People Supplement - Medicines for Older People
- MCA Guidance Note 14
- NHS Executive (2000) 2004 update for consultation, Manual of Cancer Services Standards www.doh.gov.uk/cancer/mcss.htm
- Building a safer NHS for patients and implementing OWAM
- Guidance for the Purchase and Supply of Unlicensed Medicinal Products – Notes for prescribers and pharmacists. NHS Pharmaceutical Quality Control Committee 2nd Edition, June 2001
- Department of Health. The prevention of intrathecal medication errors. April 2001
- Department of Health. External inquiry into the adverse incidents that occurred at Queen's Medical Centre, Nottingham, 4th January 2001. 2001
- NHS Executive (2000) Patient group directions HSC 2000/026 20000
- 28 Day Dispensing on Discharge from Hospital. Letter Circular HSS SC (804) BP411/01
- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the

Health and Personal Social Services (February 2008, 4th reprint), DHSSPS.

- Medicines legislation – what it means for midwives. NMC Circular 1/2005 SAT/rc 6 January 2005
- Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft)
- Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)
- National Confidential Enquiry into Patient Outcome and Death report 2008, 'Systemic Anti-Cancer Therapy: for better, for worse?

Guidance

Prescription Only Medicines (POM) may only be supplied to a patient against the prescription or written direction of an 'appropriate practitioner', as stated in section 52 of the Medicines Act. The principle supply route is through the pharmacist. Comprehensive guidance is available in both the BNF and Ethics and Practice. Doctors, dentists and independent nurse prescribers may prescribe, administer or supply Prescription Only Medicines in areas where they are competent directly to a patient. Supplementary prescribers may only prescribe in accordance with an agreed patient specific clinical management plan and the patient's agreement. Other Nurses and healthcare workers, however, supply medicines under the direction of a doctor. Midwives may administer specified controlled drugs, under a supply order, which is signed by a Doctor or Supervisor of Midwives and any of the substances that are specified in medicines legislation under midwives' exemption, provided it is in the course of their professional midwifery practice.

No-one can administer parenteral POMs otherwise than to himself, unless he is a practitioner or is acting in accordance with the directions of a practitioner. Exceptions to this include:

- Certain life saving drugs used in an emergency
- Medicines available to particular health professionals, for example paramedics, in the course of their professional practice.

Legislation is framed to ensure that the majority of clinical care should be provided on an individual, patient-specific basis. Where the direction of a doctor is not patient specific, the responsible organisation would need to ensure that the appropriate patient group direction meets the criteria (some of which are statutory) set out in Circular HSS 09/2000. In particular such directions should be authorised by a senior doctor and senior pharmacist. Additionally, they should be approved on behalf of the organisation. They should be undertaken by sufficiently competent, trained, experienced personnel, and offer genuine benefit for patients, which cannot be fulfilled by the usual prescription route.

As with other circumstances when medicines are prescribed, supplied and administered, there must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

Appropriate protocols should be in place to ensure that arrangements for communication and transfer of patient information relating to medicines, prescribing and medication history support safe practice and confidentiality.

Medicine defects or safety alerts, including those relating to devices, must be implemented as appropriate.

Unlicensed medicines should only be used where a licensed alternative is not available and pharmaceutical quality assurance has been demonstrated for both the procurement and use of such products.

Chemotherapy prescribing, supply, and administration should be in accordance with the policy of the local cancer network. In addition, prescribing, supply and administration of intrathecal chemotherapy must comply with HSS (MD) 45/2003 and HSS (MD) 39-02.

A House Officer, who holds a qualification, which entitles him to be registered, but has yet to complete the relevant period of experience, is entitled to be provisionally registered. The effect is that he may issue prescriptions for POMs or CDs only as part of his required duties in that post. He may not order for private patients or for his own use.

The BNF contains guidance on how to write prescriptions to ensure clarity and safety. These principles should be adopted, and adapted for local use as appropriate. Ward pharmacy services should be in place to ensure that prescriptions are safe, clear, legible etc, and comply with local and national guidance. (See Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (February 2008, 4th reprint), DHSSPS).

In accordance with the EU directive, patient information leaflets should be supplied each time a medicine is dispensed to a patient.

Examples of Verification

- Staff groups are subject to regular qualification checks:
- Nurses: Nursing and Midwifery Council registration checked
- Doctors GMC/GDC registration or pre-registration checked
- Pharmacists' membership of the Pharmaceutical Society of Northern Ireland
- All patient group directions have been identified, located and reviewed for compliance with Circular HSS 09/2000.
- Dispensing complete with patient information leaflet

- Evidence of the implementation of Medicine defects or safety alerts, including those relating to devices.
- Robust procedures in place for the procurement and use of unlicensed medicines
- Compliance with Manual of Cancer standards
- Register of staff authorised to prescribe, administer and supply intrathecal chemotherapy
- Record of verification of nurse training for drug administration
- Audit of prescriptions and treatment cards (e.g. using ward pharmacist intervention records).

Links with other Standards

Human Resources
Medical Devices and Equipment
Records Management
Risk Management

CRITERION 7

The prescribing, supply, administration, safe custody and destruction of controlled drugs complies with the appropriate legislation.

Source

- Medicines Act 1968 (as amended) The Stationery Office, London
- Misuse of Drugs Act 1971 (c. 38) The Stationery Office, London
- The Misuse of Drugs Regulations (Northern Ireland) 2002 SR No 1 The Stationery Office, London
- The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 The Stationery Office, London
- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (February 2008, 4th reprint), DHSSPS.
- The Prescription Only Medicines (Human Use) Order 1997 as amended . The Stationery Office, London
- Health Act 2006
- The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted).
- Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft)
- Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)

Other Reading

- RPSGB Fitness to Practise and Legal Affairs Directorate Fact Sheet: One, Controlled Drugs and Community Pharmacy, September 2007
- RPSGB Fitness to Practise and Legal Affairs Directorate Fact Sheet: Two, Controlled Drugs and Hospital Pharmacy, Currently being revised.
- The Handling of Medicines in Social Care (2007)
- Guidelines for the Control and Administration of Medicines in Residential Care Homes and Nursing Homes. NHSSB Nov 2003 (The same or similar policy exists in all HSS Board Areas)(Refer to RQIA for further guidance)
- Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005
- The Freedom of Information Act 2000

Guidance

- Possession, supply, storage and record keeping of controlled drugs must meet the requirements of both the Medicines Act and the Misuse of Drugs Act and regulations made under the legislation. Comprehensive guidance is available in the BNF, Ethics and Practice, Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft) and Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft),

Legal requirements include:
The pharmacy must keep a register in the form set out in Regulations 19 and 20 of the Misuse of Drugs Regulations (Northern Ireland) 2002.

Requisitions must be in writing and contain the information detailed in Regulation 14 of the Misuse of Drugs Regulations (Northern Ireland) 2002.

In addition, a midwife authorised by Regulation 11(1) to have any Schedule 2 controlled drug in their possession, is also required to keep a record of supplies received and drugs administered, in a book solely for that purpose.

There must be documented systems and procedures in place for the destruction of all Controlled Drugs, including patients' own drugs, which adhere to regulations where these apply.

A number of recommendations from the Shipman Inquiry have been introduced through the Health Act 2006 and will be implemented in Northern Ireland under The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. The legislation will require a Designated Body to appoint an Accountable Officer (AO). The AO will be responsible for ensuring the Designated Body, and any body or person providing services on behalf of, or providing services under arrangements made with the Designated Body, develops and monitors safe and effective systems relating to the use and management of controlled drugs. Standard Operating Procedures (SOPs) will be mandatory under this legislation. The legislation will also place a duty to collaborate and share intelligence by Responsible Bodies and will establish a Central Investigative Resource. In addition, the legislation will provide a power of entry and inspection for certain authorised persons.

Examples of Verification

- There is an internal audit process in place, including regular and periodic checks by pharmacy and nursing staff, which evaluates and documents compliance to controlled drug, prescription writing and record keeping legislation where appropriate
- Prescription audit
- Self-assessments and standard declarations (when implemented)
- SOPs
- There is a suitable policy in place for dealing with discrepancies in reconciliation:

The policy should include when to involve

- external organisations
- pharmacy destruction records where appropriate

Links with other Standards

Records Management
Health and Safety
Human Resources
Waste Management

CRITERION 8

All medicines no longer required are destroyed or otherwise disposed of in accordance with safety, legal and environmental requirements.

Source

- Environmental Protection Act 1990 (c. 43) The Stationery Office, London
- Environmental Protection (Prescribed Processes and Substances) Regulations 1991 SI No 472 The Stationery Office, London
- The Misuse of Drugs Regulations (Northern Ireland) 2002 SR No 1 The Stationery Office, London
- Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 The Stationery Office, London
- The Special Waste Regulations (Northern Ireland) 1998 SR No 289
- The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009
- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (February 2008, 4th reprint), DHSSPS).
- Pharmaceutical Society of Northern Ireland (2004 Edition), Ethics, and Practice: A Guide for Pharmacists in Northern Ireland.
- A guide to pharmaceutical clinical waste (2002), DHSSPS

Other Reading

- The Hazardous Waste (England and Wales)Regulations 2005
- The Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005
- Guidelines for Drug Donations (WHO)
- Guidelines for the Handling and Disposal of Pharmacy Wastes - NHS QC Committee
- Guidelines on the Handling and Disposal of Pharmacy Wastes NHS Pharmaceutical Quality Assurance Committee (September 2002, under review)
- Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft)
- Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)

Guidance

A number of principles should be adopted when disposing of medicines:

- Witnessed accountability
- Secure transit

- Adequate documentation
- Legally authorised persons to carry out and, where necessary, witness the destruction
- Adherence to legislation

Some clinical waste is also classified as 'special waste' and is subject to controls under the Special Waste Regulations 1998 Prescription-only medicines ('Medicinal Product' is the term used in the SI) are classed as special waste. The regulations require all movements to be tracked using consignment notes, with adequate records being kept for three years.

Any person required by the Misuse of Drugs Regulations (Northern Ireland) 2002 to keep records of Controlled Drugs in Schedule 1, 2, 3 or 4 may only destroy them in the presence of an authorised person (update as per Criterion 7).

Examples of Verification

- There is a written policy relating to the safe disposal of medicines
- Staff are aware of, and have access to the organisation's policy
- Methods of destruction follow locally agreed procedures but they must take into account national guidance when appropriate

Links with other Standards

Environment Management
Health and Safety
Records Management
Waste Management

CRITERION 9

The supply of medicines for clinical trials is undertaken in accordance with relevant legislation and best practice guidelines

Source

- Statutory Instrument 2004:1031 The Medicines for Human Use (Clinical Trials) Regulations 2004 www.mhra.gov.uk
- Statutory Instrument 2006:1928 The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
- Statutory Instrument 2008:2984 The Medicines for Human Use (Clinical Trials) Amendment (No. 2)Regulations 2006
- Statutory Instrument 2008:941 The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008

- EU Directive 2001/20/EC. Good Clinical Practice in Clinical Trials
- EU Directive 2005/28/EC. Good Clinical Practice
- Clinical Trials Research Governance Framework for Health and Social Care R&D Office DHSSPS Dec 2006
- Guidance on Good Clinical Practice and Clinical Trials (1999), Department of Health, London
- Practice Guidance On Pharmacy Servies For Clinical Trials, RPSGB 2005
- Medicines Act 1968 (as amended) The Stationery Office, London
- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS).

Other Reading

- The International Committee on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical Practice 2006. www.emea.europa.eu
- Pharmaceutical Society of Northern Ireland (2004 Edition), Ethics, and Practice: A Guide for Pharmacists in Northern Ireland.
- The Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005 www.rpsgb.org
- Clinical Trials Toolkit - a comprehensive resource for practical help in meeting requirements of the UK Medicines for Human Use (Clinical Trials) Regulations 2004 and the EU Clinical Trial Directive. www.ct-toolkit.ac.uk
- Good Clinical Practice for Trials on Medical Products in the European Community, 111/3976/88-EN Final, Office for Official Publications of the European Community.

Guidance

All clinical trials involving medicines must comply with the Medicines for Human Use (Clinical Trials) Regulations 2004. The regulations can be found at http://www.mhra.gov.uk. The key points relating to medicines are included in Parts 5, 6, and 7 of these regulations.

Pharmaceutical Society of Northern Ireland Guidance on Clinical Trials is included in the Code of Ethics and Practise Part 3 1997.

Key points include:

- A suitably trained and competent pharmacist designated as responsible for clinical trials supplies
- Responsibility of the pharmacist to ensure that the authorisation certificate is in place before the trial starts
- Pharmaceutical input to the trial protocol
- Pharmaceutical input to the local research ethics committee
- Ordering, storage and dispensing in accordance with the requirements of 'Good Clinical Practice for Trials on Medical Products in the European Community' and the guidelines provided in the revised Duthie Report.
- Stock accountability
- Access to trial protocols
- Reimbursement of pharmacy costs

Examples of Verification

- Training records for designated, competent staff trained in GCP
- Drug trial policy
- Appropriately validated Ethics Committee approval, CTA and Trust R&D committee approval.
- Records of receipt, dispensing and study administration and waste disposal to GCP standard
- Job description for the designated pharmacist
- Appropriate records of receipt, dispensing and stock reconciliation
- Evidence of Pharmacist involvement in:
    - Protocol development
    - Documentation and designing of Standard operating procedures
    - Patient information
    - Secure Database of all the studies managed by the pharmacy department.

Links with other Standards

Health and Safety
Human Resources

Records Management
Risk Management
Waste Management

CRITERION 10

The organisation reports adverse incidents involving medicinal products and devices to the relevant agency, and appropriately manages any subsequent required action.

Source

- NIAIC Safety Notice MDEA (NI) 2008/001 Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre (NIAIC).
- DB2008(NI)01, April 2008 Reporting adverse incidents and disseminating medical device alerts. Health Estates, Northern Ireland Adverse Incident Centre (NIAIC).
- The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.
- Health Act 2006

Other Reading

- Department of Health 2000, An Organisation With A Memory. Report of An Expert Group on Learning From Adverse Events in the NHS. The Stationery Office, London.
- Department of Health 2001, Building a Safer NHS for Patients. Implementing An Organisation With A Memory, Department of Health, London
- A Guide to Defective Medicinal Products – Reporting, Investigating and Recalling Suspected Defective Medicinal Products. MHRA
- Circular HSS (PPM) 02/2006 – Reporting and follow-up on serious adverse incidents.

Guidance

Organisations must identify and learn from all patient safety incidents and demonstrate improvements in practice, based on local and national experience and from the information derived from analysis of incidents.

Adverse Drug Reactions
HPSS organisations should encourage the prompt reporting to the Medicines and Healthcare products Regulatory Agency (MHRA) of *any* suspected adverse reactions due to “black triangle” drugs and any serious or unusual suspected reactions to established products. The ‘yellow card’ should be used for reporting adverse drug reactions to the agency.

Defective Medical Products
Adverse incidents arising from any medicinal product, thought to be defective, as opposed to incidents due to error, should be reported to the Pharmaceutical Branch, DHSSPS in accordance with Guidance to Trusts on

reporting defective medicinal products (2001), DHSSPS. Any necessary recall of products is the responsibility of the licence holder. However, when defects present a significant hazard to health, the MHRA may issue a 'drug alert' letter, which provides 4 categories of urgency for recall or caution in use.

A pharmacist should be nominated to co-ordinate the reporting of such incidents and also the necessary action resulting from a 'drug alert' letter. Regular reviews should be undertaken to ensure that the procedures are effective and are being followed.

Defective medical devices

Procedures should be established and maintained to ensure the prompt reporting of adverse incidents relating to medical devices to the Northern Ireland Adverse Incident Centre (NIAIC) to conform with the Safety Notice "Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts" [MDEA (NI) 2004/01].

A Liaison Officer should be nominated to co-ordinate the reporting of incidents and the local dissemination of NIAIC safety warnings. Regular reviews should be undertaken to ensure that the procedures are effective and are being followed.

Medication Incidents

The organisation should also have a local, multidisciplinary, medication incident (prescribing, dispensing, and administration) reporting and monitoring system as part of the risk management system. Medication incidents should be reported on existing clinical incident report forms or on separate medication incident form such as the Medicines Governance Team form. Trusts should consider facilitating online reporting of medication incidents. Medication incident reports should be monitored by a multi-professional management committee.

The organisation should contribute to the regional analysis of medication incidents undertaken by the Northern Ireland Medicines Governance Team.

The Northern Ireland Medicines Governance Team has been established to support organisations in their actions to prevent and protect patients from medicine related adverse events through:

- development of the risk management process itself, including the identification, analysis, evaluation and treatment of medicines-related risk.
- development of 'good practice' policies exemplified through education and training, ward and pharmacy procedures and protocols.

Organisations should ensure that:

Adverse Drug Reactions

- Staff are aware of the process for reporting an adverse drug reaction and report suspected adverse reactions via the yellow card system

Defective medicinal products and devices

- Defective medicinal products are reported to the relevant agency
- Products are kept and, if necessary quarantined, until the option of investigating the incident has been dismissed.
- Staff are aware of the mechanisms for reporting a defect with a medicinal product
- An auditable procedure is in place in primary and secondary care relating to the management of drug recalls.

Medication Incidents

Staff are aware of the process for reporting medication incidents and the reported incidents are investigated locally. These incidents should also be analysed for regional trends, to inform the priorities of the Medicines Governance Team.

The best practice policies, safety memos and learning bulletins issued by the Northern Ireland Medicines Governance Team should be evaluated and implemented.

Organisations are expected to comply with implementation requests as designated in DHSSPS guidance

Duty of Collaboration (controlled drugs)

- Under The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 there will be a legal duty placed on Responsible Bodies to share information and intelligence (within certain constraints), about controlled drugs in the healthcare sector. Those bodies required to share information will include DHSSPS Inspectorate, RQIA, healthcare organisations, Police Service for Northern Ireland, Social Service Authorities, other relevant inspectorates and professional bodies. It is proposed to establish a single Local Intelligence Network where concerns about the activities of any healthcare professional or organisation could be shared. While joint action may be agreed, each Agency would retain responsibility for taking appropriate action where required.

Examples of Verification

- There are policies that outline:
  a. required action to be taken in the event of a suspected defect with a medicinal product or device and staff are aware of the policies;

b. response to drug alerts, including out of hours, with a named lead professional and annual audit of results from the system;
c. reporting and analysis of adverse medication incidents.

- Regular reviews are undertaken to ensure the procedures are effective and are being followed.
- Implementation of best practice policies/safety memos/learning bulletins/guidance from the Medicines Governance Team and DHSSPS e.g. Circular HSS(MD)22/2005; Circular HSS(SQSD)07/08.
- Medication incident report file or database.
- Minutes from the organisation's multi-professional management committee for medication incidents.
- Induction/training schedule and content

Links with other Standards

Health and Safety
Human Resources
Medical Devices and Equipment
Risk Management

CRITERION 11

Supervision of pharmaceutical dispensing processes is undertaken in accordance with relevant legislation and current professional standards.

Source

- Medicines Act 1968 (as amended) The Stationery Office, London
- Pharmaceutical Society of Northern Ireland (2004 Edition), Ethics, and Practice: A Guide for Pharmacists in Northern Ireland.

Guidance

Pharmacists have a legal and professional duty to ensure the safe, accurate and clinically appropriate dispensing of medicines, including those that are extemporaneously prepared.

For inpatient medication, where pharmaceutical oversight may commence with the clinical check at ward level with subsequent delegation of dispensing tasks, the accountable pharmacist must ensure that the staff involved in carrying out the delegated tasks are suitably trained and competent to undertake the tasks required

Similarly, good practice dictates that such controls should be in place for the dispensing of medicines for patients to take home, for one stop dispensing for discharge and for inpatient use. Appropriate clinical pharmacy input should also be provided.

The accountable pharmacist, must at all times, be satisfied that suitable systems are in place to discharge their legal and professional duties of supervision. These systems must be fully documented in suitable standard operating procedures (SOPs), which adequately cover all the processes by which dispensing, and its associated activities are undertaken. The SOPs should be reviewed at least annually.

The SOPs should include a suitable system for reporting, recording and prompt review of known dispensing errors.

Pharmacists are also reminded of their responsibility under the Code of Ethics & Standards with regard to extemporaneous preparation.

Examples of Verification

- Staffing schedules are in place to ensure adequate cover
- SOPs are present, suitable and recently reviewed
- Maintenance records
- COSHH records
- Relevant post-basic training schemes (e.g. accredited technician checking) are suitable and are appropriately accredited

- Documentation of training present
- Procedures for dealing with errors present
- Relationship with Risk Management

Links with other Standards

Health and Safety
Human Resources
Records Management
Risk Management

CRITERION 12

The risk management process contained within the risk management standard is applied to the safe and secure handling of medicines.

Source

- Standards Australia Risk Management AS/NZS 4360:2004

Guidance

Risks should be systematically identified and recorded on a continuous basis. Risks associated with the safe and secure handling of medicines can be systematically identified using a number of approaches including:

- Control self assessment workshops
- Use of checklists
- Judgements based on experience and records
- Flow charts
- Systems analysis
- Scenario analysis
- And systems engineering techniques

Historic data, including adverse event data, medication incident reports, complaint and claim information, staff sickness/absence details can also be a valuable source of information to identify risk.

The following risk management elements should be in place:

- All identified risks should be documented as part of a 'risk register' and systematically assessed and prioritised.
- Risk treatment plans should be developed and implemented (in order of priority and alongside other risk treatments which are necessary to deal with wider risks faced by the organisation, where appropriate) in order to minimise risk.
- Risks and the effectiveness of implemented risk treatments should be monitored and reviewed on a continuous basis.
- Senior management and the Board should be informed of any significant risks and associated risk treatment plans.
- Upon induction all medical, nursing and pharmacy staff including those on fixed term contracts, and other relevant stakeholders should receive information and training on systems in place to minimise risks associated with the safe and secure handling of medicines.
- Ongoing staff training in the safe and secure handling of medicines should be undertaken.

Examples of Verification

- Risk Register
- Risk treatment plans
- Staff training/information log

- Induction schedule and content
- Correspondence with stakeholders
- Reporting mechanisms that inform risk management process

Links with other Standards

Human Resources
Records Management
Risk management

CRITERION 13

All healthcare staff involved with medicines undertake continuing professional development to ensure that there are safe and secure handling processes in place.

Source

- Best Practice Best Care (2001) - A framework for setting standards, delivering services and improving monitoring and regulation in the HPSS.
- Standards Australia Risk Management AS/NZS 4360:2004.
- Pharmaceutical Society of Northern Ireland Ethics and Practice (2004): A Guide for Pharmacists in Northern Ireland

Guidance

All staff involved with medicines have a duty to ensure safe and secure handling of medicines through compliance with relevant legislation, DHSSPS guidance and local Trust policies.

Staff must be aware of and apply these requirements at all times.

The requirements for safe and secure handling of medicines may change over time. It is therefore **essential** that all practitioners keep up to date with current practice. This involves continuing learning i.e. continuing professional development (CPD). CPD is an essential element in improving service quality.

Examples of Verification

- CPD policy
- Training and development plans for all staff
- Staff CPD log books
- Training records
- Audit of adherence to local medicines policies

Links with other Standards

Human Resources

CRITERION 14

The organisation, through the Chief Pharmacist, has access to up-to-date legislation and guidance relating to the safe and secure handling of medicines.

Source

- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (February 2008, 4th reprint), DHSSPS).

Guidance

Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the DHSSPS.

As a minimum, the organisation should have access to the key references listed on the front page of this standard.

There should be appropriate mechanisms in place for the dissemination of information.

There are many sources of information on legislation and guidance on the safe and secure handling of medicines, including books and, through subscriptions to specialist information providers, CD-ROMs containing the full text. Up-to-date DHSSPS guidance can be accessed on the Internet on the DHSSPS website (http//www.dhsspsni.gov.uk). Equivalent NHS documents can be accessed via the Department of Health COIN database (http://www.doh.gov.uk). The Medicines and Healthcare products Regulatory Agency (http://www.mhra.gov.uk) contains some information. Full text copies of all legislation issued from 1 January 1997 can be downloaded from http://www.official-documents.co.uk, which contains information on UK official documents.

Wherever possible, the DHSSPS Governance website www.dhsspsni.gov.uk/hss/governance/index.asp contains the relevant information pertaining to the development of controls assurance standards for Northern Ireland. Further useful guidance can be obtained from the Health Care Standards (formerly CASU) website (http://www.hcsu.org.uk).

Examples of Verification

- Library
- CD-ROMs
- Internet access
- Cascade process chart

Links with other Standards

All standards (generic criterion)

CRITERION 15

Adequate resources support the safe, secure and appropriate use of medicines.

Source

- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.
- Circular HSS (PPM) 3/2002 – Corporate Governance: Statement of Internal Control
- Circular HSS (PPM) 8/2002 - Risk Management in the Health and Personal Social Services
- Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance

Guidance

A fundamental element of the safe and secure handling of medicines is the need for all parts of the system to be adequately resourced with competent personnel and suitable facilities and equipment. In addition it is vitally important that there is strong collaboration across Primary and Secondary Care relative to the use of medicines. In this regard the establishment of a regional centre for medicines management to agree, implement and monitor adherence to prescribing guidelines across these sectors should be undertaken.

Consideration should be given to the development of these in line with post RPA modernisation.

Examples of Verification

- Baseline data for services against standards
- Benchmarking
- CPD – Training budgets/staffing budget
- Audit – Critical incidents, facilities
- Capacity Planning
- Business Plan
- Review monitoring process to ensure that pharmacy remains adequately resourced
- Minutes of meeting of Drug and Therapeutics Committee
- Document joint initiatives, policies etc.,

Links with other Standards

Financial management
Medical Devices and Equipment
Risk Management

CRITERION 16

Key indicators capable of showing improvements in the safe and secure handling of medicines and the management of associated risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.
- Quality Standards for Health and Social Care – Criterion 5.3.1 (f) and Criterion 5.3.3 (f)

Guidance

The organisation should develop indicators, which demonstrate that medicines are being safely and securely handled and risks are minimised. One indicator is degree of compliance with this standard. Ideally the indicators should be designed to demonstrate improvement in the performance of pharmacy services and staff prescribing and handling medicines over time. The number of indicators devised should be sufficient to monitor all aspects of the process, including risk management. It is not necessarily the case that the board will use all the indicators. The board should select those, which are useful for ensuring that the internal controls are working satisfactorily and medicines are being safely and securely handled.

Examples of Verification

- Indicators
- Evidence of usage at all levels

Links with other Standards

All standards (generic criterion)

CRITERION 17

The system in place for the safe and secure handling of medicines, including risk management arrangements, is monitored and reviewed by management and the Board in order to make improvements to the system.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.
- The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted).
- Health Act 2006
- Quality Standards for Health and Social Care 2006 – Criterion 5.3.1 (f) and Criterion 5.3.3 (f)

Guidance

It is the responsibility of management and the board to monitor and review all aspects of the system for the safe and secure handling of medicines, including:

- Accountability arrangements
- Processes, including risk management arrangements
- Capability
- Outcomes
- Internal audit findings

The review should be carried out by individuals with the relevant knowledge and expertise of the safe and secure handling of medicines and should include review of any adverse incidents.

The committee with responsibility for risk management will play a significant role in monitoring and reviewing all aspects of the system as a basis for establishing significant information that should be presented to, and dealt with by the board. The Audit Committee should review internal audit findings.

Controlled drugs

- Under The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (draft) it is proposed that the duties of the Accountable Officer will encompass the developing and monitoring of systems to ensure the safe and effective use and management of controlled drugs subject to their oversight.

Examples of Verification

- Internal audit report(s)

- Audit Committee minutes
- Minutes of the board sub-committee(s) responsible for overseeing risk management and governance
- Self assessments/self-declarations(proposed)

Links with other Standards

All standards (generic criterion)

CRITERION 18

The board seeks independent assurance that an appropriate and effective system for the safe and secure handling of medicines is in place and that the necessary level of controls and monitoring are being implemented.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.
- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.
- Circular HSS (PPM) 3/2002 - Corporate Governance: Statement on Internal Control
- Circular HSS (PPM) 8/2002 – Risk Management in the Health and Personal Social Services
- Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance
- Quality Standards for Health and Social Care 2006 – Criterion 5.3.1 (f) and Criterion 5.3.3 (f)

Guidance

Management should consider the range of independent internal and external assurance available, and avoid duplication and omission.

The adequacy of the independent assurance will depend upon the scope and depth of the work performed, bearing in mind its timeliness and the competency of the staff performing it. The level of reliance that can be placed upon such assurances should consider, among other things, the professional standing of the assurer, their level of independence, and whether they could reasonably expect to provide an objective opinion. It is important that any review that takes place results in a report, recommendations for action where necessary, and the retention of sufficient evidence to enable other potential reviewers to rely upon the work already undertaken. The reports should be made to the appropriate sub-committee of the board.

Management arrangements will include an internal audit function, as well as other quality control and assurance functions such as clinical audit. The internal audit function is required to give an opinion to the board on the adequacy and effectiveness of the overall system of internal control. In doing so, they will seek to work with, and rely on the work of other bodies for example RQIA.

In addition, the HSC organisation will be subject to independent inspection by the DHSSPS Medicines Inspectorate on those areas subject to statutory authority.

Examples of Verification

- Schedule of planned reviews
- Copy of reports
- Committee minutes
- Action plans
- Notes of follow up of actions
- Evidence file
- Details of staff involved in the review

Links with other Standards

All Standards (generic criterion)

Royal Pharmaceutical Society of Great Britain

MAHI - STM - 097 - 9647

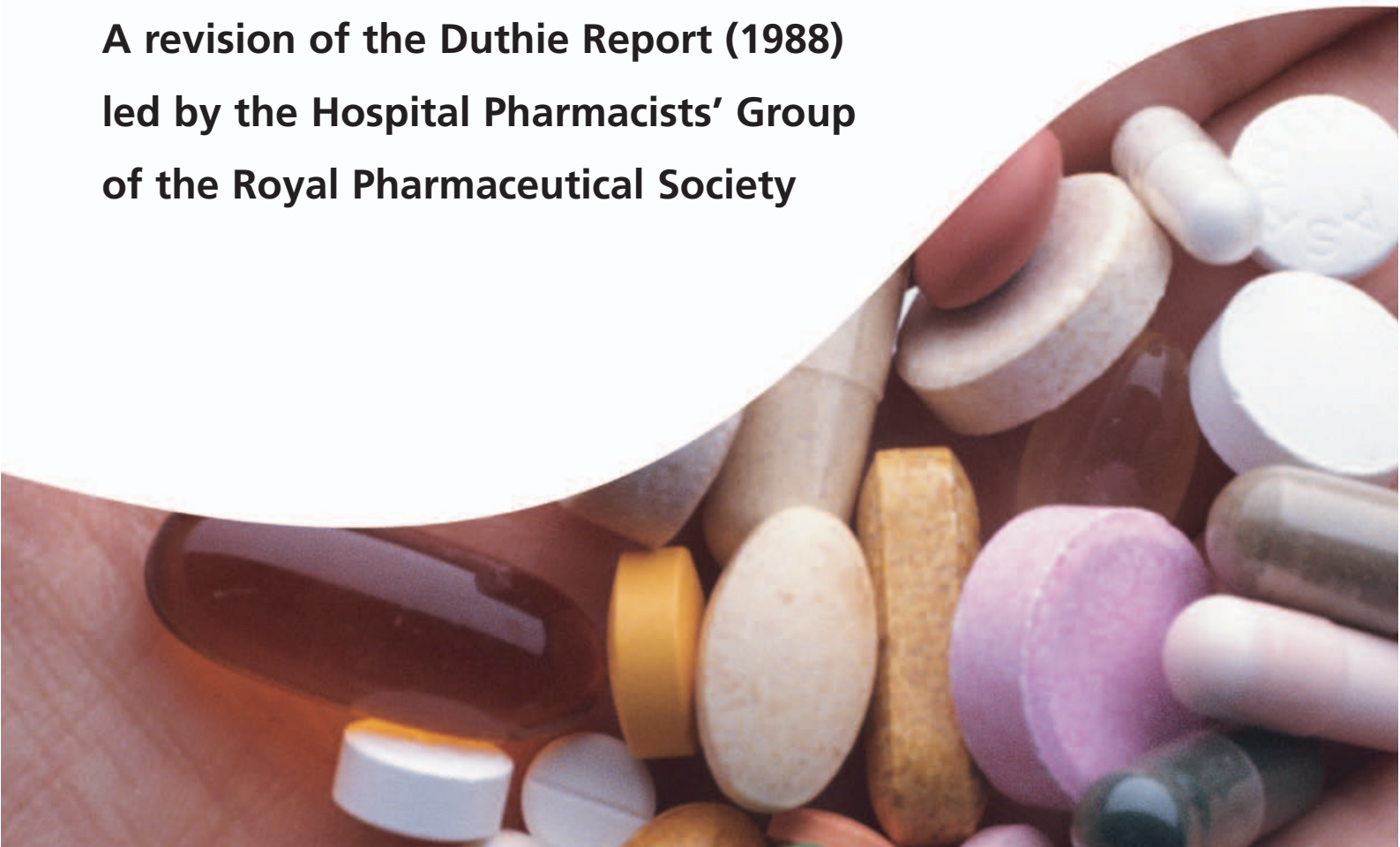
BW/150

March 2005

THE SAFE AND SECURE HANDLING OF MEDICINES:

A TEAM APPROACH

A revision of the Duthie Report (1988) led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society



MAHI - STM - 097 - 9648

Preface

A prescribed medicine is the most frequent treatment provided for patients in the NHS. Medicines must be prescribed, dispensed and administered safely and effectively. And, equally important, their storage and handling within NHS organisations must be safe, secure and comply with current legislation.

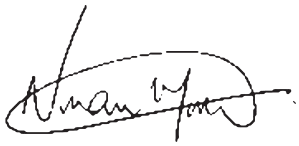
Comprehensive guidance on safe and secure handling of medicines was last issued to the NHS in 1988, in the report of a working group chaired by Professor R B Duthie. There have been many changes in legislation and practice since then, and the Royal Pharmaceutical Society of Great Britain has led a multi-disciplinary review to produce this updated report, in consultation with relevant stakeholders including medical and nursing organisations and the National Patient Safety Agency.

Thanks are due to the Royal Pharmaceutical Society and to the members of the working group who undertook the task of updating the report. We commend it to NHS organisations and to health professionals. We hope it will be a valuable resource to support the development of policy and good practice on handling and security of medicines within local arrangements for clinical governance and patient safety.

Jim Smith
Chief Pharmaceutical Adviser
for England

Carwen Wynne-Howells
Chief Pharmaceutical Adviser
for Wales

Bill Scott
Chief Pharmaceutical Officer
for Scotland



Norman Morrow
Chief Pharmaceutical Officer
for Northern Ireland

While the contents of this document have been approved for use in all four countries in the United Kingdom, there are some aspects that are not always appropriate for every country.

With the breadth of practice situations in the UK it might be appropriate for this guidance to be contextualised in each of the devolved administrations.

Editor's Note:
The Pharmaceutical Society of Northern Ireland (PSNI) has endorsed this report as good practice. They have produced their own guidance booklet in April 2004 - "Use and Control of Medicines - Guidelines for safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services" This was issued by the Department of Health, Social Services and Personal Social Services. This was published in April 2004 (2nd Edition).

The Safe and Secure Handling of Medicines: A Team Approach

The Royal Pharmaceutical Society of Great Britain (RPSGB), with encouragement from the Department of Health, established its own multi-disciplinary working group to review and update the existing guidance on safe and secure handling of medicines. The working group was established under the chairmanship of Professor G B A Veitch, reporting to the Council through the Hospital Pharmacists Group. Its terms of reference were to revise and update the Duthie report. Details of the working group membership and schedule are given in Appendix 2.

Foreword

The revision of the Duthie report was undertaken to ensure that the guidance was updated to reflect changes in legislation and developments in practice since 1988. The fundamental reasons for the guidance have not changed – in the course of using medicines for therapeutic benefit it is important for institutions and health care professionals to

- comply with current legislation;
- follow guidance issued by the Health Departments for England, Wales, Scotland and Northern Ireland and other Government Departments e.g. Home Office;
- manage the risks to patients and staff arising from the use of medicines.

The clinical and economical use of medicines and the systems to address these issues are not covered by this document.

It is perhaps useful to clarify the products that are covered by this guidance. The term ‘medicines’ embraces all products that are administered by mouth, applied to the body, or introduced into the body for the purpose of treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, contraception, inducing anaesthesia, or otherwise preventing or interfering with the normal operation of a physiological function. It follows from this definition that infusions or injections of sodium chloride 0.9% and water for injection are included as are all medicinal products covered by the European Directive on Medicines.

This revised version of the Duthie report retains some elements of the original structure and also contains some new elements, such as the chapter concerned with self administration of medicines and Appendix 1 dealing with controlled drugs.

We have maintained one important feature of the original document, namely the self-contained chapters dealing with different types of working areas. For those concerned with only one sphere of activity, this structure makes the guidelines easy to use and avoids extensive cross-referencing.

This necessarily means that the guidelines may appear repetitious for the reader going from cover to cover.

We have used the term ‘patients’ throughout to refer to service users, otherwise known as clients, consumers or customers.

We recognise that the guidelines will be used in a number of institutions, both NHS and private, and for this reason we have referred to the relevant corporate body as ‘the organisation’ – to indicate NHS Trust, PCT or equivalent in Wales, Scotland, Northern Ireland, etc.

We have defined the terms and descriptions used in the glossary at the back of these guidelines.

There is relatively little legislation concerning the handling of medicines within the hospital service. Key legislation includes the Medicines Act, the Misuse of Drugs Act and its associated Regulations, the Health and Safety at Work Act, the Control of Substances Hazardous to Health Regulations and the regulations relating to the disposal of hazardous waste. Bearing this in mind, the guidelines have been drafted, as far as possible; to say ‘should’ when recommending good practice and ‘must’ to indicate a legal requirement.

These guidelines have been drafted to reflect the current legislative framework and good practice. Inevitably, practice will continue to develop in line with social and technological developments and, on occasions, users of the guidelines may find points which, in their own area of activity, fit uneasily with their established practice. In such cases, we hope that the principles we have identified will enable them to devise safe and secure systems appropriate to their needs. There may also be local situations where new models of practice have been developed that are not specifically described here but for which a set of principles can be applied. For example, the issues concerning the handling of medicines in a Day Theatre would be similar to those in any other Operating Department and therefore the guidelines set out in Chapter 10 (Operating Departments) would be applicable.

Future editions of the guidelines will cover changes in the law.

Table of contents

Chapter 1

Background and Changing Environment

1.1.1 There have been four previous reports concerned with the control of medicines in hospitals: the Aitken Report of 1958, the Annis Gillie Report of 1970, the Roxburgh report of 1972 and the Duthie Report of 1988.

1.1.2 Since 1988 there have been changes in the structure, function, operational arrangements and the legal basis of activities within the NHS. These changes have prompted the need for up-to-date guidance on the safe and secure handling of medicines within the framework of developing NHS services.

1.2 Key factors in the current situation are:

- **Increasing emphasis on clinical governance.** Good Clinical governance demands clear lines of responsibility and accountability and clear policies for managing risk. Systems that ensure the safe and secure handling of medicines are essential elements of good clinical governance.

- **Growing awareness of medication errors.** There is growing awareness of medication errors and the establishment of the National Patient Safety Agency has demonstrated the NHS commitment to the development of safe systems of patient care.

- **Changing public expectations.** There has been a growth in the expectations by patients that their treatments will meet the highest standards.

- **Changing models of patient care.** These include reductions in the length of hospital stay, the growth of day procedures, the development of medical support units away from hospital centres and the growth of treatment at home. Patient self-administration of medicines and the continued use of patient's own medicines whilst in hospital represent further developments.

- **Technological advances.** Electronic data transfer, automation and robotic systems will become routine elements of systems for handling medicines in the near future. Computerised prescribing, automated dispensing and electronic recording of administration are already in

operation and will be widely implemented. Information technology developments allow rapid, economic procurement of medicines and rapid transfer of information between primary and secondary care.

- **Developing roles of healthcare staff, including pharmacy staff.** Agenda for Change, multi-skilling and the advent of non-medical, independent and supplementary prescribers are changing the ways in which healthcare staff are trained and practise.

1.3 The growth of drug misuse and drug-related crime means controlled access to the products and the safety of the staff involved in their control continues to be important.

Chapter 2

Approaches and Scope of the Guidance

2.1.1 This document only considers the processes associated with the physical handling of medicines. The clinical elements of the management of medicines (such as choice of medicine, dose, route of administration, frequency of administration and duration of treatment should be appropriate to the patient's condition, taking into account allergies, metabolic limitations, etc.) are beyond the scope of this guidance.

2.1.2 Application of this guidance is a multidisciplinary activity. In developing local procedures and policies, all staff groups undertaking the initiation of treatment and the handling of medicines should be involved. Appropriate use should be made of pharmaceutical advice.

It is not the intention of the document to provide detailed consideration of all possible circumstances that might apply when medicines are used. It provides the principles needed for controlling the activities of handling medicines. In support of these principles, guidance in respect of specific elements of practice is provided to enable staff to devise their own operational policies and procedures for the safe handling of medicines appropriate to local circumstances with due regard to the relevant legislation.

2.1.3 In addition to providing guidance for the development of appropriate policies and procedures, this document should be used as a tool for the auditing of safe and secure medicines handling within hospitals. In this context, the guidance should be used together with the Standards for Better Health Domain 1 - Safety.

2.1.4 The original guidance was based on the elements of a structured medicines trail. The trail covered all activities concerning medicines within the overall responsibility of the hospital concerned. This document uses a similar process and retains the focus on the aspects of responsibility, record keeping and reconciliation. A revised medicine trail is shown and the guidance is based on the stages shown within it. Transactions involving the physical handling of medicines and the control processes required for these have been addressed.

2.1.5 The document essentially deals with medicines and these are referred to throughout. However it is routine practice for other products such as disinfectants and diagnostic reagents to be supplied from the Pharmacy. Some of these may be used in ensuring the safe use of medicines and thus their control might be appropriately considered under the principles

outlined below.

2.1.6 In addition to receiving input from the members of the working group, material was received from a number of subgroups established to provide expert opinions on specialist topics. A final draft was also scrutinised by those shown in Appendix 2 .

Chapter 3

Achieving the Safe and Secure Management of Medicines

3.1 In any healthcare organisation the principles which govern the management of medicines must be applied to all the activities in which medicines or their administrative and legal control are concerned. The key principles are:

- compliance with current legislation;
- adherence to guidance issued by the Health Departments for England, Wales, Scotland and Northern Ireland and other national guidance e.g. NPC Guide;
- management of the risks to patients and staff arising from the use of medicines.

These principles should be applied to the management and physical handling processes involved in the initiation of treatment, prescribing, procurement, production, acquisition, storage, distribution, dispensing, preparation, administration to patients and the safe handling and disposal of any residual medicinal product.

3.2.1.1 It is the responsibility of the senior management of the organisation to establish, document and maintain an effective and economical system by which medicines are managed safely and securely to meet the patients' clinical needs. This should include formal performance reporting mechanisms and a commitment to promote awareness of the significance of the system within the organisation.

3.2.2 The senior management board of the organisation should designate an experienced, senior member of staff to be responsible for management of this system. This should normally be the senior pharmacist in the organisation.

3.2.3 Specific policies, incorporating references to relevant guidance and appropriate standards, should exist for each activity and should include:

- Detailed, approved, operational procedures (standard operational procedures, SOPs) to cover all facets of the activity.
- Defined responsibilities, competencies, training and performance standards of staff involved in the activity.

- Control of all materials, including equipment, containers, devices and packaging, used in the processes.

- Provision and use of suitable devices and clothing to protect the patient and staff engaged in processes from avoidable hazards.

- Provision, maintenance and correct performance of facilities and equipment, including disposables, for the whole range of activities carried out.

- Consistent approach to medicines' presentation including labelling. (see the labelling requirements of the RPSGB - Medicines, Ethics and Practice Guide)

- Full documentation of systems, processes and other related issues such as accidents, errors and client complaints related to the handling of medicines.

- Validation of all procedures.

- Routine audit of systems and consequent remedial action.

- Risk assessments for all procedures.

- Reference to other legislative requirements, where necessary, such as Control of Substances Hazardous to Health (COSHH) and ionising radiation regulations.

3.3 The paragraphs below are an aid to the completion or review of the procedures needed for the safe and secure management of medicines. The stages for a medicines trail and links between them are outlined in Section 4. This can be used as a guide to identify all the activities for which SOPs are required. The components and principles for development of comprehensive SOPs are described in Section 5. It is recognised that not all the elements or statements will be relevant to all activities, however, the principles may be used as a guide in development of new SOPs or for the review of existing SOPs.

Chapter 4

The Medicines Trail

4.1 Definition

The medicines trail (Figure 4.1, page 17) covers all the potential activities that are associated with a medicinal product, from the initiation of the patient treatment through a prescription or patient group direction to the administration of the medicine and the disposal of any waste material.

As this is a multistage process there is a need to introduce controlled links between the relevant stages. These links must be included to ensure full consideration of all aspects throughout the trail from the perspective of safe and secure handling.

Some of the activities will always be present in the treatment of an individual patient whilst others will only occur when certain medicines are used or when specific local circumstances exist.

4.2 Prescribing/ initiation of treatment

Definition: (In the strict, legal sense) - to order in writing the supply of a prescription only medicine for a named patient. (In the extended, commonly-used sense) – to authorise by means of a prescription the supply of any medicine (not just a prescription-only medicine).

Commentary:
A patient's treatment must be initiated through a formal process. This may be diagnosis and prescribing by a member of the medical staff (or any other authorised prescriber) or may be through an approved patient group direction. In certain life-threatening circumstances the process may not be formally initiated in full but retrospective records must be made to cover the treatment given.

Similarly, other activities involving products that are not directly associated with a specific patient, such as disinfection, should be undertaken using an approved procedure and the work carried out by competent members of staff. Appropriate steps must be implemented to control these procedures regardless of whether they are undertaken using a paper or electronic communication system.

There should be compliance with legal and professional requirements as well as local regulations and guidelines. Local guidelines will include any policies and procedures that limit the choice of medicines available, the length of prescribing period, the format and style of the information and the records made.

4.3 Procurement/acquisition of medicines

Definition: The activities through which a medicine is acquired for use in treating a patient

Commentary:
The medicine must be appropriate and legitimate for its intended use. Identification of potential sources of supply, specification of the medicine for its intended use, consideration of other issues such as lead times and shelf life as well as the method of procurement need to be considered.

Compliance with legal requirements, standing financial instructions, data controls etc. need to be included. In addition, policies are required to cover special products such as clinical trials medicines, medicines supplied on a "named patient" basis, imported medicines and medicines known to be used outside the indications listed on the marketing authorisation.

4.4 Manufacture /manipulation of medicines

Definition: The activity by which the medicine is made or subject to further change prior to being sent to the point of use.

Commentary:
Medicines may be produced or modified by the hospital or a third party prior to administration to a patient. This activity includes manufacturing of medicines from raw materials, repackaging of medicines into small packs from bulk supply, aseptic dispensing of parenteral nutrition solutions, reconstitution of injections, addition of parenteral medicines to intravenous solutions and the preparation of suspensions form tablets or capsules. (In some cases the point of manipulation may also be the point of issue/dispensing.)

These activities may be carried out in a suitably-equipped hospital pharmacy or contracted out to commercial manufacturers. Full controls of all the processes must be managed in order to sustain quality at the time of use.

4.5 Receipt of medicines

Definition: The formal activities undertaken when medicines are received by the organisation from any external source, or transferred from one location to another within the organisation. Storage of medicines in anticipation of latter stages in the trail is also included.

Commentary:
All medicines received by the organisation should be of the quantity and quality specified and suitable for the purpose for which they are intended. Quality issues should include confirmation of product identity and quantity, confirmation that deterioration through inappropriate storage, such as breakage of cold chain, has not occurred and confirmation of compliance with any legal and/or local requirements.

Patients' own medicines, which are brought into hospital to be used to continue their treatment, should be checked for quality and accuracy of the labelling. Records of medication brought into hospital by the patient need to be maintained, irrespective of whether it is used or not. Patients' own medicines, unless properly recorded, provide opportunities for diversion that would otherwise be difficult to trace.

Once received into the hospital, the physical condition and inventory records of medicines should be controlled. Consideration of environmental and security aspects of all storage locations should be included as well as the processes by which the records of the stock are maintained.

4.6 Issue to point of use/ dispensing or supply

Definition: The activities undertaken, in response to formal orders, when medicines are issued to the place where they will be used or supplied directly to the patient.

Commentary:
Medicines at this stage may be supplied as ward /department stock or as items for specific patients. In addition, direct issues to patients being discharged from hospital or to outpatients may be made.

Automated or robotic systems may be used to dispense medicines to minimise manual picking errors.

"One-stop" dispensing has been introduced in some hospitals. This combines the inpatient supply to individual patients with the discharge medication.

The majority of transactions at this stage will be undertaken by the Pharmacy Department.

4.7 Preparation/manipulation of medicines for administration

Definition: The activities associated with the preparation of the medicine for use. These include the calculation and selection of doses, the withdrawal of volumes from containers, the preparation of injections from vials/ampoules of dry powder and the preparation of complex admixtures.

Commentary:
Some form of manipulation of the medicine may be necessary immediately prior to its administration. This is particularly the case with parenteral medicines. The activities associated with this are fundamental in ensuring the correct medicine is administered to the patient. Although some of these activities may be undertaken at the bedside, many will be done in ward utility/clinical rooms or in special facilities with controlled environments.

Parenteral injections should be prepared aseptically in a controlled environment under pharmaceutical control, where possible. Centralised additive services are provided in a number of hospital pharmacy departments and should be used in preference to making additions on wards. In addition to the physical processes leading to safe and accurate dose administration there is a need to ensure that security and legal aspects are covered and that all appropriate records are kept.

4.8 Use of medicines/administration

Definition: The activities undertaken when a medicine is administered, i.e. given by introduction into the body, or by external application, to a patient.

Commentary:
This is the key activity in the medication use process and it is the point at which there are many opportunities for error. There may be considerable potential for deviation from the desired practice. Activities covered include identification of the patient, selection of the medicine, administration of the medicine and recording the medicine administered.

Electronic processes including optical readers that can identify the nurse/doctor, the patient and the medicine can reduce the risk of errors occurring. (see also chapter 6)

4.9 Removal/disposal of surplus/waste medicines from wards and departments

Definition: The activities associated with the removal and disposal of medicines that are no longer required or are no longer suitable for their intended use.

Commentary:
Procedures for safe removal and destruction of unwanted, damaged, out of date or part-used medicines are required from all locations where medicines are stored and administered. When carrying out these activities, safety, security, legal requirements and local environmental regulations must be considered for each product. Appropriate records should be made to complete the audit trail of the medicine from purchase (or, in the case of items received free-of-charge or patients own medicines, receipt) to destruction or reuse.

Procedures for the disposal of waste materials covered in this section may also be relevant in the earlier sections of the medicines trail, particularly manufacture, preparation and storage.

4.10 Removal/disposal of surplus/waste medicines or related materials from the hospital

Definition: The activities through which unwanted medicines or waste materials are removed from the hospital

Commentary:
This stage is primarily concerned with the safe and timely removal of surplus/waste medicines accumulated in any of the previous stages. It covers the removal of any medicine that has not been administered to a patient that is not to be retained in anticipation of such a use.

In some instances the medicines should be sent for appropriate waste disposal but in other instances, surplus medicines, which are still fit for use, may be transferred to another hospital where there is a demand.

There should be full compliance with local regulations and national regulations e.g. Waste Management Regulations, such as those issued by the water authorities, and all legal requirements should be met. In addition, appropriate records should be kept to complete the audit trail.

4.11 Links between stages

Definition: All activities associated with the transfer of information or materials between stages

Commentary:
There needs to be recognition that activities within and between stages will nearly always involve the transfer of information. Except where the same person initiates and administers treatment, there will be a need for communication with others. This communication may be confined to one location. An example would be where a prescription is written for a ward stock medicine to be administered by a nurse from the same ward. It is more likely that information will have to pass to another site such as to the pharmacy, for the supply to be made.

Particular care will be needed in those circumstances where the original document is not transferred with the request, such as when prescriptions are transcribed on to intermediate order sheets or where fax machines are used. Continuous control and security of the information and the method by which it is held are essential.

Examples of information transfer requiring particular attention include:

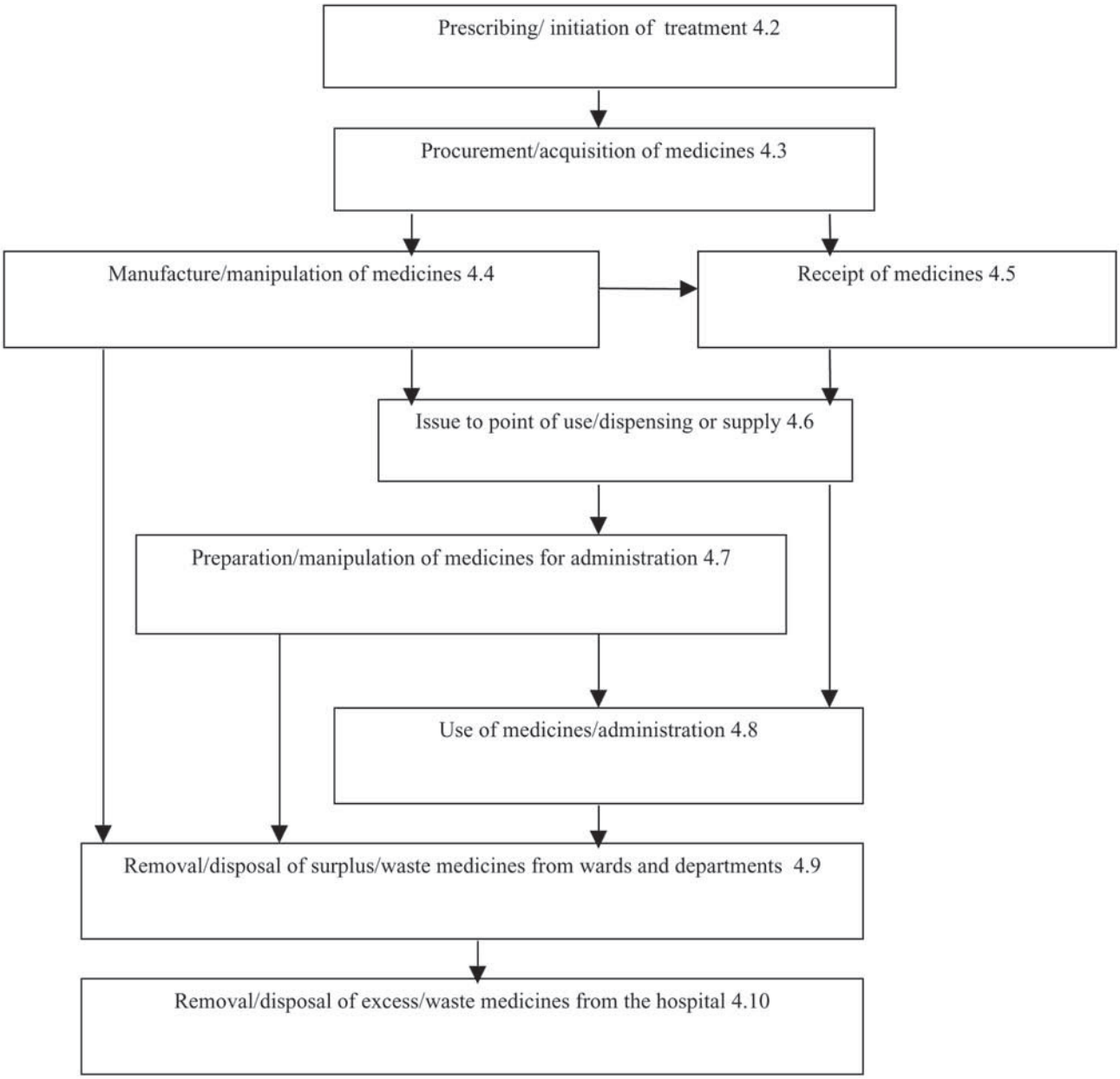
- Patient specific details necessary for dispensing.
- Information about special medicines or formulations - in hospitals where medicines are prepared, either under a "Specials Manufacturing Licence" or using exemption under Section 10 of the Medicines Act, to ensure that a medicine of the correct specification is ordered. (See Guidance Note 14 and NHS QAC document on Specials.)
- Documentation for specific medicines such as Controlled Drugs (see Appendix 1) or radioisotopes.
- Records of the movements of medicines where appropriate.
- Unlicensed medicines/unlicensed us
- Clinical trial supplies

A common feature of link activity is the physical movement of materials. Careful attention to the maintenance of product integrity is required during such movements. Environmental controls and tight security may be needed to ensure that the medicine is handled appropriately and that personnel are not exposed to hazards. In addition, consideration of other aspects such as the cold storage chain is relevant in such transfers.

There should be full compliance with legal requirements and local policies. Internal transfer links require the same attention to detail as external links in order to retain overall product control. Link stages may be eliminated, for example, where stock items are supplied directly from an external source to a ward or department or where the point of manipulation is also the point of issue/dispensing.

Figure 4.1

The simplified medicines trail



Chapter 5

Principles Applicable to the Activities Undertaken in the Medicines Trail

5.1 For each activity there are a number of elements that should be identified and included in the operational procedure.

These can be summarised as follows:

- Description of all the processes undertaken within the activity.
- Process control including documentation/records.
- Transportation of materials.
- Security of materials.
- Product integrity (to ensure quality at point of use).
- Safety (to protect staff and patients from adverse incidents).
- Risk assessment.
- Responsibility/accountability for the activities in the process.

5.2 The process description

All activities undertaken should be described, preferably in the form of a Standard Operating Procedure (SOP).

As a minimum the SOP should:

- Describe activity elements, so that the SOP is comprehensive and reproducible.
- Ensure that each element is described precisely, comprehensibly and unambiguously and should indicate who is authorised to perform it.
- Specify any equipment, facilities and data associated with the process.

- Specify the appropriate written and/or oral supporting information or instructions required in passing to the next stage.

- Include the acceptable form(s) in which instructions can be given.

5.3 Process control including documentation/records

Appropriate members of senior staff and the senior pharmacist should formally approve SOPs. SOPs and activity descriptions should be subject to routine updating and review. A record of such reviews should be maintained. SOPs should be available to any member of staff at the location at which they are used. All SOPs should be dated and the date of review should be included.

As a minimum, the SOP controlling a process should include the following:

- No process should be initiated if the instructions are not comprehensive, clear (legible and unambiguous) and current.

- All activities should comply with legal regulations and local or relevant national policies.

- The documentation should identify those persons currently authorised to undertake any particular activity. Where the authorisation requires competence checks, supporting documentation should detail the scope of the competence, record that the check has been made and confirm the period for which the authorisation remains active.

- Any supporting documentation should identify the key features including, where appropriate, essential data or design provisions should be available.

- An activity should only be carried out by a person authorised and trained to undertake that activity.

- The data required for the task in hand should be comprehensive and current.

- The systems through which quantities of materials present at the beginning and end of the stage/ transfer should be reconciled.

- Appropriate and contemporaneous records of the activity should be made including identification of those undertaking key stages and the source of any materials received. The period for which such records are to be retained should be included.

- The type of record, reporting system and action required when deviations from the process occur.

- Where electronic systems are used in support of, or as part of, the activity, a system of control should exist through which activities and menus are restricted to those authorised to use them.

- The system should indicate which elements of information are mandatory prior to initiation of the next stage and which, if any, are desirable. The initiation of the next stage should only occur when all activities required in the SOP have been completed.

5.4 Transportation (internal or external)

These principles should apply to the transfer of medicines between sites within the same organisation as well as between the organisation and an outside location.

- Transfers should be initiated through a system in which all orders and dispatches are recorded.

- Receipt of goods should be recorded.

- Procedures and equipment used in the transport of products should be designed to ensure that the integrity and quality of the product is not compromised.

- Transfer of medicines outside the healthcare organisation should always be authorised and receipt acknowledged by the receiving body.

- Staff engaged in transportation of medicines should be identified, authorised and appropriately trained. Local procedures should also cover situations where staff transport medicines in the course of their duties.

- Where intermediate carriers (agents) are used, approved systems and controls should be present, including the recording of collections and deliveries.

- Tamper-evident and, preferably, secured containers should be used when the transportation is under personal control throughout. Secured containers in secured vehicles should be used when the medicines are not under personal control throughout the transportation. Arrangements for transport of CDs must comply with current legal requirements. (see Appendix 1).

  Cold chain control, within the limits appropriate to the individual product, should be maintained for items requiring refrigeration.

5.5 Security

From the time of receipt until use or removal from the organisation, all medicines should be kept secure, with access only by authorised personnel. (This includes medicines brought in by the patient but not required for treatment and held prior to return to the patient or disposal). The legal requirements related to the category of medicine should be applied. At each stage where a medicine changes hands, there should be clear policies explaining where the responsibility lies, what should be recorded and how often reconciliation should take place.

- Procedures and policies should be consistent with the general security arrangements within the organisation and relevant staff such as risk managers, security officers and local crime prevention officers should be involved.

- Arrangements should be in place to protect, from attack, staff working in areas where medicines are stored and used.

- Medicines should be stored at a level of security appropriate to their proposed use and at a level appropriate to the staff present at any time. There is a potential cascade of security levels with the most secure area likely to be the pharmacy, followed by the ward medicine cupboard, medicine trolley, bedside cabinet and emergency trolley. Medicines not in current use or used only in an emergency should be moved to a higher security location. The level may be different in locations that are staffed continuously compared with those which are staffed intermittently even when the use of the medicine is the same in each case.

- Procedures should be in place to ensure that security is maintained in any storage area particularly where it is not continuously staffed.

- Equipment used in storage areas or during transport should comply with the relevant standards where they exist.

- Records of stock holding in any location and of transfers between locations should be made. Records should be consistent, accessible and reliable and also be stored securely. It should be possible to audit the process and account for all movements of stock and to identify any inappropriate losses.

- Procedures should cover the action to be taken and the records to be made when products are misappropriated.

- Documentation should be accessible only to those authorised.

- Documents used for procurement or issue of materials outside the organisation such as order sheets and prescriptions should be held in a secure location and all issues of these documents recorded.

- Where electronic systems are used in support of, or as part of, the activity, a system of control should exist by which activities and computer screen menus are restricted to those authorised to use them.

- When patients assume responsibility for their medicines under self-administration schemes, information and advice about keeping their medicines secure should be given (See Chapter 6)

- Staff in any supervisory position should be aware of the signs that may indicate abuse or diversion of medicines (e.g. changes in an individual's behaviour such as lack of concentration, regular unexplained absences from the work area, a change in character, "odd" behaviour, or other changes such as loss of stock, excessive ordering) and take appropriate action.

5.6 Product integrity (quality at the point of use)

- All medicines acquired for use in the organisation, from whatever source, should be subject to appropriate assessment of their fitness for use.

- Appropriate storage and environmental conditions should be specified for all the different types of medicines.

- A standard operating procedure (SOP) should be in place to ensure that medicines are kept within the specified conditions to the point of use or disposal in all locations where they may be held or during transfers. Equipment or devices associated with storage or transfer should not threaten the integrity of the product. For items that require refrigeration, the equipment used should conform to MHRA guidance. There should be monitoring of the temperature of the refrigerator on each working day using a calibrated maximum-minimum thermometer or other approved monitoring device, which is recorded and signed by the person monitoring the temperature and a written procedure should be in place indicating the action to be taken if the temperature is outside the normal range.

- A standard operating procedure (SOP) should specify the required condition of a medicine at the time of use and the checks that should be made to ensure it is used according to these conditions. These will include confirmation that the use is appropriate for the patient at that time as well as the physical state of the product.

- Sufficient data and information about the medicine should be available to the staff and/or patient to enable them to identify the product and use it correctly. As a minimum this would comprise the patient information leaflet.

- Where any of the above conditions are not met, the medicine should not be used for treating the patient.

- When patients assume responsibility for their medicines under self-administration schemes, information and advice about maintaining the integrity of the medicine should be given.

5.7 Safety from medicines (staff and patients)

- The risks associated with the handling or administration of any medicine should be assessed for both staff and patients.

- A procedure should be available and followed to minimise the risks during receipt, storage, preparation, administration or disposal of the medicine.

- The risk assessment and procedure should reflect any legal requirements specific to the individual medicine or class of medicines.

- If a medicine without marketing authorisation is used or if a medicine is to be used knowingly outside its marketing authorisation, then the organisation should have an appropriate policy for this as part of its medicines management/clinical governance arrangements.

- Equipment, devices and protective clothing should be available at the point of handling, as specified in the risk minimisation procedure.

- Training should be given to those handling any medicine and, where appropriate, competency checks should be carried out at suitable intervals.

- A standard operating procedure (SOP) should cover actions to be taken, including reporting and record keeping, in the event of unplanned incidents such as spillages.

- The organisation should have a policy for dealing with products recalls (Drug Alerts issued by the MHRA).

5.8 Responsibility/accountability

- The person accountable for any activity should be specified in the written documentation.

- Persons who may accept responsibility for any activity should be defined in the documentation.

- Persons authorised to undertake tasks must comply with legal regulations and/or local or relevant national policy requirements.

- The person assuming responsibility or accountability for a task should ensure that any registration or training requirements are met.

- Tasks should not be delegated to a member of staff who is not legally entitled, authorised or appropriately trained to carry out these tasks.

Chapter 6

Self-administration of Medicines

6.1 Patients may retain or assume responsibility for some or all of their own medicines during their stay in a hospital. Any transfer of responsibility should occur on the basis of an assessment of the patient's ability to manage the tasks involved and with the patient's agreement. The patient's agreement should be recorded with the date and time.

6.2 Schemes for this transfer of responsibility may incorporate a stage in which the patient undertakes self-administration under direct supervision of an authorised member of staff.

6.3 Safe and secure processes will be needed to ensure that the patient has controlled access to an adequate supply of the correct medicines, appropriately stored so that they are fit for use, and that the medicines cannot be subject to unauthorised removal e.g. by other patients

6.4 The organisation should have a policy for self-administration of medicines (SAM) that covers all of these issues. (See also Guidelines for the Administration of medicines. Nursing and Midwifery Council 2002)

Chapter 7

Training and Personnel

7.1 Training

7.1.1 All staff involved in the handling of medicines should be appropriately trained with regard to safety and security of medicines and with regard to safeguarding themselves and those under their supervision from any risks posed by products (e.g. cytotoxic or radioactive medicines)

7.1.2 Such training should include education about locally agreed procedures, as well as defining lines of responsibility and secure methods of handling both medicines and controlled stationery. It should also include advice on secure delegation of work (e.g. rotation of ward or department staff carrying out physical checks of stock).

7.1.3 All staff should understand their scope of practice, and work within it, and must be clearly instructed as to what documentation they may and may not complete.

7.1.4 Clear instruction should also be given in the procedures for dealing with breaches of security such as intruders, discovery of evidence of tampering with medicines etc., or delivery of medicines outside the pharmacy department, including clinical trials materials or samples.

7.1.5 Personnel whose duties may expose them to risk (e.g. porters, transport drivers, stores employees or those carrying medicines into the community) should be trained to ensure understanding of the need for security and laid-down procedures. This should include instruction on the action to be taken in the event of physical threat.

7.1.6 Personnel involved in handling medicines should be trained to ensure understanding of the need for risk management in relation to drug products and procedures.

Chapter 8

Clinical Trials

Introduction

Medicines are subject to human testing prior to licensing and established products may be investigated for new indications. Such testing is regulated by the EU Clinical Trials Directive (EC Directive 2001/20/EC), published in April 2001, and transposed into UK legislation by Regulations in May 2004. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for its implementation and monitoring and detailed guidance can be found at the MHRA website ((www.mhra.gov.uk). The Medical Research Council and the Department of Health have formed a Joint Project that has provided examples of good practice for clinical trials.

8.1 Each organisation should have a policy for medicines under investigation. Such policies should comply with the United Kingdom Regulations, transposing the provisions of EC Directive 2001/20/EC, and the principles of Good Clinical Practice (GCP) set out therein.

8.1.1 As part of the requirements, all clinical trials that fall under the Regulations, including those on human volunteers or patients, will require a favourable opinion from an ethics committee and an authorisation from the MHRA. All investigational medicinal products will need to be manufactured to Good Manufacturing Practice (GMP) Standards and trial sites will be subject to MHRA GCP inspection.

8.2 There are a variety of types of trial, some of which are comparisons of existing marketed products used within their licensed indications. However, as many products under investigation may be unfamiliar to the staff handling them and/or may be coded to prevent ready identification by either the investigator or the patient, extra precautions need to be taken with these products to ensure safety and security in their use.

8.2.1 The relevant pharmacist should hold a copy of all trial protocols, including codes and all patient information sheets for studies being undertaken in either the hospital or community services.

8.2.2 The general route of purchasing, distribution and storage of clinical trial products should follow that of other medicines, except where there are special arrangements for supplies for commercial company trials of new medicines.

8.2.2.1 Stocks of trial medicines should not be maintained on wards, clinics, university departments or in private offices unless the trial involves a medicine used in an emergency situation, when sufficient stocks should be held in the ward or department for immediate use.

8.2.3 In-hospital or clinic administration of medicines to trial participants should be in accordance with locally agreed procedures.

8.2.3.1 The patient information sheet (part of the informed consent package) should be available when medicines are given as part of a clinical trial.

8.2.4 Records should be kept of receipt, dispensing, issue, administration, and disposal of all medicines to facilitate reconciliation. Pharmacies should create standard operating procedures (SOPs) for the receipt, dispensing, issue, and disposal of clinical trial medicines. (E.g. following the guidelines prepared by the Institute for Clinical Research (www.acrpi.com) booklet, SOPs and Checklists for Pharmacy Personnel.)

8.2.4.1 The identities of all those involved with receipt, dispensing, issue, administration, and disposal of all medicines should also be recorded.

8.2.4.2 Records should be regularly audited by pharmacy staff, with reconciliation. They will also be subject to external audit by e.g. the MHRA, independent clinical trial monitors and the organisation's own R&D staff.

8.3 Risk Management

8.3.1 Risk management measures should follow the local risk management policy

8.3.1.1 Risk assessments should be carried out in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

8.3.1.2 Risk management procedures should be in place to minimise the risks from trial medicines or procedures to patients and staff.

Chapter 9

Wards and Other Bedded Units

Introduction

The guidelines in this section are intended to apply to all wards. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Many aspects may be applied to community hospitals and the private and voluntary health care establishments, continuing care establishments and community developments. (see also The Administration and Control of medicines in Care Homes and Children's Services. RPSGB, 2003)

9.1 The System for Security of Medicines

9.1.1 All wards should have standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them (see Chapter 5). Appropriate pharmaceutical advice must be sought in the development of systems for the safe and secure handling of medicines.

9.1.1.1 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

9.2 Responsibility

9.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with appropriate medical staff and senior nursing staff. Where no pharmacist is employed by the organisation, the Registered Manager or manager with designated responsibility for the unit should take responsibility and seek pharmaceutical advice when necessary.

9.2.2 The Appointed Nurse in Charge should have the responsibility for ensuring that the system is followed and that the security of medicines on the ward is maintained. Where no nurse is employed by the organisation, the Registered Manager or manager with designated responsibility for the unit will take responsibility.

9.2.3 The Appointed Nurse in Charge may decide to delegate some of the duties but the responsibility always remains with the Appointed

Nurse in Charge. Where no nurse is employed by the organisation, the Registered Manager will take responsibility.

9.3 Medicines Brought Into Hospital by Patients

9.3.1 Patients may bring their current and/or old medicines with them on admission. This may be hospital policy so that the health care practitioner/ Registered Manager can see what treatment regimen the patient is following and /or it may be because the organisation has a policy of using patients' own medicines (PODs) in some circumstances (e.g. respite care).

9.3.2 There should be a local policy for managing the medicines that patients bring in with them.

9.3.3 Local policies should be drawn up in consultation with an appropriate pharmacist and should take into account the current guidance on consent (www.dh.gov.uk) and that:

9.3.3.1 These medicines are the property of the patient, and should not, therefore, be destroyed or otherwise disposed of without the agreement of the patient or the patient's agent.

9.3.3.2 Medicines brought in by the patient should only be used in the hospital when they can be positively identified, meet defined quality criteria and are appropriately labelled. They should be approved for use by appropriately-trained staff. Where this is not the case, the patient should be advised accordingly.

9.3.4 One of the following procedures should be followed and all actions should be recorded:

9.3.4.1 The medicines may be retained on the ward, for the sole use of the patient. Responsibility and arrangements for security are the same as with all ward medicine stocks.

9.3.4.2 The medicines may be securely stored by the organisation until returned to the patient prior to or upon discharge.

9.3.4.3 If the patient or the patient's agent agrees, medicines may be sent to the pharmacy for destruction. The pharmacist should take responsibility for their destruction.

9.3.4.4 If the patient insists, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult. The patient and/or patient's agent should be advised if the medicines are not safe and/or appropriate for use.

9.4 Medicines Supplied by Pharmacy Department

9.4.1 A list of stock medicines to be held on the ward should be decided by a pharmacist in consultation with appropriate medical staff and the Appointed Nurse in Charge.

9.4.1.1 Pharmacy staff should determine the amount of each stock medicine to be held at any time from usage patterns. This amount should be stated on the record of ward orders. This may be done automatically using computer-controlled systems and electronic orders.

9.4.1.2 The list should be subject to a regular review at agreed intervals.

9.5 Ordering and Records

9.5.1 The Appointed Nurse in Charge or a member of the pharmacy staff (e.g a designated pharmacy technician) should be responsible for ordering medicines from the pharmacy for maintaining ward stocks and for individual patients.

9.5.1.1 Orders should be in a permanent record and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

9.5.1.2 Where order books are used they should be considered as controlled stationery, and stocked only in the pharmacy. Their issue should be limited to Designated Persons. Access to electronic ordering systems should be similarly secure e.g. via password.

9.5.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

9.5.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e., by confirming signatures or by using computer pass-codes).

9.6 Receipt and Records

9.6.1 Medicines coming on to the ward should be received by a Designated Person who should check them against the requisition and record that a check has been made. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

9.6.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

9.6.3 Medicines intended for patients to take home on discharge and which have been obtained directly from the pharmacy on the authorisation of an authorised prescriber should be securely stored on the ward in a way that allows them to be readily identified and separated from ward stocks. If there is a "one-stop" dispensing procedure in operation then these items will also be used for inpatient treatment. Local procedures should ensure that appropriate records of these medicines are maintained.

9.7 Samples and Clinical Trial Materials

9.7.1 Samples and clinical trial materials should be received from the manufacturer or his representatives only by a pharmacist. They should not be accepted on the ward, but if found there they should be sent to the pharmacy department. Wards may participate in clinical trials with appropriate staff and training etc (see Chapter 8).

9.7.2 Properly-labelled clinical trial medicines brought in by a patient on admission, as part of current medication, can be checked by an authorised prescriber in the ward setting, noted, prescribed and administered as directed.

9.8 Security of Ward Medicine Stocks

9.8.1 The security of hospital ward stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of ward stocks, with reconciliation where necessary.

9.9 Storage of Medicines on the Ward

9.9.1 On the ward the responsibility for the safekeeping of the medicines rests with the Appointed Nurse in Charge.

9.9.2 There should be separate lockable ward cupboards as follows:

a. Controlled Drugs Cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973)
b. Internal Medicines Cupboard
c. External Medicines Cupboard
d. Refrigerator/freezer for medicines

and separate storage should be provided as follows:

e. Cupboard for diagnostic reagents, including urine testing
f. Area for intravenous fluids and sterile topical fluids
g. Areas (separate) for flammable fluids and gases.

9.9.2.1 Drug cupboards to be used for internal and external medicines should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

9.9.2.2 Where computer controlled cabinets are used for medicines they should provide at least the same level of security as traditional, lockable cupboards.

9.9.2.3 Medicine trolleys should be lockable and immobilised when not in use.

9.9.2.4 When schemes for self-administration of medicines and/or 'one-stop dispensing' are in operation on the ward each patient involved in the scheme should have a lockable receptacle for medicines (e.g. drawer, individual cupboard), which is not readily portable.

9.9.2.5 The Appointed Nurse in Charge of a ward should be responsible for controlling access (by keys or other means) to the medicine cupboards and trolley.

9.9.2.6 The responsibility remains with the Appointed Nurse in Charge even if he/she decides to delegate the duty.

9.9.2.7 A second set of keys should be kept in an appropriate, secure location.

9.9.2.8 For clinical emergencies, e.g. cardiac arrest, all wards should have a source of urgent medicinal products.

9.9.2.9 These should be held in boxes clearly marked "for emergency use".

9.9.2.10 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites. (see also 5.5)

9.9.2.11 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

9.10 Authorisation for Administration of Medicines

9.10.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authorisation is given in one of three ways:

9.10.1.1 — an instruction written by a medical practitioner/authorised prescriber on an official chart, or in the electronic prescribing system;

9.10.1.2 — in accordance with locally-agreed clinical procedures;

9.10.1.3 — in accordance with Patient Group Directions, for patients recently admitted to the ward but not examined by a doctor since admission.

9.11 Administration of Medicines to Patients

9.11.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, section 5.6)

9.11.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, section 5.7)

9.11.3 Administration to the patient should be in accordance with locally-agreed procedures, and will be accomplished in one of four ways:

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Self-administration by an in-patient. (See Chapter 6)

— Administration by a suitably-trained person

9.11.4 Where a system of one-nurse administration is used, the nurse should follow full, locally-agreed checking procedures.

9.11.5 A record of administration should be made, and the administering nurse identified.

9.11.6 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

9.11.7 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse.

9.11.8 For continuous administration (e.g. via intravenous infusions, or syringe drivers) there should be a record of those involved in setting-up the medication and of those involved in monitoring the administration.

9.12 Disposal of Medicines (also see Chapter 19)

9.12.1 Out-of-date medicines and any stock no longer required should be returned to the pharmacy with appropriate security precautions.

9.12.2 The Assigned Nurse in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

9.12.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework. The senior pharmacist should be responsible for devising such local procedures

Other Medicines Liable to Diversion

9.12.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

9.13 Risk Management

9.13.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

9.13.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the ward.

Chapter 10

Operating Departments

Introduction

The guidelines in this section are intended to apply to all areas of Operating Departments. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas which have a limited staff presence may need special precautions.

10.1 The System for Security of Medicines

10.1.1 The Operating Department should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them (see Chapter 5).

10.1.1.1 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

10.2 Responsibility

10.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of the Senior Pharmacist in consultation with the Operating Department manager, appropriate medical staff and senior nursing staff. Where no pharmacist is employed by the organisation, the Registered Manager should take responsibility and seek pharmaceutical advice when necessary.

10.2.2 The Appointed Nurse in Charge should have the responsibility for ensuring that the system is followed and that the security of medicines in the Department is maintained.

10.2.3 The Appointed Nurse in Charge may decide to delegate some of the duties but the responsibility always remains with the Appointed Nurse in Charge.

10.2.4 Responsibility of individuals within the Operating Department may be summarised as follows:

10.2.4.1 The Appointed Nurse in Charge is responsible for:

— receiving, checking and recording stock from Pharmacy

— the secure storage of stock

10.2.4.2 If a pharmacy-led top-up system is in operation then authority for receiving, checking and recording stock from Pharmacy may be delegated to a suitable member of the pharmacy staff but the Appointed Nurse in Charge will retain overall responsibility. If a computer-controlled drug cabinet is in use it should be designed to ensure secure storage.

10.3 Medicines Supplied by Pharmacy Department

10.3.1 A list of the medicines to be held in the Department should be decided by the Senior Pharmacist in consultation with the Operating Department manager, appropriate medical staff and the Appointed Nurse in Charge.

10.3.1.1 The list should be subject to a regular review at agreed intervals.

10.3.1.2 Pharmacy staff should determine the amount of each medicine to be held at any time from usage patterns. This should be stated on the record of department orders. This may be done automatically using computer-controlled systems and electronic orders.

10.4 Ordering and records

10.4.1 A Designated Person should be responsible for ordering medicines from the pharmacy to maintain department stocks.

10.4.1.1 This will normally be the Appointed Nurse in Charge of the Operating Department or where a "satellite" dispensary exists, the pharmacist in charge. If a pharmacy-led top-up system is in operation then the designated member of pharmacy staff should be responsible. If a computer-controlled drug cabinet is in use, ordering may be manual or automatic.

10.4.1.2 All orders should be in a permanent record. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

10.4.1.3 Where order books are used they should be considered as controlled stationery, and stocked only in the pharmacy. Their issue should be limited to Designated Persons. A Controlled Drugs order book should be kept separately and locked away. Access to electronic ordering systems should be similarly secure e.g. via password.

10.4.1.4 Where ordering is done using computer technology access to passcodes/terminals should be restricted to Designated Persons.

10.4.1.5 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an appropriate person (i.e. by confirming signatures or by using computer pass-codes).

10.5 Receipt and Records

10.5.1 Medicines coming into the department should be received by a Designated Person who should check them against the requisition and record that a check has been made. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

10.5.1.1 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

10.6 Samples and Clinical Trial Materials

10.6.1 Samples and clinical trial materials should be received from the manufacturer or his representatives only by a pharmacist. They should not be accepted in the Operating Department, but if found there they should be sent to the pharmacy department. Clinical trials of surgery involving medicines may fall within the ambit of the Clinical Trials Directive when additional considerations are necessary (see Chapter 8).

10.7 Security of Theatre Medicine Stocks

10.7.1 The security of Operating Department stocks should be checked by pharmacy staff periodically, in accordance with designated procedures. They should carry out inspections of department stocks, with reconciliation where necessary.

10.8 Storage in Department

10.8.1 In the Operating Department, the responsibility for the safekeeping of the medicines rests with the Appointed Nurse in Charge.

10.8.2 There should be separate lockable cupboards as follows:

a. Controlled Drugs Cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973)
b. Internal Medicines Cupboard
c. External Medicines Cupboard
d. Refrigerator/freezer for medicines

and separate storage should be provided as follows:

e. Cupboard for diagnostic reagents, including urine testing
f. Area for intravenous fluids and sterile topical fluids
g. Areas (separate) for flammable fluids and gases.

10.8.3 Drug cupboards to be used for internal and external medicines should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

10.8.4 Where computer controlled cabinets are used for medicines, they should provide the same level of security as traditional, lockable cupboards.

10.8.5 The Appointed Nurse in Charge should be responsible for controlling access (by key or other means) to the medicine cupboards.

10.8.6 To ensure that medicines are readily available, the Appointed Nurse in Charge may delegate control of access to a qualified deputy or medical practitioner (e.g. anaesthetist) or, exceptionally, to an Operating Department Practitioner (ODP) or an Operating Department Assistant (ODA).

10.8.7 The responsibility for all medicines remains with the Appointed Nurse in Charge, even if he/she decides to delegate the duty of controlling access.

10.8.7.1 A second set of keys should be kept in an appropriate, secure location.

10.8.8 When the theatre is not in use, or between operating sessions, all medicines should be returned to lockable medicine cupboards.

10.8.9 There should be a local policy for secure storage of emergency and resuscitation medicines held in the Operating Department.

10.9 Authorisation for Administration of Medicines

10.9.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of two ways:

10.9.1.1 — an instruction written by a medical practitioner/ authorised prescriber on an official chart or in the electronic prescribing system;

10.9.1.2 — in accordance with locally agreed clinical procedures;

10.10 Administration of Medicines to Patients

10.10.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

10.10.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

10.10.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of three ways:

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably-trained person

10.10.4 A record of all administrations should be made. For Controlled Drugs, Theatre Controlled Drugs Registers should show issue, receipt, form of administration (including administration via intravenous infusion or driven syringes), names of patients receiving the Controlled Drugs and ampoules/vials returned/disposed of.

10.10.4.1 For continuous administration (e.g. via intravenous infusion or driven syringes) there should be a record of those involved in setting-up the medication, including the witness.

10.10.5 Where a system of one-nurse administration is used, the nurse should follow full, locally-agreed checking procedures.

10.10.6 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse.

10.10.7 For Controlled Drugs, the prescriber concerned in each transaction should sign for the medicines received on the Controlled Drugs Register and record the amount of drug administered on the anaesthetic record in the patient's notes.

10.11 Disposal of Medicines (also see Chapter 19)

10.11.1 Out-of-date medicines and any stock no longer required should be returned to the pharmacy, with appropriate security precautions.

10.11.2 The Assigned Nurse in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

10.11.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework. The senior pharmacist should be responsible for devising such local procedures

Other Medicines Liable to Diversion

10.11.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

10.12 Risk Management

10.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

10.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the ward.

Chapter 11

Emergency Departments and Outpatient Departments

Introduction

The guidelines in this section are intended to apply to all areas of Accident and Emergency departments and outpatient departments. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas that provide open access to the public, or have a limited staff presence may need special precautions.

11.1 The System for Security of Medicines

11.1.1 Each department should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them. (see Chapter 5)

11.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

11.2 Responsibility

11.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with appropriate medical staff and the senior nursing staff.

11.2.2 The Appointed Nurse in Charge should have the responsibility for ensuring that the system is followed and that the security of medicines in the Department is maintained.

11.2.3 The Appointed Nurse in Charge may decide to delegate some of the duties but the responsibility always remains with the Appointed Nurse in Charge.

11.3 Medicines Coming into the Department with the Patient

11.3.1 Patients seen in the Department may bring old or current medication with them. Such medicines should stay with the patient for the admission process. Proper evaluation will only be possible after admission.

11.3.2 There should be a local policy for managing the medicines that patients bring in with them.

11.3.3 Local policies should be drawn up in consultation with an appropriate pharmacist and should take into account the current guidance on consent (www.dh.gov.uk) and that:

11.3.3.1 These medicines are the property of the patient, and should not, therefore, be destroyed or otherwise disposed of without the agreement of the patient or the patient's agent.

11.3.3.2 Medicines brought in by the patient should only be used in the hospital when they can be positively identified, meet defined quality criteria and are appropriately labelled. They should be approved for use by appropriately-trained staff. Where this is not the case, the patient should be advised accordingly.

11.3.4 Should the patient be admitted as an in-patient, then the medicines should be handled according to the procedures set out in section 9.3

11.4 Medicines Supplied by Pharmacy Department

11.4.1 A list of medicines to be held in the Department should be determined by pharmacy staff with appropriate consultation.

11.4.1.1 Pharmacy staff should determine the amount of each medicine to be held at any time from usage patterns. This amount should be stated on the records of department orders. This may be done automatically using computer-controlled systems and electronic orders.

11.4.1.2 The list should be subject to a regular review at agreed intervals.

11.5 Ordering and Records

11.5.1 The Appointed Nurse in Charge or a member of the pharmacy staff should be responsible for ordering medicines from the pharmacy to maintain department stocks and for individual patients.

11.5.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

11.5.1.2 Where order books are used they should be considered as controlled stationery, and stocked only in the pharmacy. Their issue should be limited to Designated Persons. Access to electronic ordering systems should be similarly secure e.g. via password.

11.5.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

11.5.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or by using computer pass codes).

11.6 Receipt and Records

11.6.1 Medicines coming into the Department should be checked against the requisition by a Designated Person who should record that a check has been made. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

11.6.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal frame-work. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

11.7 Samples and Clinical Trial Materials

11.7.1 Samples and clinical trial materials should be received, from the manufacturer or his representatives only by a pharmacist. They should not be accepted in the Department, but if found there they should be sent to the pharmacy department. If patients attending the Emergency Department are found to be participants in a clinical trial, the relevant trial sponsor or investigator should be informed at once.

11.8 Security of Department Medicine Stocks

11.8.1 The security of department stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of department stocks, with reconciliation where necessary.

11.9 Storage of Medicines in the Department

11.9.1 In the Department, the responsibility for the safekeeping of the medicines rests with the Appointed Nurse in Charge.

11.9.2 There should be separate lockable medicines cupboards as follows:

a. Controlled Drugs Cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973)
b. Internal Medicines Cupboard
c. External Medicines Cupboard
d. Refrigerator/freezer for medicines

and separate storage should be provided as follows:

e. Cupboard for diagnostic reagents, including urine testing
f. Area for intravenous fluids and sterile topical fluids
g. Areas (separate) for flammable fluids and gases.

11.9.3 Drug cupboards to be used for internal and external medicines should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

11.9.3.1 Where there is perceived to be an extra risk, the advice of security specialists or Crime Prevention Officers, in consultation with the Senior Pharmacist, should be sought.

11.9.4 Where computer controlled cabinets are used for medicines, they should provide the same level of security as traditional, lockable cupboards.

11.9.5 Medicine trolleys should be lockable and immobilised when not in use.

11.9.6 The Appointed Nurse in Charge should be responsible for controlling access (by keys or other means) to the medicines cupboards and trolley.

11.9.6.1 The responsibility remains with the Appointed Nurse in Charge even if he/she decides to delegate the duty.

11.9.7 A second set of keys should be kept in an appropriate, secure location.

11.9.8 Where emergency bags or kits are held (e.g. for emergency teams working outside hospitals, or for major incidents), and it is impractical for these to be locked away they should be placed in an area that is most likely to have a constant staff presence.

11.9.8.1 These kits should be tamper-evident, and once a kit has been opened a replacement should be provided by the pharmacy and the opened kit returned to the pharmacy.

11.9.8.2 Neither the emergency kits themselves nor their contents should be obvious to the general public.

11.9.9 For clinical emergencies (e.g. cardiac arrest), emergency sources of urgent supplementary medicines may be held.

11.9.9.1 These should be held in boxes clearly marked "for emergency use".

11.9.9.2 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites.

11.9.9.3 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

11.10 Authorisation for Administration of Medicines to Patients

11.10.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

11.10.1.1 — an instruction written by a medical practitioner/authorised prescriber on an official chart or in the electronic prescribing system;

11.10.1.2 — in accordance with locally agreed clinical procedures;

11.10.1.3 — in accordance with Patient Group Directions, in the Emergency Department where the patient is not known, or a Patient Specific Direction in the Outpatient Department where the patients will be know (e.g. by referral letter from GP).

11.11 Administration of Medicines to Patients

11.11.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

11.11.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

11.11.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of three ways:

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably trained person

11.11.4 Where a system of one-nurse administration is used in hospitals the nurse should follow full, locally-agreed checking procedures.

11.11.5 A record of administration should be made, and the administering nurse identified.

11.11.6 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

11.11.7 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded. However, the ultimate responsibility remains with the administering nurse.

11.11.8 For continuous administration (e.g. via intravenous infusions, or driven syringes) there should be a record of those involved in setting-up the medication and of those involved in monitoring the administration.

11.12 Issue of Medicines to Patients

11.12.1 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

11.12.2 For systems in which "take-home" pre-packed medication is issued from the department, the senior pharmacist is responsible for ensuring that there is a legal system to ensure that all medicines handed out to patients are recorded and properly labelled.

11.12.2.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

11.13 Disposal of Medicines (also see Chapter 19)

11.13.1 Out-of-date medicines and any stock no longer required should be returned to the pharmacy, with appropriate security precautions.

11.13.2 The Assigned Nurse in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

11.13.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework. The senior pharmacist should be responsible for devising such local procedures

Other Medicines Liable to Diversion

11.13.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

11.14 Risk Management

11.14.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

11.14.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the ward.

Chapter 12

Intensive Therapy Units, Cardiac Care Units, and Transplant Units

Introduction

The guidelines in this section are intended to apply to all Intensive Therapy Units, Cardiac Care Units, and Transplant Units, however, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas where visitors have access may need special precautions.

12.1 The System for Security of Medicines

12.1.1 Each unit should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them. (see Chapter 5)

12.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

12.2 Responsibility

12.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with appropriate medical staff and the Appointed Nurse in Charge.

12.2.2 The Appointed Nurse in Charge should have the responsibility for ensuring that the system is followed and that the security of medicines on the unit is maintained.

12.2.3 The Appointed Nurse in Charge may decide to delegate some of the duties but the responsibility always remains with the Appointed Nurse in Charge.

12.3 Medicines Coming Into the Unit with the Patient

12.3.1 Patients admitted to one of these units may bring their current medication with them.

12.3.2 There should be a local policy for managing the medicines that patients bring in with them.

12.3.3 Local policies should be drawn up in consultation with an appropriate pharmacist and should take into account the current guidance on consent (www.dh.gov.uk) and that:

12.3.3.1 These medicines are the property of the patient and should not, therefore, be destroyed or otherwise disposed of without the agreement of the patient or the patient's agent.

12.3.3.2 Medicines brought in by the patient should only be used in the hospital when they can be positively identified, meet defined quality criteria and are appropriately labelled. They should be approved for use by appropriately-trained staff. Where this is not the case, the patient should be advised accordingly

12.3.4 One of the following procedures should be followed and all actions should be recorded:

12.3.4.1 The medicines may be retained on the Unit, for the sole use of the patient. Responsibility and arrangements for security are the same as for other medicines on the ward or unit.

12.3.4.2 The medicines may be stored by the organisation until returned to the patient prior to or upon discharge.

12.3.4.3 If the patient or the patient's agent agrees, medicines may be sent to the pharmacy for destruction. The pharmacist should take responsibility for their destruction.

12.3.4.4 If the patient insists, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult. The patient and/or patient's agent should be advised if the medicines are not safe and/or appropriate for use.

12.4 Medicines Supplied by Pharmacy Department

12.4.1 A list of stock medicines to be held in the Unit should be decided by the Senior Pharmacist in consultation with appropriate medical staff and the Appointed Nurse in Charge.

12.4.1.1 Pharmacy staff should determine the amount of each stock medicine to be held at any time from usage patterns. These should be stated on the records of unit orders. This may be done automatically using computer-controlled systems and electronic orders.

12.4.1.2 The list should be subject to a regular review at agreed intervals.

12.5 Ordering and Records

12.5.1 The Appointed Nurse in Charge, or designated member of the pharmacy staff should be responsible for ordering medicines from the pharmacy to maintain unit stocks and/or for individual patients.

12.5.1.1 Orders should be in a permanent record and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

12.5.1.2 Where order books are used they should be considered as controlled stationery, and stocked only in the pharmacy. Their issue should be limited to Designated Persons. Access to electronic ordering systems should be similarly secure e.g. via password.

12.5.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

12.5.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or by using computer pass codes).

12.6 Receipt and Records

12.6.1 Medicines coming on to the Unit should be checked against the requisition by a Designated Person who should also record that the check has been made. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

12.6.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

12.7 Samples and Clinical Trial Materials

12.7.1 Samples and clinical trial materials should be received from the manufacturer or his representatives only by a pharmacist. They should not be accepted in the Unit, but if found there they should be sent to the pharmacy department.

12.8 Security of Unit Stocks

12.8.1 The security of Unit stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of unit stocks with reconciliation where necessary.

12.9 Storage of Medicines in the Unit

12.9.1 In the Unit, the responsibility for the safekeeping of the medicines rests with the Appointed Nurse in Charge.

12.9.2 There should be separate lockable medicines cupboards as follows:

a. Controlled Drugs Cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973)
b. Internal Medicines Cupboard
c. External Medicines Cupboard
d. Refrigerator/freezer for medicines

and separate storage should be provided as follows:

e. Cupboard for diagnostic reagents, including urine testing
f. Area for intravenous fluids and sterile topical fluids
g. Areas (separate) for flammable fluids and gases.

12.9.3 Drug cupboards to be used for internal and external medicines should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

12.9.4 Where computer controlled cabinets are used for medicines, they should provide the same level of security as traditional, lockable cupboards.

12.9.5 Medicine trolleys should be lockable and immobilised when not in use.

12.9.6 The Appointed Nurse in Charge of the Unit should be responsible for controlling access (by keys or other means) to the medicines cupboards and trolley.

12.9.6.1 The responsibility remains with the Appointed Nurse in Charge even if he/she decides to delegate the duty.

12.9.7 A second set of keys should be kept in an appropriate, secure location.

12.9.8 For clinical emergencies (e.g. cardiac arrest) units should have sources of urgent supplementary medicinal products.

12.9.8.1 These should be held in boxes clearly marked "for emergency use".

12.9.8.2 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites.

12.9.8.3 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

12.10 Authorisation for Administration of Medicines

12.10.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authorisation is given in one of three ways:

12.10.1.1 — an instruction written by a medical practitioner/authorised prescriber on an official chart, or in the electronic prescribing system;

12.10.1.2 — in accordance with locally-agreed clinical procedures;

12.10.1.3 — in accordance with Patient Group Directions. (PGDs only apply to areas where a patient has been admitted but has not been assessed by a doctor e.g. CCU. It is unlikely that such a situation would arise in ITU or a Transplant Unit)

12.11 Administration of Medicines to Patients

12.11.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

12.11.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

12.11.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of three ways:

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines;

— Administration by a suitably qualified practitioner;

— Administration by a suitably trained person

12.11.4 Where a system of one-nurse administration is used, the nurse should follow full, locally-agreed checking procedures

12.11.5 A record of administration should be made, and the administering nurse identified.

12.11.6 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

12.11.7 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse.

12.11.8 For continuous administration (e.g. via intravenous infusions, or driven syringes) there should be a record of those involved in setting-up the medication and of those involved in monitoring the administration.

12.12 Disposal of Medicines (also see Chapter 19)

12.12.1 Out-of-date medicines and any stock no longer required should be returned to the pharmacy with appropriate security precautions.

12.12.2 The Assigned Nurse in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

12.12.3 Disposal of Controlled Drugs should follow the agreed local procedure and national guidance and must comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures.

Other Medicines Liable to Diversion

12.12.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

12.13 Risk Management

12.13.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

12.13.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the unit.

Chapter 13

Midwives

13.1 General

13.1.1 Midwives should comply with all the good practice guidance. In addition, midwives should pay special attention to the provisions relating to Controlled Drugs, and must also refer to the appropriate, up-to-date guidance in the National Prescribing Centre guidelines, Nursing and Midwifery Council Midwives' Rules and Code of Practice and follow any local policy and/or procedures specified by the Local Supervising Authority or the Supervisor of Midwives.

13.2 Supply and Administration of Controlled Drugs

13.2.1 The Misuse of Drugs Regulations 2001 in conjunction with the provisions of the Medicines Act 1968 provide for the supply of pethidine, pentazocine, morphine and diamorphine to midwives using a supply order signed by the Supervisor of Midwives, or other Appropriate Medical Officer.

13.2.1.1 The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate etc).

13.2.2 Supplies of pethidine, pentazocine, morphine and diamorphine should be obtained from a hospital pharmacy, a dispensing general practitioner within the territory in which the midwife works, or a pharmacist in the community to whom he/she has been officially introduced.

13.2.2.1 It should be the duty of the pharmacist or the dispensing GP to ensure that medicines are only supplied on the instruction of an authorised person.

13.2.3 Once medicines are received by midwives working in the community or independent midwives, they become the responsibility of the midwife, and should be stored safely and securely.

13.2.3.1 Where it is necessary for midwives to keep medicines in their homes, the medicines should be placed in a secure, locked fixture. If necessary, this should be provided by the employing body.

13.2.4 Midwives should record full details of supply and administration of pethidine or other Schedule 2 drugs in their Controlled Drugs Register, which should be made available for inspection as required by the Supervisor of Midwives.

13.2.4.1 Administration of Controlled Drugs by midwives should be in accordance with locally agreed procedures.

13.2.4.2 A record of administration of the Controlled Drugs should also be kept in the patient's records.

13.3 Supply and Administration of other Medicines

13.3.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

13.3.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

13.3.3 A list of medicines (prescription-only and others) which may be supplied to, and used by midwives in accordance with Part III of the Medicines Act 1968 and listed in Schedule 5 Parts I and III of the Prescription Only Medicines (Human Use) Order 1997 should be decided by the Supervisor of Midwives in accordance with local policy. Any medicines to be supplied or administered by a midwife under a PGD should be taken into account in compiling the list.

13.3.3.1 Medicines are usually obtained from the hospital pharmacy. Where the local arrangement is that medicines are obtained from the hospital Maternity Unit stock, the midwife should complete the Unit records.

13.3.3.2 Where local arrangement (e.g. for a rural area) is that a Community Pharmacist supplies these medicines, the pharmacist should keep a record of supply.

13.3.3.3 Midwives should keep a record of supply, administration and disposal of all prescription-only medicines issued to them.

13.3.4 When in the custody of the midwife, the midwife is responsible for the safe and secure transport and storage of medicines.

13.4 Return/Disposal of Controlled Drugs

13.4.1 When a midwife is in possession of reusable stock that is no longer required this should be returned to the pharmacist from whom it was obtained, or to an Appropriate Medical Officer.

13.4.1.1 A record of the return should be made.

13.4.2 When a Schedule 2 Controlled Drug has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current regulations. (see Appendix 1).

13.4.2.1 A record of the destruction should be made in the midwife's Controlled Drugs Register.

13.4.3 Controlled Drugs obtained by a woman by prescription from her doctor, for use in her home confinement are her own property and are not the midwife's responsibility. Even when no longer required they should not be removed by the midwife, but the woman should be advised to return them to the community pharmacy for destruction.

13.5 Return/Disposal of other Medicines

13.5.1 Where a midwife is in possession of other medicines, which are no longer required, but are still usable, they should be returned to the supplying pharmacy.

13.5.1.1 A record of the return of prescription-only medicines should be made in the midwife's record.

13.5.2 When a midwife returns a prescription-only medicine to the supplying pharmacist a receipt should be obtained, and an entry made in the midwife's records.

13.6 Audit of Records

13.6.1 Supervisors of midwives should, as part of their duties, periodically audit and reconcile the records of Controlled Drugs and prescription-only medicines kept by each midwife. Any discrepancies should be investigated.

13.7 Midwives Working in Hospitals and Birth Centres

13.7.1 Administration of Controlled Drugs and other medicines to patients by midwives working in hospitals should be in accordance with locally agreed procedures.

13.7.1.1 It may be locally decided that midwives within the hospital may follow the same practice as midwives working in the community, regarding administration of medicines. This is seen to pose no additional safety or security problems provided that full record-keeping procedures are strictly followed, noting that each patient should have only one medicine record.

13.8 Risk Management

13.8.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

13.8.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced.

Chapter 14

Community Health Services (including Sexual Health Clinics)

Introduction

The guidelines in this section are intended to apply to all Community Health Clinics. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas that have a high degree of public access may need special precautions.

14.1 The System for Security of Medicines

14.1.1 Each clinic site should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in it. (see Chapter 5) Appropriate pharmaceutical advice must be taken in the development of systems for the safe and secure handling of medicines.

14.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

14.2 Responsibility

14.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with medical staff and appropriate nurse manager. Where no pharmacist is employed by the organisation, the Registered Manager or manager with designated responsibility for the unit should take responsibility and seek pharmaceutical advice when necessary.

14.2.2 A Designated Person should control access to the medicines for each speciality or department on the site. That Designated Person should have responsibility for ensuring that the system is followed and that the security of medicines in the clinic site is maintained.

14.2.3 The Designated Person may decide to delegate some of the duties but the responsibility always remains with that Designated Person

14.3 Supply of Medicines

14.3.1 It is the responsibility of the senior pharmacist to ensure there is a secure method of supply and storage of medicines for Community Clinic sites.

14.3.1.1 A list of medicines to be held in the Clinic should be determined by pharmacy staff with appropriate medical staff and the clinic's nursing staff.

14.3.1.2 Pharmacy staff should determine the amount of each stock medicine to be held at any time from usage patterns. This amount should be stated on the record of medicine orders. This may be done automatically using computer-controlled systems and electronic orders.

14.3.1.3 The list should be subject to a regular review at agreed intervals.

14.4 Ordering and Records

14.4.1 One Designated Person should be responsible for ordering medicines from the pharmacy to maintain agreed stocks.

14.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

14.4.1.2 Where order books, pads of requisitions or prescriptions pads are used these should be treated as controlled stationery, and kept under lock and key by a Designated Person in the clinic. Access to electronic ordering systems should be similarly secure e.g. via password.

14.4.1.3 Prescription pads should only be held by qualified practitioners who have been issued with them and who should be responsible for their security.

14.4.1.4 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

14.4.1.5 It should be the duty of the community health services pharmacist to ensure that systems are in place to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or using computer pass-codes).

14.5 Receipt and Records

14.5.1 Medicines coming into the Clinic should be checked against the requisition by a Designated Person who should record that he/she has so checked.

14.5.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

14.6 Security of Clinic Medicine Stocks

14.6.1 The security of medicine stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of the clinic's stock, with reconciliation where necessary.

14.7 Storage of Medicines in the Clinic

14.7.1 On the clinic site the responsibility for the safekeeping of the medicines lies with the Designated Person who controls access to the medicines.

14.7.2 Lockable cupboards that comply with the relevant regulations should be used for the storage of medicines in the clinic.

14.7.2.1 If heat-sensitive products are kept (e.g. vaccines), a suitable dedicated fridge and/or deep freeze should also be available. There should be monitoring of the temperature of the refrigerator on each working day using a calibrated maximum-minimum thermometer or other approved monitoring device, which is recorded and signed by the person monitoring the temperature and a written procedure should be in place indicating the action to be taken if the temperature is outside the normal range.

14.7.2.2 Where premises are shared by a number of clinics, each clinic should be responsible for its own stock of medicines, which should be stored separately.

14.7.2.3 Medicine cupboards should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

14.7.3 Medicines for clinical emergencies should be held in packs clearly marked "for emergency use".

14.7.3.1 These packs should be tamper-evident and should be accessible to all practitioners during clinic sessions. They should be secured when the clinic or section is not running sessions.

14.7.3.2 Once a box has been opened, it should be replaced.

14.8 Authorisation for Administration of Medicines

14.8.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

14.8.1.1 — an instruction written by a medical, or dental practitioner or authorised prescriber on an official chart or in the electronic prescribing system; (this might be evidenced by the label on a dispensed medicine);

14.8.1.2 — in accordance with locally agreed clinical procedures;

14.8.1.3 — in accordance with Patient Group Directions, for new patients attending clinic or a Patient Specific Direction for patients who are returning to the clinic for a further supply.

14.9 Administration of Medicines to Patients

14.9.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

14.9.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

14.9.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of four ways:

— Self-administration by patient following out-patient dispensing.

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably trained person

14.9.4 A record of administration should be made, and the administering nurse/doctor/practitioner identified (e.g. an entry in the medicines record book or electronic health record (EHR).

14.9.5 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

14.9.6 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse/doctor.

14.10 Issue of Medicines to Patients

14.10.1 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

14.10.2 Contraceptive pills are prescription only medicines and should be issued accordingly.

14.10.3 For systems in which "take-home" pre-packed medication is issued from the department, the senior pharmacist is responsible for ensuring that there is a legal system to ensure that all medicines handed out to patients are recorded and properly labelled.

14.10.3.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

14.11 Disposal of medicines (see Chapter 19)

14.11.1 Out-of-date medicines and any stock no longer required should be returned to the supplying pharmacy, with appropriate security precautions.

14.11.2 Designated staff should be responsible for their return

Controlled Drugs

14.11.3 Disposal of Controlled Drugs should follow the agreed local procedure and national guidance and must comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures

Other Medicines Liable to Diversion

14.11.4 Any medicine liable to diversion should be disposed of in a safe and secure manner. Disposal of individual doses of other medicines, which are liable to diversion and which have not been administered, should follow an agreed local procedure. The senior pharmacist should be responsible for devising such local procedures.

14.11.5 Sealed unit doses need not be destroyed and may be returned to clinic stock. This action should be recorded.

14.12 Risk Management

14.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

14.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the clinic.

Chapter 15

Walk-in Centres and Minor Injuries Units

Introduction

The guidelines in this section are intended to apply to NHS Walk-in Centres and Minor Injuries Units. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas which have a high degree of public access may need special precautions.

15.1 The System for Security of Medicines

15.1.1 Each Walk-in Centre/ Minor Injuries Unit site should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in it. (see Chapter 5)

15.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

15.2 Responsibility

15.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with medical staff and appropriate nurse manager. Where no pharmacist is employed by the organisation, the Registered Manager should take responsibility and seek pharmaceutical advice when necessary.

15.2.2 A Designated Person (who should be a professional) should control access to the medicines. That Designated Person should have responsibility for ensuring that the system is followed and that the security of medicines in the Walk-in Centre/ Minor Injuries Unit site is maintained.

15.2.3 The Designated Person may decide to delegate some of the duties but the responsibility always remains with that Designated Person.

15.3 Supply of Medicines

15.3.1 It is the responsibility of a senior pharmacist to ensure there is a secure method of supply and storage of medicines for NHS Walk-in Centre/ Minor Injuries Unit sites. Where no pharmacist is employed by the organisation, the Registered Manager should take responsibility for this.

15.3.1.1 A list of all stock medicines should be decided by the WIC nursing staff, who should seek pharmaceutical advice when necessary.

15.3.1.2 The amount of each stock medicine to be held at any time should be reviewed periodically and pharmaceutical advice sought, if necessary. This amount should be stated on the record of medicine orders. This may be done automatically using computer-controlled systems and electronic orders.

15.3.1.3 The list should be subject to a regular review at agreed intervals.

15.4 Ordering and Records

15.4.1 One Designated Person (but not a lay-worker) should be responsible for ordering medicines from the pharmacy to maintain agreed stocks.

15.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

15.4.1.2 Where order books, pads of requisitions or prescriptions pads are used these should be treated as controlled stationery, and kept under lock and key by a Designated Person in the Walk-in Centre/ Minor Injuries Unit. Access to electronic ordering systems should be similarly secure e.g. via password.

15.4.1.3 Prescription pads should only be held by qualified practitioners who have been issued with them and who should be responsible for their security.

15.4.1.4 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

15.4.1.5 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or using computer pass-codes).

15.5 Receipt and Records

15.5.1 Medicines coming into the Walk-in Centre/ Minor Injuries Unit should be checked against the requisition by a Designated Person who should record that he/she has so checked.

15.5.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures. Where no pharmacist is employed by the organisation, the Registered Manager will take responsibility for this. (see Appendix 1).

15.6 Security of Clinic Medicine Stocks

15.6.1 The security of medicine stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of the Walk-in Centre's/ Minor Injuries Unit's stock, with reconciliation where necessary. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

15.7 Storage of Medicines

15.7.1 On the Walk-in Centre/ Minor Injuries Unit site the responsibility for the safekeeping of the medicines lies with the Designated Person who controls access to the medicines.

15.7.2 Lockable cupboards should be used for the storage of medicines in the Walk-in Centre/ Minor Injuries Unit.

15.7.2.1 If Controlled Drugs are kept then a cupboard that complies with the Misuse of Drugs (Safe Custody) Regulations 1973 will be required.

15.7.2.2 If heat-sensitive products are kept (e.g. vaccines), a suitable dedicated fridge and/or deep freeze should also be available. There should be monitoring of the temperature of the refrigerator on each working day using a calibrated maximum-minimum thermometer or other approved monitoring device, which is recorded and signed by the person monitoring the temperature and a written procedure should be in place indicating the action to be taken if the temperature is outside the normal range.

15.7.2.3 Where premises are shared by a number of clinics, each should be responsible for its own stock of medicines.

15.7.2.4 Medicine cupboards should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

15.7.3 Medicines for clinical emergencies should be held in boxes clearly marked "for emergency use".

15.7.3.1 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites.

15.7.3.2 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

15.8 Authorisation for Administration of Medicines

15.8.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

15.8.1.1 — an instruction written by a medical, dental practitioner or authorised prescriber on an official chart or in the electronic prescribing system;

15.8.1.2 — in accordance with locally agreed clinical procedures;

15.8.1.3 — in accordance with Patient Group Directions.

15.9 Administration of Medicines to Patients

15.9.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

15.9.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

15.9.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of four ways:

— Self-administration by patient following out-patient dispensing.

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably trained person

15.9.4 A record of administration should be made, and the administering nurse/doctor/practitioner identified (e.g. an entry in the medicines record book or electronic health record (EHR).

15.9.5 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

15.9.6 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse/doctor.

15.10 Issue of Medicines to Patients

15.10.1 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

15.10.2 Contraceptive pills are prescription only medicines and should be issued accordingly.

15.10.3 For systems in which "take-home" pre-packed medication is issued from the department, pharmaceutical advice should be sought to ensure that there is a legal system to ensure that all medicines handed out to patients are recorded and properly labelled.

15.10.3.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

15.11 Disposal of medicines (see Chapter 19)

15.11.1 Out-of-date medicines and any stock no longer required should be returned to the supplying pharmacy, with appropriate security precautions.

15.11.2 Designated staff should be responsible for their return.

Controlled Drugs

15.11.3 Disposal of Controlled Drugs should follow the agreed local procedure and national guidance and must comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures. Where no pharmacist is employed by the organisation, the Registered Manager will take responsibility.

Other Medicines Liable to Diversion

15.11.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

15.12 Risk Management

15.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

15.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the Walk-in Centre or Minor Injuries Unit.

Chapter 16

Drug Addiction Treatment Units

Introduction

The security system devised for each Drug Addiction Treatment Unit should be suitable for the degree of risk perceived to be involved. In view of the large amounts of Controlled Drugs in use in the Units staff should receive additional training to ensure that they have a good understanding of the legal framework, the need for security and laid-down procedures. Training should include appropriate action to be taken in the event of physical threat. (Also see Chapter 7 -Training and Personnel)

16.1 The System for Security of Medicines

16.1.1 Each unit should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them. (see Chapter 5)

16.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

16.2 Responsibility

16.2.1 The responsibility for establishing and maintaining a system for the security of the Unit's medicines should be that of the Senior Pharmacist in consultation with appropriate medical staff and senior nursing staff. Where no pharmacist is employed by the organisation, the Registered Manager should take responsibility and seek pharmaceutical advice when necessary.

16.2.2 One doctor or the Appointed Nurse in Charge should be designated responsible for control of access to the Unit's medicines and should therefore have responsibility for ensuring that the system is followed and that the security of medicines in the Unit is maintained.

16.2.3 The Designated Person who controls the access to the Unit's medicines may decide to delegate some of the duties but the responsibility always remains with that Designated Person.

16.2.4 Where patients have medicines prescribed for their own use, which are kept in their homes and only brought to the Unit for self-administration, these should, where possible, remain the responsibility of the patients themselves and a lockable receptacle should be provided for their storage.

16.3 Supply of Medicines

16.3.1 It is the responsibility of a Senior Pharmacist to ensure that there is a secure method of supply and storage of medicines for Drug Treatment Units.

16.3.2 A list of all stock medicines to be held should be decided by a pharmacist in consultation with appropriate medical staff and the Unit's nursing staff.

16.3.3 Pharmacy staff should determine the amount of each stock medicine to be held at any time from usage patterns. This amount should be stated on the record of medicine orders. This may be done automatically using computer-controlled systems and electronic orders.

16.3.4 The list should be subject to a regular review at agreed intervals.

16.3.5 The method and frequency of delivery should be decided by pharmacy staff in consultation with appropriate medical staff and senior nursing staff. The advantages of irregular delivery patterns, to increase security, should be considered.

16.4 Ordering and Records

16.4.1 One Designated Person (but not a lay-worker) should be responsible for ordering medicines from the pharmacy, to maintain agreed stocks.

16.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

16.4.1.2 Where order books or pads of requisitions are used these should be treated as controlled stationery, and kept under lock and key by a Designated Person Their issue should be limited to Designated Persons. Access to electronic ordering systems should be similarly secure e.g. via password.

16.4.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

16.4.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or using computer pass-codes).

16.4.2 Where prescription pads are held in a unit their security should be the responsibility of qualified practitioners, who should keep them locked away.

16.5 Receipt and Records

16.5.1 Medicines coming into the Unit should be checked against the requisition and a Designated Person should record that he/she has so checked. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

16.5.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

16.6 Security of Unit Medicine Stocks

16.6.1 The security of medicine stocks should be checked by pharmacy staff periodically, normally every three months, in accordance with locally agreed procedures. They should carry out inspections of the Unit stocks, with reconciliation where necessary.

16.7 Storage of Medicines

16.7.1 In the Unit, the responsibility for the security of medicines lies with the Designated Person who controls access to the medicines.

16.7.2 Lockable cupboards and alarm systems should at least conform to current British Standards, where available.

16.7.3 If heat-sensitive products are kept (e.g. vaccines), a suitable dedicated fridge and/or deep freeze should also be available. (see paragraph 5.6)

16.7.4 Medicines for clinical emergencies should be held in boxes clearly marked "for emergency use".

16.7.4.1 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites.

16.7.4.2 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

16.8 Authorisation for Administration of Medicines

16.8.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

16.8.1.1 — an instruction written by a medical, practitioner or authorised prescriber on an official chart or in the electronic prescribing system;

16.8.1.2 — in accordance with locally agreed clinical procedures;

16.8.1.3 — in accordance with Patient Group Directions for new patients attending clinic or a Patient Specific Direction for patients who are returning to the clinic for a further supply.

Controlled Drugs

16.8.1.4 The prescribing of Controlled Drugs to addicted persons must comply with the Misuse of Drugs Act 1971 and the most up-to-date Misuse of Drugs Regulations (see Appendix 1) issued by the Home Office.

16.9 Administration of Medicines to Patients

16.9.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

16.9.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

16.9.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of four ways:

— Self-administration by patient following dispensing on prescription.

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably trained person.

16.9.4 A record of administration should be made, and the administering nurse/doctor identified (e.g. an entry in the medicines record or electronic health record (EHR).

16.9.4.1 In the case of self-administration by the patient, the person witnessing the administration should sign that they have so witnessed.

16.9.5 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

16.9.6 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse/doctor.

16.9.7 For systems in which "take-home" pre-packed medication is prescribed by a doctor/authorised prescriber and issued by a nurse, the senior pharmacist is responsible for ensuring that there is a system to ensure that all medicines handed out to patients are recorded, and properly labelled.

16.9.7.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

16.10 Issue of Medicines to Patients

16.10.1 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

16.10.2 For systems in which "take-home" pre-packed medication is issued from the department, the senior pharmacist is responsible for ensuring that there is a legal system to ensure that all medicines handed out to patients are recorded and properly labelled.

16.10.2.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

16.11 Disposal of Medicines (see Chapter 19)

16.11.1 Out-of-date medicines and any stock no longer required should be returned to the supplying pharmacy, with appropriate security precautions.

16.11.2 A Designated Nurse or member of pharmacy staff should be responsible for their return.

Controlled Drugs

16.11.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework. The senior pharmacist should be responsible for devising such local procedures.

16.11.4 Unwanted Controlled Drugs brought into the Unit by a patient are the property of the patient. Local procedures for handling these products should be in place.

Other Medicines Liable to Diversion

16.11.5 Disposal of individual doses of other medicines, which are liable to diversion and which have not been administered should follow an agreed local procedure. The senior pharmacist should be responsible for devising such local procedures.

16.12 Risk Management

16.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

16.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the unit.

Chapter 17

Community Psychiatric Services

17.1 The System for Security of Medicines

17.1.1 Each clinical base for Community Psychiatric Nurses (CPNs), community mental health centre or sector base, where medicines are stored and used, should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure their safety and security. (see Chapter 5)

17.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

17.2 Responsibility

17.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with senior nurse managers and appropriate medical staff.

17.2.2 The nurse team leader should be responsible for control of access to the medicines and should therefore have responsibility for ensuring that the system is followed and that the security of medicines in the clinical base is maintained.

17.2.2.1 In the absence of a nurse team leader, the CPNs should bear the responsibility individually

17.3 Supply of Medicines

17.3.1 There should be a stock of medicines (excluding Controlled Drugs) held at the CPN's clinical base.

17.3.2 It is the responsibility of the supplying pharmacist to ensure that there is a secure method of supply and storage of those medicines for CPN clinical bases.

17.3.2.1 A list of medicines to be held in stock should be decided by a pharmacist in consultation with appropriate medical staff and senior nursing staff.

17.3.2.2 Pharmacy staff should determine the amount of each medicine to be held at any time from usage patterns. This amount should be stated on the record of medicine orders. This may be done automatically using computer-controlled systems and electronic orders.

17.3.2.3 The list should be subject to a regular review at agreed intervals.

17.4 Ordering and Records

17.4.1 A Designated Nurse should be responsible for ordering medicines from the pharmacy to maintain agreed stocks.

17.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

17.4.1.2 Where order books, pads of requisitions or prescriptions pads are used these should be treated as controlled stationery, and kept under lock and key by a Designated Person. Their issue should be limited to Designated Persons Access to electronic ordering systems should be similarly secure e.g. via password.

17.4.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

17.4.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or by using computer pass-codes).

17.5 Receipt and Records

17.5.1 Medicines coming into the clinical base should be checked against the requisition by a Designated Person who should record that he/she has so checked. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

17.6 Security of Base Medicine Stocks

17.6.1 The security of medicine stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of the base's stocks, with reconciliation where necessary.

17.7 Storage of Medicines at the Base

17.7.1 In the clinical base the responsibility for the safekeeping of medicines rests with those holding means of access to the stock.

17.7.1.1 It is recognised that for clinical bases having no continuous nursing presence it is impractical to have only one person with access to medicines. It is therefore important that records be maintained of all those having such access, by whatever means (e.g. keys, keycards, magnetic swipe cards etc).

17.7.2 Lockable cupboards should be used for storage of all medicines, which should at least comply with current British Standards or otherwise authorised as suitable. (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

17.8 Authorisation for Administration of Medicines

17.8.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

17.8.1.1 — an instruction written by a medical practitioner or authorised prescriber on an official chart or in the electronic prescribing system;

17.8.1.2 — in accordance with locally agreed clinical procedures;

17.8.1.3 — in accordance with Patient Group Directions for new patients attending clinic or a Patient Specific Direction for patients who are returning for a further supply.

17.9 Domiciliary Visits

17.9.1 When medicines are issued to nursing staff for use in the community, these medicines become the responsibility of the person to whom they are issued.

17.9.1.1 All medicines carried by the CPN should have been either prescribed as a specific dose for a named patient by a qualified medical practitioner/authorised prescriber or covered by the terms of a PGD under which the CPN may supply or administer the medicine.

17.9.1.2 Each medicine carried should be accompanied by the written prescription on the relevant medicines card and the dosage given should be recorded.

17.9.2 The issue of all medicines from base stocks should be recorded in a record held at the base.

17.9.2.1 The CPN should record administration, along with a note of all medicines refused, wasted or returned to stock.

17.9.2.2 Other medicines no longer required by the CPN should be returned to the pharmacy of origin, and a receipt obtained.

17.9.3 Where it is deemed to be in the patient's best interest for medication to be kept at the base for administration over a series of visits, this should be kept in a lockable cupboard, and used for that patient only.

17.9.3.1 Such medicines should be clearly labelled and kept separately from base stocks (or in a separate part of the same cupboard).

17.9.3.2 Where it is necessary for a CPN to keep medicines under his/her control at home overnight, they should be placed in a secure lockable fixture. If necessary, this should be provided by employing body.

17.10 Clinics Held by CPNs

17.10.1 Sufficient information about medicines should be available to the CPNs and/or patient to enable identification and correct use of the products. (See Chapter 5, paragraph 5.6)

17.10.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. CPNs should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

17.10.3 Patients should be encouraged, wherever possible, to store their medications in their own homes, subject to appropriate risk assessments, and bring them to the clinic for administration.

17.10.3.1 Where it is deemed to be in the patient's best interest to keep these medicines at the base they should be locked away, in a separate cupboard/or an area of the cupboard separated from base stocks.

17.10.4 In the event of patients not bringing medication with them, the issue of all medicines from stock should be recorded.

17.10.4.1 The patient's treatment card or electronic health record (EHR) should be annotated to show the amount that has been administered from base stocks.

17.10.4.2 The base's record book should also be completed to show details of administration, along with the signature of the nurse administering the medicine.

17.10.5 Where clinics are held away from the base where medicines are stored, medicines may be issued from an agreed list, in accordance with local policy, to an individual CPN.

17.10.5.1 These medicines should be the responsibility of that CPN.

17.10.5.2 Full record-keeping procedures should be followed.

17.11 Disposal of Medicines (see Chapter 19)

17.11.1 All out-of-date medicines and any stock no longer required should be returned to the supplying pharmacy, with appropriate security precautions.

17.11.1.1 When there is a nurse team leader he/she should be responsible for their return.

17.11.1.2 In the absence of a nurse team leader, CPNs should individually bear this responsibility.

17.11.1.3 All actions should be recorded in the base records.

17.11.1.4 Medicines obtained by patients for home use, by prescription from authorised prescribers are the patients' own property. When no longer required, the patient should be advised to return them to a local pharmacy for destruction.

17.12 Risk Management

17.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and CPNs.

17.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the clinic.

Chapter 18

NHS Ambulances

Introduction

Medicines are carried on ambulances in both paramedic bags and locked medicines boxes, which themselves contain specialist kits of equipment as well as medicines (e.g. cardiac arrest, respiratory failure etc). The security of medicines within the ambulance service is subject to the same general principles as in any other ward, unit or department.

18.1 System for Security of Medicines

18.1.1 Each ambulance service should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used by it. (see Chapter 5)

18.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

18.2 Responsibility

18.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of the Medical Director in consultation with the Senior Pharmaceutical Advisor, the Paramedic Steering Group and the Chief Executive.

18.2.2 The Chief Executive should have the responsibility for ensuring that the system is followed and that the security of medicines handled by the ambulance service is maintained.

18.2.3 The Chief Executive may decide to delegate some of the duties but the responsibility always remains with the Chief Executive.

18.2.4 Where medicines are carried on an ambulance the Chief Executive should ensure that there is a written protocol for their procurement, storage, administration and handling.

18.2.5 Staff who have undergone the paramedic training programme, and who have been registered as paramedics with the Health Professions Council (HPC), should be personally responsible for the security of all medicines while they are in their possession.

18.2.5.1 These medicines should be stored in a locked receptacle specifically for that purpose, when not in use.

18.3 Supply of Medicines

18.3.1 A list of medicines to be carried in each ambulance should be decided by the Paramedic Steering Group (which includes a Senior Pharmacist) in consultation with appropriate medical staff and the Chief Executive. A recommended list of medicines to be carried by the ambulance service staff has been agreed by the Joint Royal Colleges and Ambulance Liaison Committee (JRCALC) Trusts may wish to refer to this list when drawing up local policies.

18.3.1.1 The amount of each medicine to be carried in each vehicle should be determined by pharmacy staff from usage patterns. This may be done automatically using computer-controlled systems and electronic orders.

18.3.1.2 This list should be subject to a regular review at agreed intervals.

18.3.2 The pharmacy supplying medicines should usually be the pharmacy approved by the Senior Pharmaceutical Advisor.

18.3.2.1 The Senior Pharmacist, in consultation with the Chief Executive should agree a fully documented method of supply from the pharmacy to the authorised ambulance staff.

18.3.3 Ambulance Paramedics are permitted to carry and administer the Controlled Drug, morphine sulphate. JRCALC recommends that an approved process for the safe collection, delivery and use of morphine sulphate be in place. This must include correct order books, hard-backed record books with space for recording all transfers of drugs and doubly-secured containers. Individual vehicle logbooks must be maintained, with use and restocking of drugs recorded against a double signature. Trusts may wish to refer to this when designing local policies and procedures, however, all legal and regulatory requirements must still be complied with.

18.4 Ordering and Records

18.4.1 The Chief Executive should be responsible for ordering specialist kits from the pharmacy for use in his/her ambulance service.

18.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

18.4.1.2 Kits should be tamper-evident and once opened should be replaced. The opened kit should be returned to the original source of supply.

18.4.1.3 Where there is a local arrangement for kits to be supplied via the Accident and Emergency Department, there should be a record of issue held in that department, which should include the signature of the person to whom each kit is ultimately issued.

18.4.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or using computer passcodes).

18.5 Storage of Medicines

18.5.1 While in the possession of the ambulance service the responsibility for the safekeeping of the medicines rests with the Chief Executive.

18.5.2 The security of medicines in specialist kits should be checked by pharmacy staff periodically, normally every 3 months, in accordance with locally agreed procedures. They should carry out inspections of medicines in specialist kits with reconciliation, where necessary.

18.5.3 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

18.6 Administration of Medicines to Patients

18.6.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

18.6.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

18.6.3 Each ambulance crew member should keep a record of the administration of all medicines.

18.6.3.1 Administration to the patient should be in accordance with locally agreed procedures.

18.6.3.2 A record of administration should be made, and the administering person identified (e.g. an entry on the medicines record, with the crew member's signature).

18.6.4 Medicines refused, wasted or disposed of should be recorded.

18.7 Risk Management

18.7.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

18.7.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced.

Chapter 19

Return of Medicines for Destruction

19.1 General Principles

19.1.1 Medicines that are no longer to be administered to a patient, for whatever reason, should normally be returned to the relevant pharmacy or dispensing doctor for disposal. Professional disposal arrangements must comply with the paragraph 16 of the Code of Ethics and Standards (set out in the current issue of Medicines, Ethics and Practice: A guide for pharmacists. (RPSGB).

19.1.1.1 In the case of product recalls, the product should be quarantined until a decision has been made about what to do with it.

19.1.2 Destruction of Controlled Drugs must comply with current legislation and good practice guidance (see Appendix 1).

19.1.3 Local SOPs for the disposal of medicines should take account of the current environmental protection regulations.

19.2 Medicines returned within hospitals and other similar institutions

19.2.1 All out-of-date medicines and any stock no longer required should be returned to the pharmacy, with appropriate security precautions.

19.2.1.1 Medicines brought in by the patient remain the property of the patient and may only be sent to the pharmacy for destruction with the prior agreement of the patient or his/her agent. Details of patients own medicines sent to the pharmacy for destruction should be recorded.

19.2.2 The Assigned Nurse/Person in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

19.2.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework. The senior pharmacist should be responsible for devising such local procedures.

Other Medicines Liable to Diversion

19.2.4 Disposal of individual doses of other medicines, which are liable to diversion and which have not been administered should follow an agreed local procedure. The senior pharmacist should be responsible for devising such local procedures. A record should be maintained of medicines liable to diversion that are returned to the pharmacy for destruction.

19.3 Cytotoxics

19.3.1 Containers of part-used cytotoxics should be carefully disposed of in accordance with hospital procedures, which should take account of current environmental protection regulations.

19.3.2 Unused solutions/powders/vials or unopened ampoules/vials should be returned to the pharmacy.

19.3.2.1 The pharmacist should then dispose of these in accordance with guidance laid down by the Health and Safety Executive (or regulations which apply in Northern Ireland).

19.3.3 All actions, and the identities of those involved, should be recorded

19.4 Midwives

19.4.1 The particular arrangements to be followed by Midwives in the community are detailed in Chapter 13.

19.5 Community Psychiatric Nurses

19.5.1 The particular arrangements to be followed by Community Psychiatric Nurses are detailed in Chapter 17.

19.6 Risk Management

19.6.1 Risk management measures should follow the local risk management policy

19.6.1.1. Risk assessments should be carried out in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to staff.

19.6.1.2 Over and above what is normally required for the safe and effective destruction of CDs, there is a professional need to take into account the management of the additional risks associated with the disposal of devices and equipment that could be classified as clinical waste.

APPENDIX 1

Controlled Drugs

A-1 General

All medicines should be handled safely, with due care and attention given to the current legal framework and good practice requirements.

Controlled Drugs are "dangerous or otherwise harmful drugs". This category of medicines is subject to additional requirements over and above those that apply to other categories of medicines (such as Pharmacy (P) medicines or Prescription Only Medicines (POMs)

Controlled Drugs are covered by both the Medicines Act (1968) and the Misuse of Drugs Act (1971) with associated Regulations. Whenever Controlled Drugs are handled careful attention must be paid to the additional regulatory requirements.

Medicines currently classified as Controlled Drugs are listed in the current Misuse of Drugs Regulations
(see www.homeoffice.gov.uk or current issue of the British National Formulary.)

Much of the legislation concerning Controlled Drugs has been written to avoid diversion and abuse. It needs to be implemented in a practical and sensible way in a healthcare setting, taking account of both the legal framework and accepted good practice, in order to ensure that patients receive the treatment that they need.

In order to support the NHS (in England) in the safe and secure handling of Controlled Drugs, the National Prescribing Centre has prepared, A Guide to Good Practice in the Management of Controlled Drugs in Primary Care. This document attempts to set out, as far as possible, the current legal framework and what is deemed to be good practice within that framework. In addition to primary care issues it also covers primary/secondary care interface issues. This document is available on the National Prescribing Centre website (www.npc.co.uk).

The legal framework affecting Controlled Drugs has been brought in to sharp focus by issues arising from the Shipman case and it is likely to be affected significantly by the recommendations of the Shipman Inquiry. The National Prescribing Centre guidance will be updated in the light of the inquiry recommendations.

We recommend that anyone using these guidelines (Duthie) should refer to the Misuse of Drugs Act 1971 and associated Regulations, the Medicines Act 1968, the latest version of NPC document, A Guide to Good Practice in the Management of Controlled Drugs in Primary Care and any other relevant national guidance, for up-to-date information on the handling of Controlled Drugs.

A-2 Controlled Drugs in hospitals

It will normally be the responsibility of the Senior Pharmacist to devise local procedures for the handling of Controlled Drugs in hospitals. Such procedures should comply with up-to-date legislation and good practice guidance. Reference may be made to the current issue of the RPSGB document, Professional standards factsheet no. 2: Controlled Drugs and Hospital Pharmacy (www.rpsgb.org.uk). The NPC guidance document, although largely concerned with primary care, may also contain information that is of value in the hospital situation. It is advised to consult this guidance to keep abreast of changes to storage, record and disposal requirements. These requirements will obviously change as a result of the Shipman Enquiry. In addition, the following points may be taken into consideration when drafting local procedures.

Receipt

Controlled Drugs coming on to the ward, theatre or other department should be received by a Designated Person who should check them against the requisition and record that a check has been made.

Storage and Security

Storage arrangements for Controlled Drugs must comply with the Misuse of Drugs (Safe Custody) Regulations.

This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case the advice of security specialists or Crime Prevention officers should be sought.

The security of Controlled Drugs should be checked, by pharmacy staff, with audit and reconciliation, at least every three months and when overall responsibility for drugs changes (e.g. change of appointments).

Registers

Details of Controlled Drugs should be entered in the ward or department Controlled Drugs Register, along with the details of the person who has received them.

Each area should have its own Controlled Drugs Register.

Controlled Drugs Registers should be kept in a secure place.

The stock balance of Controlled Drugs should be reconciled regularly, however the frequency of this check should be decided on the basis of local operational considerations by the Appointed Nurse in Charge in consultation with the nurse manager. It is intended that maintenance of a running balance will eventually become a legal requirement.

Disposal

Individual doses of Controlled Drugs, which are prepared, but not administered, should be destroyed on the ward in the presence of a second person who may be a pharmacist, nurse or doctor.

All other drugs should be sent to the pharmacy for destruction.

Controlled drugs whose shelf life has expired may be returned, via a pharmacist, for destruction according to the Special Waste Policy (see paragraph 19.2.4)

In all cases an entry should be made in the ward Controlled Drugs Register, including the names of those involved.

A-3 Supervision of Destruction of Controlled Drugs

Any person required by the regulations to keep records of Controlled Drugs may only destroy them in the presence of a person authorised by the Secretary of State. Since devolution, each of the home countries has become responsible for making its own arrangements for witnessing destruction of Controlled Drugs. Up-to-date guidance should be sought from the Office of the Chief Pharmacist in each of the Devolved Administrations For England guidance can be found in EL(97)22 and at http://www.dh.gov.uk

APPENDIX 2

Members of working party

MEMBERSHIP OF THE ORIGINAL DUTHIE REVIEW GROUP SELECTED BY THE HOSPITAL PHARMACISTS GROUP 1997

*Professor G B A Veitch	University of Wales, Chair
Professor L Strunin	Vice-President, Royal College of Anaesthesia
Ms E McAnulty	UKCC – Midwifery London
Mrs S Richards	Community Nurse Penzance
Mr J Whitmore	Chief Pharmacist Ipswich
Dr R Calvert	Chief Pharmacist Leeds
Dr P Harrowing	Bristol
Ms H Howe	Chief Pharmacist Cambridge

*Later replaced by Dr J Farewell

OBSERVERS:

Mr K Ridge	Pharmaceutical Division DH
Ms C W-Howells	Welsh Office
Ms S O'Kane	NI Pharmacy Manager

The final report was revised and edited on behalf of the RPSGB Hospital Pharmacist Group by:

Gillian Arr-Jones, Senior Professional Adviser Pharmacist, Healthcare Commission

Dr Christine Clark, Freelance Medical Writer and Consultant Pharmacist

Dr Richard Needle, Pharmacy Department, Colchester General Hospital, Colchester

Professor Roger Tredree, Chief Pharmacist, St George's Hospital, Tooting, London

Sources consulted in the process of preparing the final revised and edited version of the report by Gillian Arr-Jones, Dr Christine Clark, Dr Richard Needle, and Professor Roger Tredree

General

The Hospital Pharmacists' Group Committee

David Green, Interface Development Pharmacist, Colchester General Hospital, Member of PCCP Network National Committee.

Diane Heath, All Wales Principal Pharmacist, Community Services

Clinical trials/ethics committees

Mr Stephen Baker (previously Director of Pharmacy at the Royal Hallamshire Hospital).

Authorisation of persons to supervise the destruction of controlled drugs

John Gerrard, Senior Inspector, Home Office Drugs Inspectorate – and several members of his staff.

Mrs Gul Root, Office of the Chief Pharmacist, DH, England

Miss Carwen Wynne-Howells Chief Pharmaceutical Adviser, The National Assembly for Wales.

Mr Bill Scott, Chief Pharmaceutical Officer for the Scottish Executive Health Department.

Dr Norman Morrow, Chief Pharmacist, Northern Ireland and Dr Michael Mawhinney, Misuse of Drugs Inspector for Northern Ireland.

National Prescribing Centre

Clive Jackson, Appendix 1, Controlled Drugs.

NHS Walk-in clinics

Ms Beth Taylor, Manager, Community Services Pharmacy Team, Southwark PCT and Regional Principal Pharmacist, Community Care London/South East Regions.

Ambulance services

Judith Fisher, Medical Director, Essex Ambulance Service.

Mental Health services

John Woolven, Chief Pharmacist, St Georges and South West London Mental Health Trust

Midwifery services

Jean Duerden, LSA Midwifery Officer, Yorkshire and North Lincolnshire LSA Consortium

Other Organisations that responded to the consultation process

The Ambulance Service Association
The British Medical Association
Dispensing Doctors Association
Guild of Healthcare Pharmacists
Home Office – Drug Legislation & Enforcement Unit
National Patient Safety Agency
Nursing Midwifery Council
Primary and Community Care Pharmacy Network
Royal College of Midwives
Royal College of Nursing
Royal College of Paediatrics and Child Health
Royal College of Physicians
Royal College of Ophthalmologists
Royal College of Surgeons

Welsh Nursing and Midwifery Committee

Association of Scottish Trust Chief Pharmacists
Lothian Primary Care NHS Trust
NHS Education for Scotland (Nursing)
Royal College of Nursing Scotland

The above does not represent a complete list of individuals or organisations that responded to the consultation process. The committee was originally convened in 1997 and the report was completed in 2005. Sincere apologies for any omissions to the list of contributors. The full list of individuals organisations and that were consulted and contributed to the preparation of the revised report can be found on the website of the Royal Pharmaceutical Society of Great Britain (www.rpsgb.org)

GLOSSARY

Appointed Nurse-in-Charge	The senior nursing appointment for the ward or department (e.g. Ward Sister, Charge Nurse, Clinical Ward Manager etc.)
Appropriate Medical officer	A doctor who is for the time being authorised in writing by the local supervising authority for the purposes of Regulation 11 of the Misuse of Drugs Regulations 1985 or (for signing Midwives' Supply orders only) a Supervisor of Midwives who is so authorised for the purposes of Regulation 11(2) of those Regulations.
Assigned Nurse in Charge	The senior nurse on duty for the ward or department who has been identified as the Nurse-in-Charge for that shift.
Audit trail	A system whereby all transactions regarding a specific medicine can be traced from the act of purchase to the point of use.
Authorised Nurse	Any registered nurse who satisfies the criteria to enable him/her to administer medicines without supervision — i.e. First Level Registered Nurse or Second Level Nurse under the conditions outlined in Rule 18(2) of Statutory Instrument 1983 No 873. (No nurse should be expected to accept the responsibility for administering such medicines against his/her will and those who do accept the responsibility must remember the requirements of the NMC Code of Conduct.)
Authorised prescriber	A person who is authorised to undertake independent or supplementary prescribing according to current legislation. (see Department of Health website)

Care Commission	The Commission for Healthcare Audit and Inspection (CHAI), known as Healthcare Commission (regulates Private and Voluntary Healthcare in England) www.healthcarecommission.org.uk The Commission for Social Care Inspection (CSCI) (regulates Care Homes, Children's services and agencies in England). www.csci.org.uk The Care Standards Inspectorate for Wales (CSIW) www.wales.gov.uk/subisocialpolicycare-standards; The Scottish Commission for the Regulation of Care (SCRC) www.carecommission.com
Controlled Drugs	Controlled Drugs (CDs) are classified in various schedules depending on their therapeutic usefulness and potential for harm. Each schedule has different requirements in relation to storage, handling, record-keeping. The classifications are set out in the current Misuse of Drugs Regulations.
Controlled Stationery	All stationery, which in the wrong hands, could be used to obtain medicines fraudulently.
Community Pharmacy	A retail pharmacy i.e. not attached to an NHS hospital.
Computer-controlled cabinet	A secure cabinet for the storage of medicines, access to which is controlled by computer passcode. Such a cabinet may also be linked electronically to the pharmacy department.
Designated Nurse	Any registered nurse who has been identified by the Appointed Nurse in charge as competent and appropriate to perform a specific function and his/her designation as such has been communicated to and recognised by any other relevant professional.
Designated Person	A person who has been identified as being suitable for, and therefore given responsibility for a specific duty, by the person having overall responsibility for the security system.

Diversion (of medicines)	The prevention of part or all of a medicine from reaching its intended destination (i.e. patient, storage place, or point of destruction).
External Medicines	Those medicines applied to body surfaces (e.g. lotions, creams etc).
First Level Registered nurse	A nurse whose name is on the First Level part of the Register, i.e. MHN, RN, RNMH, HV, RSCN or RM.
Form of Access	May be key, key-card, magnetic strip-card, or computer pass-code (depending on the system in use).
"High-Risk" medicines	Those medicines whose potential for diversion is high. Note: this may include Family Planning requisites and steroids as well as the recognised drugs of abuse.
Immobilised (in reference to medicine trolleys)	Secured to a floor or wall, or inside a locked room.
Internal Medicines	Those medicines given by mouth or injection to include eye drops, eardrops, suppositories, pessaries and inhalers.
Locally Restricted Medicines	Medicines or groups of medicines over which individual districts wish to exert tighter control. This may involve anything from specified signatures to full stock balance and record-keeping.
Local Supervising Authority	Local Supervising Authority as defined in the Nurse, Midwives and Health Visitors Act 1997 (In England and Wales, Health Authorities; in Scotland, Health Boards; and in Northern Ireland, Health and Social Services Boards.)
Medicine	Medicinal products as defined in Section 130 of the Medicines Act i.e., a substance administered by mouth, applied to the body, or introduced into the body for the purpose of treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, contraception, inducing anaesthesia, or otherwise preventing or interfering with the normal operation of a physiological function.

Medicines and Healthcare products	Regulatory Agency (MHRA) The Medicines and Healthcare products Regulatory Agency (MHRA) was established on 1st April 2003 as a result of the merger of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA).
Operating Department	Aggregate of all the theatre suites — which may be in more than one physical location.
Organisation	NHS Trust, PCT or equivalent in Wales, Scotland, Northern Ireland or relevant corporate body.
Paramedic, State Registered	A person who is registered in the register of paramedics maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001.
Patients	Service users, clients, consumers or customers of the health services
Patient Group Direction (PGD)	A written instruction to enable a healthcare professional to supply and/or administer a medicine to groups of patients who may not be individually identified before presentation for treatment. The majority of clinical care should be provided on an individual, patient-specific basis.
Patient Specific Direction (PSD)	A patient-specific direction is a written instruction from a doctor or dentist for a medicine or appliance to be supplied or administered to a named patient. In primary care, this might be a simple instruction in the patient's notes. Examples in secondary care include instructions on a patient's ward drug chart. Where a patient-specific direction exists, there is no need for a Patient Group Direction.
Private and voluntary health care establishments	Private hospitals, Hospices, Mental Health Hospitals, clinics and other establishments which in England are registered to provide health care with the Healthcare Commission
Reconciliation	The process of using any audit trail to ensure the integrity of individual transactions.

Registered Manager	Registered Person – A person carries on the home and registered to do so with a Care Commission or who manages the home and is registered with a Care Commission to do so.
Second Level Nurse	A nurse whose name is on the Second Level part of the Register, i.e. EN(G), EN(M), EN(MH).
Senior Pharmacist	The pharmacist appointed by the health authority/board (to assume responsibility for medicines control) who would normally have managerial responsibility for the provision of a major proportion of pharmaceutical services in a health authority/board.
Specialist Kits	Items (equipment as well as medicines) put together for specialist use (e.g. cardiac arrest or ambulance use).
Suitably qualified practitioner	For the purposes of these guidelines - usually a doctor or dentist, but additionally a midwife within professional and statutory restrictions.
Suitably trained person	For the purposes of these guidelines – someone trained in the administration of medicines to a locally-agreed level of competence
Theatre Suite	One operating theatre and its anaesthetic room.

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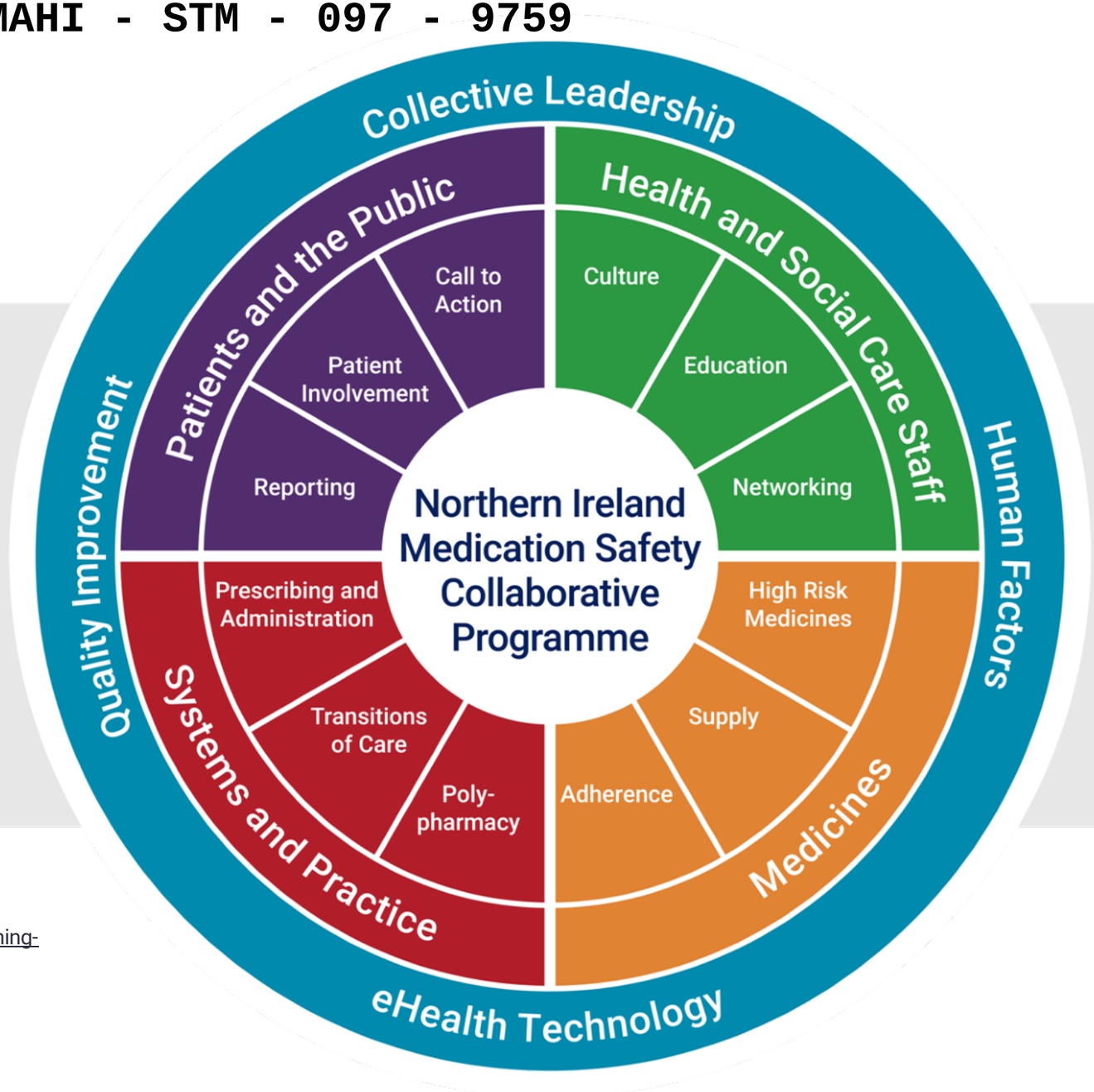
Transforming medication safety in Northern Ireland

Aligning our medication safety priorities to the World Health Organization Third Global Patient Safety Challenge 'Medication Without Harm'



This document has been produced in an interactive electronic book format and therefore this downloadable PDF version will not contain the links to additional information. Access to it can be found at https://view.pagetiger.com/Transforming-medication-safety-in-Northern-Ireland

Foreword

Safety matters with medication. Medicines are the most commonly used medical intervention in Northern Ireland, and at any one time 70% of our people take prescribed or over the counter medicines to treat or prevent ill health.

In Northern Ireland, we are fortunate to benefit from effective systems for the safe prescribing, dispensing and administration that have developed over many years. Despite this, the prevalence and burden of medication harm remains too high, and avoidable harm related to medicines occurs too often.

We want medication safety to be a priority for everyone receiving and providing care within our health and social care service. The World Health Organization's (WHO) third Global Patient Safety Challenge 'Medication Without Harm' provides us with the opportunity to re-energise our approach to ensuring the safe use of medicines in Northern Ireland. Our response sets out what we commit to do over the next five years to improve safe practices with medicines and support a medication safety culture within our population. Our commitments have been informed and shaped by those who receive and deliver safe and effective care across Northern Ireland, and we thank all of you for your contributions.

Achieving the WHO target of reducing severe, avoidable medication-related harm by a further 50% over the next five years will be challenging. Our response seeks to harness the energy and impetus provided by the Challenge to tackle some of our known 'wicked problems' through strong collective leadership, increasing public engagement, and new approaches to delivering transformational change. In short, we seek to build a new social movement. Join us on this journey.

Our aim is to build on existing successes and to progress from 'a good position' to one that is 'great'.

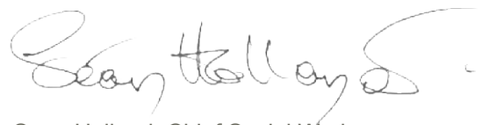
WHO Campaign video →

Dr Michael McBride, Chief Medical Officer

Cathy Harrison, Chief Pharmaceutical Officer

Charlotte McArdle, Chief Nursing Officer

Jenny Keane, Chief Allied Health Professions Officer



Sean Holland, Chief Social Worker

Simon Reid, Chief Dentall Officer

The Need for Safer Use of Medicines in Northern Ireland

Ensuring that medicines are used safely is challenging. The medicines use process is highly complex, with multiple steps involved: from the decision to initiate treatment to ordering, prescribing, dispensing, administration and monitoring.

Each step is associated with a potential risk of harm and our health service has good systems in place to identify and mitigate risk and ensure patient safety.

However 'to err is human', and both health care workers and patients will make mistakes, often as a result of poorly designed systems, tasks and processes. All medication errors are potentially avoidable and can therefore be greatly reduced or even prevented.

Every year in Northern Ireland it is estimated that...

11.7 Million
Medication errors occur

Acute Care	3.1 Million
Primary Care Includes Care Homes	8.6 Million

41.9 Million prescription items
are issued in primary care

- **1.7 Million** prescribing errors
- **1.4 Million** dispensing errors

4 in 10 adults are dispensed **5** or more prescription items

9 in 10 patients aged **75 and over** are dispensed **5** or more prescription items

800 non-elective hospital admissions are due to avoidable medication related adverse events

Avoidable medication errors:

- Cost the HSC **£1.9 Million**
- Consume **5,500 Bed Days**
- Cause **20 Deaths**
- Contribute to **54 Inpatient Deaths**

2.4 Million
Inpatient prescription items issued in secondary care

212,000
Prescribing errors in secondary care

14.2 Million
Doses of medication administered in secondary care

0 10 20

2.6 Million
Administration errors in secondary care

Four drug groups account for **more than half** of preventable drug-related hospital admissions:

- Antiplatelets
- Diuretics
- NSAIDs
- Anticoagulants

HOSPITAL

2,000 inpatients
experience an avoidable adverse event due to medications

What people said...

Half of people
prescribed medication felt fully involved in decisions about the best medication for them

9 in 10
inpatients understood instructions on how to take their medication

The methodology applied to calculate the prevalence and burden of medication errors in Northern Ireland was informed by the 2018 research study, Prevalence and Economic Burden of Medication Errors in The NHS in England. Rapid evidence synthesis and economic analysis of the prevalence and burden of medication error in the UK. Policy Research Unit in Economic Evaluation of Health and Care Interventions. Universities of Sheffield and York.

The 3rd WHO Global Patient Safety Challenge ‘Medication Without Harm’

Global Patient Safety Challenges focus on patient safety burdens that pose a significant risk to global health.

Previous Challenges ‘Clean Care is Safer Care’ and ‘Safe Surgery Saves Lives’ sought to gain a worldwide commitment to action to reduce health care associated infection and risk associated with surgery respectively, and have delivered real and lasting improvements thanks to strong and rapid commitment from governments, health system leaders, professionals and civic society.

Building on the success of previous Challenges, the WHO launched their third Global Patient Safety Challenge ‘Medication Without Harm’ in March 2017. The Challenge focuses on improving medication safety by strengthening the systems for reducing medication errors and avoidable medication related harm.

The goal of the third Global Patient Safety Challenge on Medication Safety is to gain worldwide commitment and action to reduce severe, avoidable medication-related harm by 50% in the next five years, specifically by addressing harm resulting from errors or unsafe practices due to weaknesses in health systems.

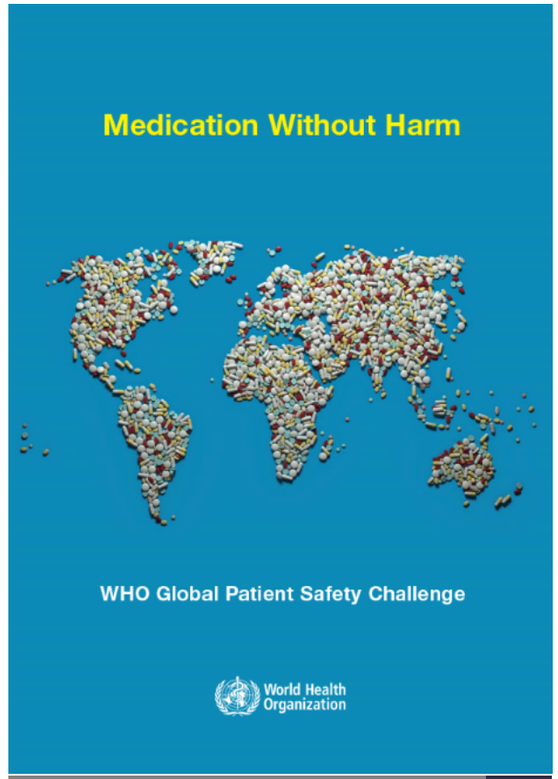
The requirements of the Challenge are for countries to:

1. Target three priority areas:

   - High-risk situations
   - Polypharmacy
   - Transitions of care

2. Design specific programmes of action for improving safety in each of four domains in which medications can cause inadvertent harm:

   - Health care professionals’ behaviour
   - Systems and practices of medication
   - Medicines
   - Patients and the public



WHO’s Global Patient Safety Challenge: Medication Without Harm brochures →

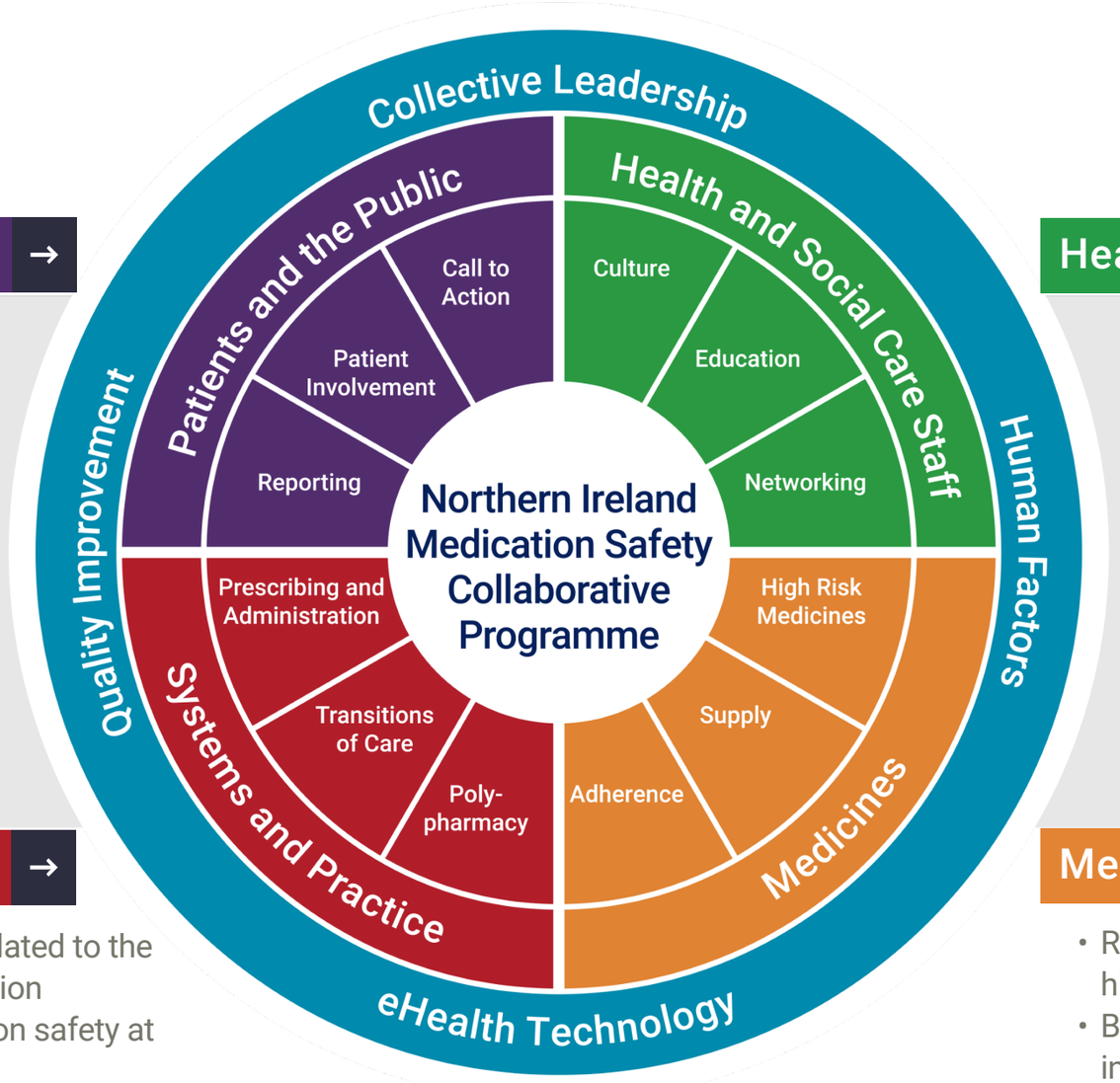
The Northern Ireland Response to the WHO Challenge 'Medication Without Harm'

Patients and the Public →

- Increase public awareness of the importance of using medication safely
- Support people to be more involved in decisions about their medication
- Help patients to report issues and concerns about their medication

Systems and Practice →

- Introduce systems to help reduce harm related to the prescribing and administration of medication
- Introduce a standard system for medication safety at transitions of care
- Take action to ensure that patients are taking the right medication for optimal benefit



Health and Social Care Staff →

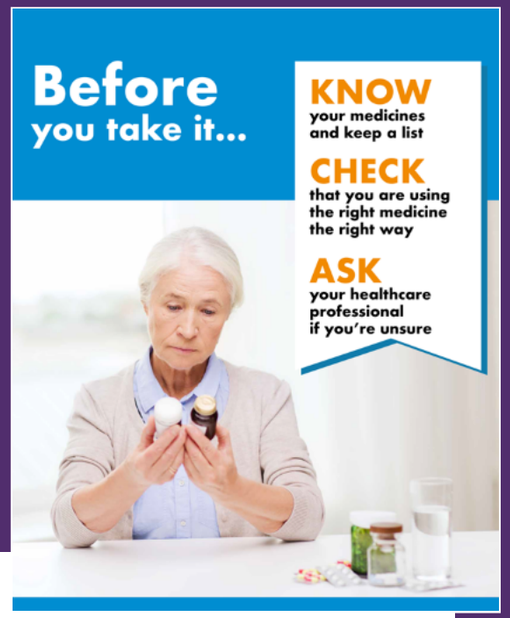
- Raise awareness among health and social care staff that medication safety is everyone's responsibility
- Ensure health and social care staff have the skills to be medication safety wise
- Facilitate new ways of connecting staff to share and spread best practice

Medicines →

- Reduce the burden of avoidable harm from high-risk medicines
- Build good practice in medication safety into the supply of all medicines
- Support improvements in adherence to medication

Patients and the Public

"Patients and the public are not always medication-wise. They are too often made to be passive recipients of medicines and not informed and empowered to play their part in making the process of medication safer." WHO



AIMS

1 Increase public awareness of the importance of using medication safely

What do we want to achieve?

We want people to take an active role in the management of their medication and move away from a passive culture where people do not feel able to ask questions of their health care professional and feel they must '*do as the doctor says*'.

This will require us to encourage and help people to be more curious about their medication. They should know what medication they are using and how to use it safely. People should feel able to ask their health care professionals questions about their medicines. Raising awareness that medication safety is important also empowers people to 'speak up' and prevent a potential medication error and harm from occurring.

Our commitments

We will deliver a public 'call to action' based on the WHO 'Know, Check, Ask' campaign. This campaign will be repeated annually to encourage a long term cultural change so that being *'medication safety wise'* becomes the social norm.

We will work with schools and education partners to help equip our children and young people with the knowledge and skills they need to be medication safety wise throughout life.

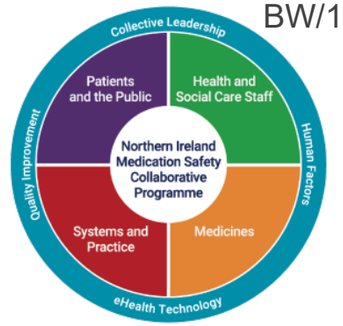
WHO Know, Check, Ask Campaign →

AIMS

2 Support people to be more involved in decisions about their medication

Our commitments

We will work with health and social care providers, patient groups, community and voluntary organisations to support patients, families or caregivers to use the WHO '5 Moments for Medication Safety' tool.



What do we want to achieve?

We want to help people to ask their health care professional questions about their medication, treatment and care plan. This will assist them to manage their medication safely and enable them to get the best intended outcomes.

The '5 Moments for Medication Safety' patient engagement tool provides patients, families or caregivers with information about what types of questions they can ask a health care professional.

The '5 Moments' are when medication is started, when they are taking it and when medications are; added, reviewed and stopped.

The tool aims to engage and empower patients to be involved in their own care and when decisions are made about their medicines. It can be used in collaboration with any health care professional during any of these 'moments', and helps patients to record valuable information that will support them to manage their medication safely.

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

World Health Organization

5 Moments for Medication Safety

WHO '5 Moments' app →

Starting a medication

- What is the name of this medication and what is it for?
- What are the risks and possible side-effects?

Taking my medication

- When should I take this medication and how much should I take each time?
- What should I do if I have side-effects?

Adding a medication

- Do I really need any other medication?
- Can this medication interact with my other medications?

Reviewing my medication

- How long should I take each medication?
- Am I taking any medications I no longer need?

Stopping my medication

- When should I stop each medication?
- If I have to stop my medication due to an unwanted effect, where should I report this?

AIMS

3 Help patients to report issues and concerns about their medication

What do we want to achieve?

We want people to feel able and confident to report problems with their medication early and so help reduce avoidable harm.

Reporting problems that have occurred or had the potential to cause harm ('*near misses*') with medicines is essential for patient safety. It can help to identify previously unknown issues with the medication itself, and highlight potential areas for improvement in prescribing, dispensing and administration processes.

Reporting issues helps the health care system to better understand medication safety risks and to learn from mistakes by taking action that can help keep patients safe in future.

Our commitments

We will work with health and social care providers, patient groups, community and voluntary organisations to raise public awareness of the benefits of reporting medication issues, and support patients and carers to report any issues and concerns by addressing barriers to reporting.

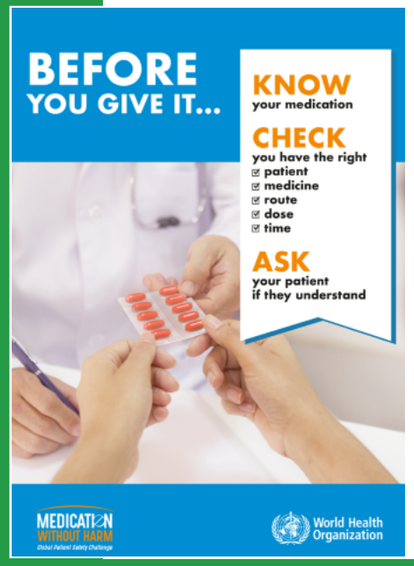
Health and Social Care Staff

"Health care professionals sometimes prescribe and administer medicines in ways and circumstances that increase the risk of harm to patients."

WHO

AIMS

1 Raise awareness among health and social care staff that medication safety is everyone's responsibility



What do we want to achieve?

We want all health and social care staff to recognise their roles and responsibilities to ensure that medicines are used safely.

In addition to those that prescribe, administer or dispense medication, many other staff groups are directly or indirectly involved in the medication use process. This includes healthcare assistants, social and domiciliary care workers, porters and medical secretaries who interact directly with patients and their medication.

All of these staff need to be aware of their own responsibilities and that ensuring medication safety is part of their role. These responsibilities also include reporting and learning from incidents where harm has occurred or potential risks are identified, as well as *learning from excellence* and celebrating when things go right.

A culture of medication safety across health and social care is essential to ensuring patient safety.

Our commitments

We will involve our health and social care staff in the delivery of WHO's 'Know Check Ask' Campaign so that before a medication is prescribed, dispensed or administered by them they:

- **Know** 'the medication'

- Have **Checked** if they have the right patient, medicine, route, dose and time

- **Ask** the patient or carer if they understand.

We will encourage and support our health and social care staff to report and learn from medication related adverse effects and incidents, including 'near misses'.

We will work with the other UK countries to explore the development of a multi-disciplinary medication safety competency framework for health and social care staff to identify their medication safety learning and development needs for current and future roles.

WHO Know, Check, Ask Campaign →

AIMS

2 Ensure health and social care staff have the skills to be medication safety wise

What do we want to achieve?

We want health and social care staff that work together to learn together in a consistent way about medication safety and to develop self and situational awareness skills that will help them to navigate uncertain and complex scenarios.

Medication safety education is already incorporated within undergraduate and postgraduate training for medical, nursing and pharmacy professionals. Moving towards an integrated approach will better reflect how staff work together after qualification.

Education programmes will need to continually evolve to equip staff with the skills needed to respond to future technological advances that will change how medicines are managed.

Our commitments

We will work with universities, postgraduate training providers and professional bodies to incorporate the principles of the revised WHO Medication Safety Curriculum Guide and Human Factors training within multi-disciplinary medication safety programmes that are responsive to future needs.

AIMS

3 Facilitate new ways of connecting staff to share and spread best practice

What do we want to achieve?

We want to harness the energy and ideas of our health and social care staff and help them to come together to develop, test and implement solutions for known problems.

Nurturing a medication safety learning and improvement culture is essential for improvement, and is enabled by providing people with the opportunity to meet physically or virtually to share and learn together.

There are already many examples of initiatives and networks within the health and social care system that apply the '*all teach, all learn*' philosophy to support the safer use of medicines which could be further developed and spread to other areas via greater collaboration and engagement.

Our commitments

We will encourage networks that enable people to learn and work together to improve medication safety across the health and social care system, building upon existing communication platforms and structures.

We will hold an annual Northern Ireland medication safety conference that brings practitioners together to share best practice and learn from each other.

We will encourage health and social care staff to showcase examples of exemplar practice through participation in UK, ROI and international safety events.

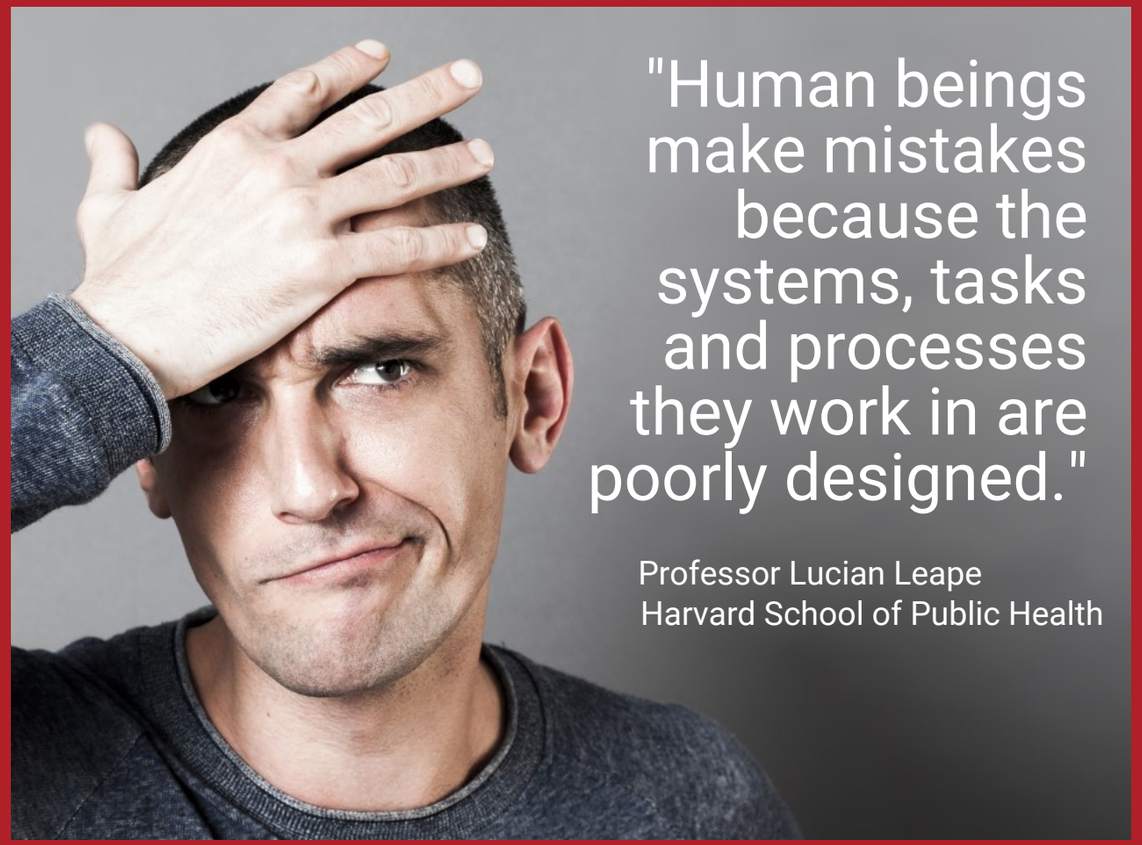
"Networks are primarily innovative creative places, they are useful for rapid learning and development and for amplifying members' effectiveness."

The Health Foundation

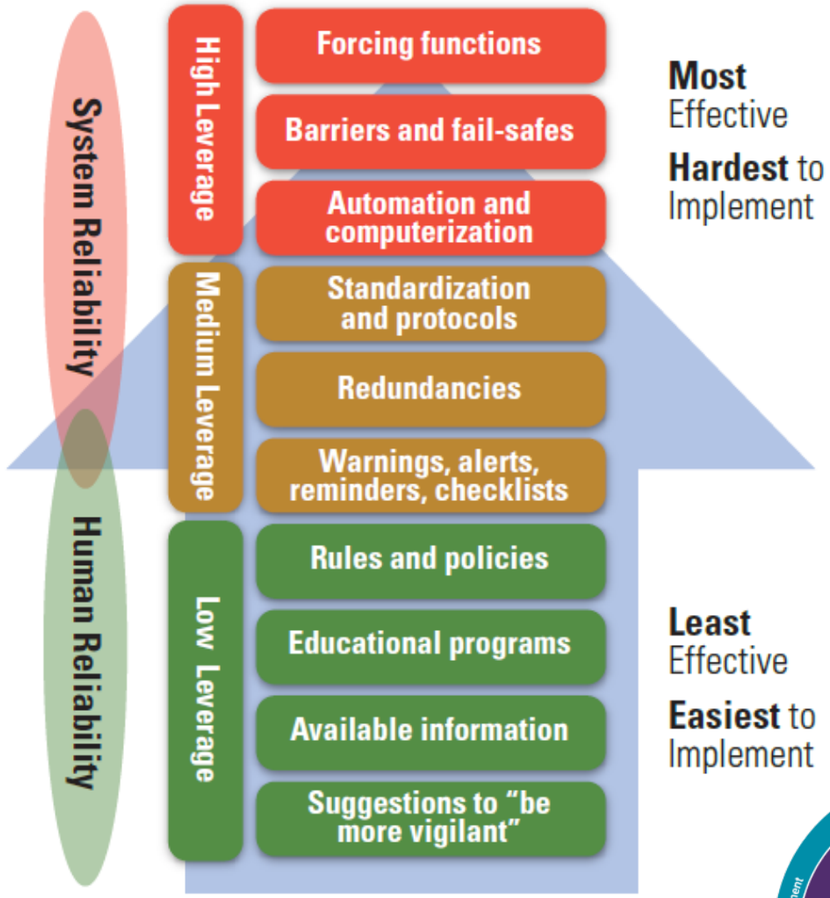
Systems and Practice

"Systems and practices of medication are complex and often dysfunctional, and can be made more resilient to risk and harm if they are well understood and designed."

WHO



The Hierarchy of Intervention Effectiveness



AIMS

1

High Risk Situations

Introduce systems to help reduce harm related to the prescribing and administration of medication

What do we want to achieve?

We want to support safer prescribing and administration practices across the HSC to help staff to '*get it right first time'.*

We want to do this through standardisation of practice, improved access to protocols and guidelines, and better communication between teams.

Our commitments

We will support safer prescribing and administration of medication by introducing Electronic Prescribing and Medicines Administration (EPMA) and Closed Loop Medicines Administration (CLMA) systems in our hospitals, and prescribing decision support and risk identification systems in general practice.

We will undertake a targeted improvement programme to reduce the number of inappropriate omitted doses within our hospitals and care homes.

We will extend the standardisation of our secondary care prescription and administration documentation (Kardex) to our care home settings.

2 Safer Transitions of Care

Introduce a standard system for medication safety at transitions of care

What do we want to achieve?

We want to adopt a co-ordinated approach across Northern Ireland that will help to ensure that medicines reconciliation is deliverable and sustainable for all patients.

Many prescribing incidents in Northern Ireland are attributable to systems failures during transitions of care in a complex health and social care system involving many different care providers.

Communication failures between providers can lead to unintended harm and unnecessary readmissions to hospital. This harm is largely preventable with effective and consistent medicines reconciliation.

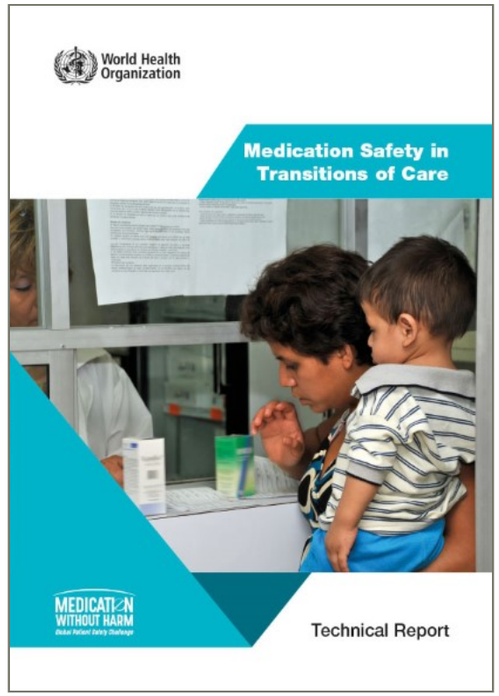
Northern Ireland has established systems that can deliver medicines reconciliation in primary and secondary care. The challenge is to ensure that we have a reliable system whereby every patient, every time, has their medication reconciled when transferring between care settings.

Our commitments

We will develop a co-ordinated Northern Ireland approach to ensure safer transitions of care between care providers, through the consistent delivery of medicines reconciliation that is aligned to the National Institute of Clinical Excellence recommendations.

"Meeting the complex challenge of reducing medication-related harm arising at transitions requires long-term leadership commitment, coordination and collaboration, formulation of goals and strategies and investment in resources."

WHO Technical Report Medication Safety in Transitions of Care



A Patient's Journey video →

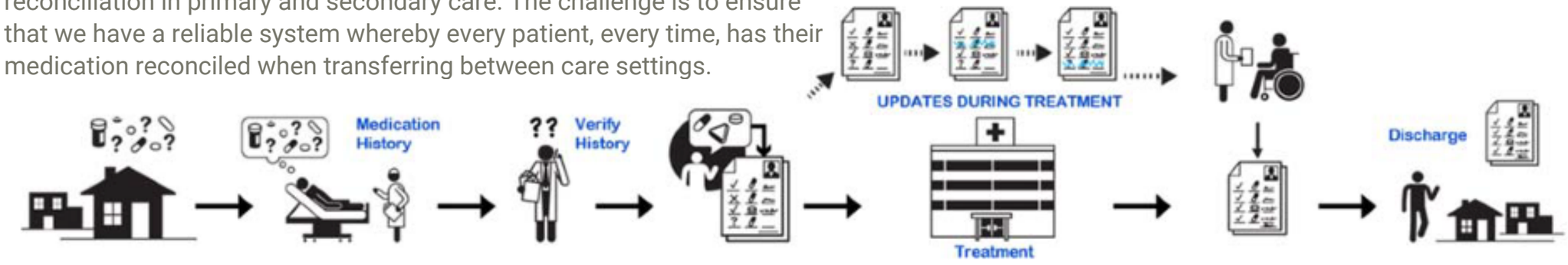


Image reprinted from the World Health Organization's The High 5s project Implementation Guide. Assuring Medication Accuracy at Transitions in Care. Medicines Reconciliation.

AIMS

3

Polypharmacy

Take action to ensure that patients are taking the right medication for optimal benefit

What do we want to achieve?

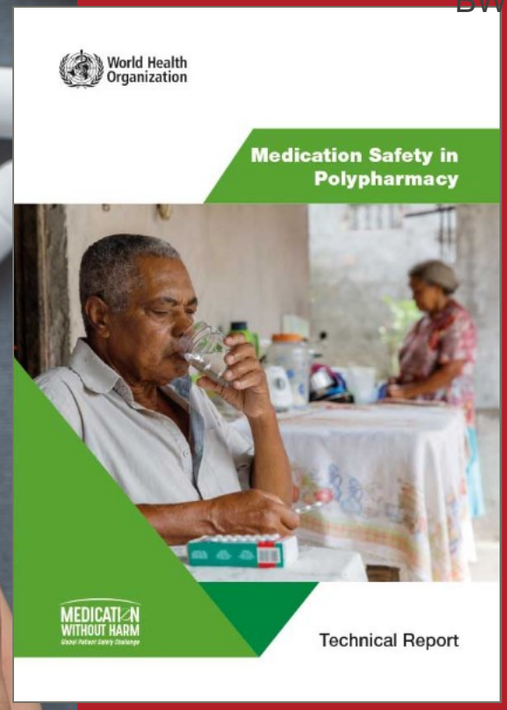
We want to build on our existing examples of best practice and reduce harm from inappropriate polypharmacy by adopting a robust and consistent approach to medication review across care settings.

The prevalence of polypharmacy in Northern Ireland continues to increase, with our ageing population suffering from increasing frailty and multiple long-term conditions. Polypharmacy can be appropriate, based on clinical evidence and patient characteristics, or inappropriate, due to the irrational prescribing of too many medicines.

Inappropriate polypharmacy can cause significant harm to patients from increased adverse effects, interactions between medicines, and medication errors, particularly at transitions of care.

Our commitments

We will work to reduce inappropriate polypharmacy by ensuring that all patients who are most at risk from harm receive at least an annual medication review.



32% of patients receiving 5 or more medicines have prescribing or monitoring errors. This increases to 47% in patients receiving 10 or more medicines.

11% of unplanned hospital admissions are attributable to harm from medicines, and over 70% of these being due to older people on multiple medicines.

"Ensuring medication safety in polypharmacy is one of the key challenges for medication safety today."

WHO

Medicines

“Medicines are sometimes complex and can be puzzling in their names, or packaging and sometimes lack sufficient or clear information. Confusing ‘look-alike sound-alike’ medicine names and / or labelling and packaging are frequent sources of error and medication-related harm that can be addressed.”

WHO

AIMS

1 Reduce the burden of avoidable harm from high-risk medicines

What do we want to achieve?

We want to ensure the safer use of medicines where published evidence and our incident reporting data shows are associated with a risk of significant harm if used incorrectly. Causes of error are frequently multifactorial and may involve a range of health and social care staff, patients and carers. They are complex to solve and require multiple approaches and innovative thinking to address inherent risks.

Our commitments

We will undertake a targeted improvement programme with the aim of reducing preventable harm associated with the following groups of high-risk medicines.

- Anticoagulants
- Insulin
- Opioids
- NSAIDs

HSC High Risk Medicines Poster →

AIMS

2 Build good practice in medication safety into the supply of all medicines

What do we want to achieve?

We want to enhance our medication supply processes to reduce the risk of preventable harm involving high risk medicines, look-alike sound-alike Medicines and omissions or delays relating to supply chain issues and shortages. Effective use of technology should be used to support safe supply of medication.

Patients and their carers should receive appropriate advice and support to help them gain the best outcomes from their treatment and avoid harm. Health and social care staff should provide patients with appropriate reassurance of continued efficacy after changes to brand or presentation of their medication.

Our commitments

We will develop strategies that will prevent incidents involving look-alike sound-alike medicines.

We will support better identification and management of medicines supply chain issues and shortages.

We will use risk stratification tools in primary and secondary care to ensure that patients taking high risk medicines receive the advice and support they need to reduce the risk of harm.

We will work with the MHRA and Pharmaceutical Industry to identify and manage existing and emerging medication risks.

We will work to introduce digital solutions including the electronic transfer of prescriptions in primary care.

3 Support improvements in adherence to medication

What do we want to achieve?

We want all of our health and social care staff to work with patients to reduce non-adherence to prescribed medication. Reasons for non-adherence may include an individual's own concerns and beliefs about their medication, low health literacy or physical, cognitive or visual barriers, and challenges accessing services. Supporting patients to take the right medicine at the right time is the final step in ensuring the safe use of medicines, and can prevent significant harm and sub-optimal clinical outcomes.

Northern Ireland has led the way in the development of many examples of best practice, such as the Medicines Optimisation in Older People (MOOP) model. We want to build on these successes so that people across Northern Ireland are supported at every contact with a health and social care provider to agree the best way for them to use their medicines in a safe and effective way.

Our commitments

We will develop, test and implement integrated models of care that support patients to take their medicines as recommended by their healthcare professional.

Ten days after starting a medicine, almost a third of patients are already non-adherent - of these 55% don't realise they are not taking their medicines correctly, whilst 45% are intentionally non-adherent.

Only 16% of patients who are prescribed a new medicine take it as prescribed, experience no problems and receive as much information as they need.

Delivering Our Commitments

Our commitments are ambitious, and are intended to reinvigorate our approach to medication safety while building on past successes. Successful implementation will require a whole system approach, which embraces multi-professional leadership and ownership across the HSC. A new approach is needed to support this, where:

- Collective leadership empowers people to lead in all areas at all levels, enabled to take responsibility for ensuring medicines are used safely.
- Our health and social care staff have the confidence and skills to deliver and lead quality improvement initiatives, and utilise Human Factors principles to improve patient safety.
- Transformation at scale and pace is facilitated by eHealth technologies, including digitalisation of our clinical processes.

These enablers will allow us to build on the collaborative approach utilised in the development of this response, and support the sustained, system-wide transformation that is required to meet the WHO goal of a 50% reduction in severe avoidable medication-related harm over the next five years.

To achieve this, our aim is that a Medicines Safety Collaborative for Northern Ireland will be established during 2020, jointly led by the HSC Board and the HSC Quality Improvement Hub. This will work with multi-disciplinary partners across the system to implement our commitments by fully utilising the expertise and experience of staff, including our HSC Medicines Governance Team and Medicines Optimisation Innovation Centre.

MOIC video →

HSCQI Inspire • Connect • Improve

HSC Health and Social Care Board

Medicines Governance Team

moic Medicines Optimisation Innovation Centre

Pharmaceutical Society NI
Protecting Registering Regulating

THE CODE

Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland

Effective from 1 March 2016

PRINCIPLE 1: ALWAYS PUT THE PATIENT FIRST

PRINCIPLE 2: PROVIDE A SAFE AND QUALITY SERVICE

PRINCIPLE 3: ACT WITH PROFESSIONALISM AND INTEGRITY AT ALL TIMES

PRINCIPLE 4: COMMUNICATE EFFECTIVELY AND WORK PROPERLY WITH COLLEAGUES

PRINCIPLE 5: MAINTAIN AND DEVELOP YOUR KNOWLEDGE, SKILLS AND COMPETENCE

ABOUT THE PHARMACEUTICAL SOCIETY OF NORTHERN IRELAND

The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists in Northern Ireland.

Our purpose is to set the standards of professional practice in the Code, and ensure that practising pharmacists are fit to practise, keep their skills and knowledge up to date and deliver quality and safe care to patients.

It is the responsibility of this organisation to protect and maintain patient and public safety in pharmacy by:

- setting and promoting standards for admission to and retention on the Registers;
- maintaining publicly accessible Registers of pharmacists, pre-registration students and pharmacy premises;
- handling concerns about the fitness to practise[1] of pharmacists, acting as a complaints portal and taking action to protect the public;
- ensuring high standards of education and training for pharmacists and pre-registration students in Northern Ireland.

Every pharmacist is responsible for their conduct, personal behaviour and professional practice and must be able to justify their actions and decisions.

[1] A statement explaining the purpose of the fitness to practise processes for the nine UK healthcare regulators is published on the website of the Professional Standards Authority at: http://www.professionalstandards.org.uk/docs/default-source/psa-library/140704-purpose-of-ftp-processes-final-statement---for-web.pdf?sfvrsn=0

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INTRODUCTION

The Pharmacy (Northern Ireland) Order 1976 as amended[2] imposes an obligation on the Council to "set standards relating to the conduct, ethics and performance expected of registered persons."

The purpose of the Code is to guide and support registrants in their scope of practice, professional development and decision-making. The Code should facilitate innovation and development of pharmacy practice whilst ensuring the consistent delivery of professional standards. It puts patients' interests first and reinforces the concept of patient-centered professionalism and care.

In this Code the Pharmaceutical Society NI outlines the standards of conduct, ethics and professional performance to be upheld and expected of every registrant regardless of their scope of practice. It supports the organisation's regulatory policies[3] and procedures, and, it underpins all other professional standards and guidance documents issued by the regulator.

There are circumstances where the ethical, professional and/or personal conduct of the registrant will be examined and determined against the Code. A breach of the Code will be considered if a question arises about a registrant's fitness to practise and may lead to a finding of impairment in relation to the registrant's fitness to practise.

Every registrant has a responsibility to be conversant with the laws and regulations, standards and guidance that affect their professional practice and to comply with them. The Code imposes obligations on registrants in relation to many aspects of their conduct, including:

- to exercise professional judgement in the best interests of patient and public safety
- to uphold the reputation and good name of the profession
- to keep their knowledge and skills up-to-date and relevant to their scope of practice
- to be accountable for professional practice to establish and maintain good relationships with others
- to be answerable for any acts and/or omissions, regardless of the advice or directions from a manager, employer or another professional
- to justify their actions when asked to do so.

[2] Paragraph 1(1a) of Schedule 3 to the Pharmacy (Northern Ireland) Order 1976 (as amended)
[3] Including future proposals for introducing a new process to ensure registrants' continuing fitness to practise

PATIENT AND PUBLIC EXPECTATIONS

The Code is of relevance not only to pharmacists but also seeks to inform patients and the wider public what they can expect from their pharmacist. The Code:

- identifies, confirms and reinforces for patients and the public the unequivocal obligation of the pharmacy profession to put their interests first
- identifies and informs patients and the public of the standards of ethical behaviour and professional conduct that can be expected from all members of the pharmacy profession
- seeks to foster, strengthen and secure public trust and confidence in the profession
- most importantly, promotes the provision of a quality service with respect to patient care whilst assuring patient and public safety.

The Code sets out five broad Principles and regulatory Professional Standards which, taken together, articulate the standards of conduct, ethics and professional performance expected of a registrant in their professional practice. Each Principle begins with a discussion of the types of obligations or matters which the Principle is intended to address or impose. However, if there is any conflict between the matters set out in the introduction and the specific Standards, the Standards should prevail.

These Principles are all equally important and are not listed in order of priority. These Principles are not negotiable or discretionary. These are mandatory Principles that apply to all members of the pharmacy profession. Whilst we do not specify how a registrant should meet our regulatory Professional Standards, a registrant must exercise professional judgement in interpreting them. A registrant must always act consistently with them. Compliance with Professional Standards will ultimately be assessed by the Pharmaceutical Society NI. If a concern is raised against a registrant, these Standards will be taken into consideration when considering whether we need to take any action.

THE PRINCIPLES

PRINCIPLE 1: ALWAYS PUT THE PATIENT FIRST

STANDARD 1.1 - Treat those in your care with respect and dignity
STANDARD 1.2 - Uphold the duty of candour and raise concerns appropriately
STANDARD 1.3 - Maintain and protect confidential information
STANDARD 1.4 - Obtain patient consent

PRINCIPLE 2: PROVIDE A SAFE AND QUALITY SERVICE

STANDARD 2.1 - Provide safe, effective and quality care
STANDARD 2.2 - Manage risk
STANDARD 2.3 - Record, store and process data clearly and accurately

PRINCIPLE 3: ACT WITH PROFESSIONALISM AND INTEGRITY AT ALL TIMES

STANDARD 3.1 - Act with honesty and integrity at all times
STANDARD 3.2 - Maintain professional boundaries
STANDARD 3.3 - Use social networking and electronic communication appropriately
STANDARD 3.4 - Be open and honest in relation to legal or disciplinary proceedings

PRINCIPLE 4: COMMUNICATE EFFECTIVELY AND WORK PROPERLY WITH COLLEAGUES

STANDARD 4.1 - Communicate effectively
STANDARD 4.2 - Establish effective partnerships with patients
STANDARD 4.3 - Work collaboratively with colleagues
STANDARD 4.4 - Supervise and delegate effectively

PRINCIPLE 5: MAINTAIN AND DEVELOP KNOWLEDGE, SKILLS AND COMPETENCE

STANDARD 5.1 - Maintain and develop professional knowledge, skills and competence

PRINCIPLE 1: ALWAYS PUT THE PATIENT FIRST[4]

The care of the patient must come before all other considerations.

Always work with patients and service users to achieve their healthcare goals as well as taking account, in a holistic way, of their non-medical needs. At all times, exercise professional judgment and do so in a way that gives priority to the patient or service user's best interests. Even if not in direct contact with patients, your decisions and behaviour can still affect their care and safety.

Take responsibility for all acts or omissions and be professionally accountable for the decisions that you make.

Any concern about patient safety must be raised in an appropriate manner. Should something go wrong with treatment or care, patients and service users must feel supported and protected and be offered guidance in seeking an appropriate remedy.

YOU MUST:

Standard 1.1: Treat those in your care with respect and dignity	
1.1.1	Always consider, and act in, the best interests of the patient or service user.
1.1.2	Act always with integrity and respect towards patients or service users.
1.1.3	Respect diversity in the cultural differences, beliefs and value-systems of others and always act with sensitivity and understanding.
1.1.4	Not act in a way that unfairly discriminates against any person.
1.1.5	If, for any reason, you are unable to provide a professional service, you have a professional responsibility to take reasonable steps to refer the patient or service user to an appropriate alternative provider for the service they require.

[4] This is one of the key recommendations from the Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry (the Francis Report, 2013), http://www.midstaffspublicinquiry.com

Standard 1.2: Uphold the duty of candour and raise concerns appropriately

1.2.1	Contribute to and foster a culture of openness, honesty and learning.
1.2.2	Ensure that an effective complaints procedure is readily available for the patient or service user and follow that procedure at all times.
1.2.3	Respond quickly and appropriately to any complaint about the care or service you provide and take all necessary and appropriate measures.
1.2.4	When something goes wrong with a pharmacy service, explain fully to the patient or service user what has happened, and where appropriate: • offer an apology • offer an appropriate and effective remedy • explain the short and long term effects • provide support and assist to put matters right.
1.2.5	Be open and honest with patients, service users, colleagues, and employers when something goes wrong.
1.2.6	If you employ, manage or lead staff, make sure that there is an effective procedure in place that allows staff to raise concerns openly and safely without fear of reprisals.
1.2.7	Raise a concern, at an appropriate level, if you become aware of a colleague or other healthcare professional whose actions, omissions, working practices, professional performance or mental or physical health may compromise patient safety.

Standard 1.3: Maintain and protect confidential information

1.3.1	Respect the confidentiality of information, professional or otherwise, acquired in the course of professional practice and only use it for the purposes for which it is given and in compliance with current legislation.
1.3.2	Maintain systems and procedures which ensure security of information and take reasonable steps to prevent unauthorised access to it.
1.3.3	Ensure that all who are authorised to have access to confidential patient or service user's information know about, understand, and maintain, its confidential nature.
1.3.4	Ensure that confidential information is not disclosed without consent, except where legally required or permitted.

Standard 1.4: Obtain patient consent

1.4.1	Obtain appropriate consent from patients for the treatment and/or professional service provided, taking particular care to act in accordance with the law where you suspect that a patient lacks or may lack capacity to consent.
1.4.2	Ensure you record, where it is appropriate to do so, patient consent, either in writing or electronically, before providing a professional service and at appropriate intervals during the service provision.
1.4.3	Respect the right of the patient to refuse to take their medicines or to receive treatment or care.

PRINCIPLE 2: PROVIDE A SAFE AND QUALITY SERVICE

Patient safety is essential and lies at the heart of quality patient care.

Deliver quality patient-centered care in a properly managed and safe environment by having working systems which are effective, simple and clear. Proactively identify potential areas of risk in your practice and utilise learnings when things go wrong.

Be aware that your obligations extend beyond the patient and immediate service user into the general community. Always act responsibly, in the public interest, and ensure public safety.

Ensure that all roles and responsibilities for functions related to the safety and quality of pharmacy services are clearly defined and governed.

YOU MUST:

Standard 2.1: Provide safe, effective and quality care	
2.1.1	Promote and ensure the safe, effective and rational use of medicines, medicinal products and therapies.
2.1.2	Effectively control and manage the sale or supply of medicinal and related products paying particular attention to those with a potential for abuse or dependency.
2.1.3	Ensure that both you and those you employ or supervise have an appropriate level of skills, including language competency.
2.1.4	Ensure that workload or working conditions do not compromise patient care or public safety.
2.1.5	Make sure that your actions do not prevent or inhibit others from complying with their legal or professional obligations.
2.1.6	Ensure that you do not, whether by your actions or omissions, create a risk to patient care or public safety.
2.1.7	Ensure that all professional activities undertaken by you, or under your control, are covered by appropriate professional indemnity arrangements.
2.1.8	Purchase medicines only from suppliers and sources known to be reputable to ensure the safety, quality and efficacy of products supplied to patients.
2.1.9	Ensure you have the facilities, equipment and materials necessary to provide services to professionally acceptable standards.
2.1.10	Take all reasonable steps to ensure that patients have safe and timely access to their medicines and pharmaceutical care.
2.1.11	Avoid treating yourself or anyone with whom you have a close personal relationship except for minor ailments or in an emergency.
2.1.12	Ensure you are aware of and adhere to all relevant legislation, and all current standards and guidance which apply to your practice.

Standard 2.2: Manage risk

2.2.1	Undertake a regular risk assessment in relation to your professional practice and the procedures that you follow.
2.2.2	Apprise staff of medication safety issues, identify areas of high-risk practice and implement procedures and processes to minimise medication safety risks or associated issues arising.
2.2.3	Where any risk, issue or problem is identified, arises, or occurs in your practice, take prompt action to prevent, minimise, follow up and resolve any such risk, issue or problem, and this includes risks, issues or problems relating to medicines and appliances.
2.2.4	Keep abreast of medication safety alerts and other publications to ensure the safety and quality of pharmacy services.
2.2.5	Contribute appropriately to 'near-miss' and error reporting systems.

Standard 2.3: Record, store and process data clearly and accurately

2.3.1	Complete records promptly or as soon as reasonably practicable after the patient intervention or activity has occurred.
2.3.2	Do not tamper with patient records in any way.
2.3.3	Ensure all entries in any record are accurate, clearly and legibly written and attributable.
2.3.4	Keep all records securely and in an organised manner and for the appropriate period of time.

PRINCIPLE 3: ACT WITH PROFESSIONALISM AND INTEGRITY AT ALL TIMES

Being a member of the pharmacy profession is a privilege and brings with it many benefits, but also obligations.

All registrants must act with honesty and integrity, at all times. Your professional values, conduct, behaviour and relationships must be above reproach. Justify the trust that patients and service users put in you as a professional. Your behaviour and professionalism are judged by what you do both inside and outside your work environment.

Be a role model for other registrants and for colleagues in the broader multi-professional healthcare team.

YOU MUST:

Standard 3.1: Act with honesty and integrity at all times

3.1.1	Adhere to accepted and acceptable standards of personal and professional conduct at all times both inside and outside your work environment.
3.1.2	Maintain public trust and confidence in your profession by acting with honesty and integrity in your dealings with others. This applies to your professional, business and educational activities.
3.1.3	When providing information or advice, in whatever format, do so accurately, clearly and unambiguously.
3.1.4	Honour commitments, agreements and arrangements for the provision of professional services.
3.1.5	Conduct research and development with integrity and obtain any necessary approval from the appropriate authorities.
3.1.6	Promptly inform the regulator, your employer and other relevant authorities of any circumstances that may call into question your fitness to practise or has the potential to bring the profession of pharmacy into disrepute.
3.1.7	Make sure that any documents you complete or sign are not false or misleading, or contain false or misleading information. Take all steps that are reasonably necessary to ensure that recorded information is correct and complete. Do not omit relevant information.

Standard 3.2: Maintain professional boundaries

3.2.1	Maintain proper and appropriate relationships with patients and service users. Take special care when dealing with vulnerable individuals, both adults and children
3.2.2	Ensure that your professional judgement is not compromised by personal or commercial interests, incentives, targets or similar measures.

Standard 3.3: Use social networking and electronic communication appropriately

3.3.1	Ensure appropriate and responsible use of social networking sites and other forms of electronic communication.

Standard 3.4: Be open and honest in relation to legal or disciplinary proceedings

3.4.1	Co-operate with any investigation into the fitness to practise of either yourself or another healthcare professional.
3.4.2	Abide by any undertakings you give and/or any restrictions placed on your practice.

PRINCIPLE 4: COMMUNICATE EFFECTIVELY AND WORK PROPERLY WITH COLLEAGUES

Good communication is at the heart of effective working relationships with patients, service users, colleagues and other healthcare professionals; this builds confidence and respect across all areas of the healthcare team.

Having respect for each other's roles, and understanding what you are accountable for, will ensure effective team working.

YOU MUST:

Standard 4.1: Communicate effectively

4.1.1	Listen to patients and service users, respect the choices they make about their treatment and care and respond appropriately to their need(s).
4.1.2	Provide information that the patient or service user either requests or requires about their treatment and care, in a way that they can understand so they are engaged and supported to use or take their medicines safely and effectively.
4.1.3	Communicate clearly and effectively with patients and service users and take reasonable steps to meet their language and communication needs. You may need to check for mutual understanding where appropriate.

Standard 4.2: Establish effective partnerships with patients

4.2.1	Work properly and meaningfully in partnership with patients and service users to manage treatment and care and seek to achieve better health outcomes.
4.2.2	Act in partnership with patients and service users to ensure prescribing is carried out in a manner which promotes safety and better health outcomes.
4.2.3	Encourage and seek to empower patients and service users to be knowledgeable about their medicines.

Standard 4.3: Work collaboratively with colleagues

4.3.1	Treat colleagues in a professional manner at all times.
4.3.2	Work effectively as part of the pharmacy team and the multi-professional healthcare team and within the governance arrangements of the organisation in which you work.
4.3.3	Where appropriate, refer or signpost patients or service users to other health or social care professionals, or to other relevant organisations.
4.3.4	Be aware of how your conduct and behaviour may influence and impact on others within and outside the team.

Standard 4.4: Supervise and delegate effectively

4.4.1	Take personal responsibility for all work carried out by you and by others under your supervision.
4.4.2	Ensure that individuals to whom you delegate tasks are fit to practise, competent to carry out such tasks and have undertaken, or are in the process of undertaking, the training required for their duties.
4.4.3	Ensure the provision of an acceptable and proper standard of professional service by you and those working under your direct supervision.
4.4.4	Contribute to the development, education and training of colleagues and students, sharing relevant knowledge, skills and expertise.
4.4.5	Take all reasonable steps to ensure that those persons you employ, or supervise, comply with all legal and professional requirements and best practice guidance.
4.4.6	Be honest and objective when appraising the performance of others.
4.4.7	Be supportive of colleagues with performance or health issues while having due regard for patient and public safety.

PRINCIPLE 5: MAINTAIN AND DEVELOP YOUR KNOWLEDGE, SKILLS AND COMPETENCE

The greatest benefit to patient safety will be achieved by keeping your knowledge, skills and competence up to date throughout your working life. Lifelong learning enables you to keep abreast of change in your professional practice and is essential for the safe and effective practice of pharmacy.

Reflect continually on your practice and act on feedback to improve your practice. Maintain a Continuing Professional Development (CPD) portfolio by systematically recording your reflections, learning aims, activities and outcomes.

Apply all relevant knowledge, skill and experience in order to maintain the requisite standards of professional practice and patient-centered care.

YOU MUST:

Standard 5.1: Maintain and Develop professional knowledge, skills and competence

5.1.1	Practise only when you are competent and fit to do so.
5.1.2	Identify development needs and undertake continuing professional development (CPD) relevant to your scope of practice and maintain appropriate records.
5.1.3	Keep your knowledge and skills up to date, evidence-based and relevant to your scope of practice.
5.1.4	Apply your knowledge and experience appropriately to your scope of practice.

GLOSSARY OF TERMS

Acts and omissions:
To act is to do something, while an omission is a failure to act in circumstances where one has the ability and opportunity to act. Omission is a neglect of duty. Law imposes a duty on every person to take adequate action to prevent a foreseeable injury. In criminal law, omissions may give rise to litigation and will constitute a guilty act if a person breaches his/her duty. If a person fails to act knowingly, that his/her failure would cause a harm or injury to other person(s), then such a failure constitutes an omission.

Capacity:
Please refer to http://www.psni.org.uk/Standards+on+Patient+Consent.pdf

Carer:
A person of any age, adult or child, who provides help and support to a partner, child, relative, or friend who may not otherwise be able to live independently or whose health or wellbeing would deteriorate without this help.

Consent:
Please refer to http://www.psni.org.uk/Standards+on+Patient+Consent.pdf

Evidence-based care:
Clinical practice and care that incorporates the best available evidence from research, the expertise of the pharmacist and the preference of the patient.

Health:
'a state of complete physical, mental and social wellbeing not merely the absence of disease or infirmity' *World Health Organisation.*

Must:
It is compulsory for the registrant to comply with the requirement set out in the standard.

Patient(s): encompasses:

- Any individual(s) or groups who access or are affected by professional pharmacy services or advice.
- Any animal whose owner accesses a pharmacy service on their behalf.

Prescribing:
Is used to describe many related activities including:

- supply of prescription only medicines
- the provision of written information or advice to patients
- advice to patients on the purchase of over the counter medicines, appliances or other remedies
- prescribing for minor ailments from an approved list as part of an accredited Minor Ailments Scheme.
- supplementary or independent pharmacist prescribing. For details refer to section 1.1 'Types of Pharmacist Prescribers', available at http://www.psni.org.uk/Standards-and-Guidance-for-Pharmacist-Prescribing-April-2013.pdf.

Professionalism:
Demonstrating characteristics of effective communication, maintaining expertise, integrity, being accountable, showing respect for others while all the time focusing on patients and the public.

Record:
Document containing personal information and information relating to the treatment and care of the patient or service user.

Service user:
Users of pharmacy services include clients, carers, customers, colleagues, other healthcare professionals and members of the public.

Scope of practice:
Describes the areas of practice in which you have the knowledge, skills and experience to practise safely and effectively in the best interests of patients.

Standards:
Reflect the agreed way of doing something. Standards, used correctly, will bring about a common understanding about what providers and users of services, goods and establishments can realistically expect to provide and receive. Standards will, as the "agreed" way of doing things, have an authority which may be enforceable or accepted without being technically enforceable due to the weight of the expertise used in developing them.

STANDARDS AND GUIDANCE

The Pharmaceutical Society NI has issued the following documents to underpin the Code; These are available to download at **www.psni.org.uk**

- Professional Standards and Guidance for Patient Consent
- Professional Standards and Guidance for Patient Confidentiality
- Professional Standards and Guidance for Sale and Supply of Medicines
- Professional Standards and Guidance for Advertising of Medicines and Professional Services
- Professional Standards and Guidance for Internet Pharmacy Services
- Professional Standards and Guidance for Pharmacist Prescribing
- Guidance for Pharmacists on Raising Concerns.

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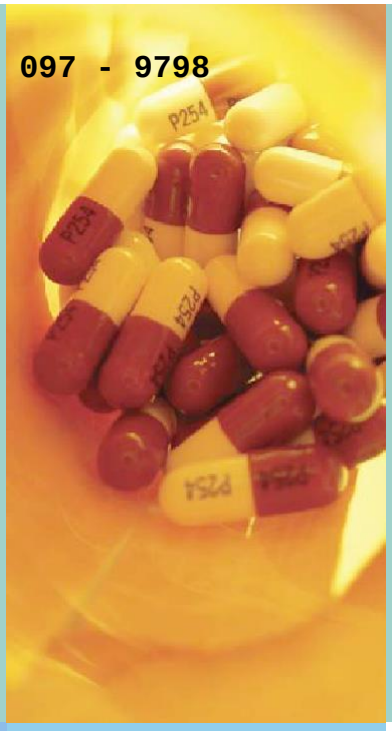

PROFESSIONAL STANDARDS AND GUIDANCE FOR PATIENT CONFIDENTIALITY

Pharmaceutical Society of Northern Ireland

PROFESSIONAL STANDARDS AND GUIDANCE FOR PATIENT CONFIDENTIALITY

CONTENTS

STATUS OF THIS DOCUMENT

This guidance is addressed to pharmacists but may also help patients and the public understand the nature and level of confidentiality that may be expected of their pharmacist.

Standard 2.1.12 of the Code states that a pharmacist must adhere to all relevant legislation, standards and guidance.

This document contains:

- mandatory professional standards (indicated by the word 'must' and 'have to') for all registered pharmacists;
  and
- guidance on good practice (indicated by the word 'should', 'might', 'may', 'would', 'will' and 'could') which should be followed in all normal circumstances.

Serious or persistent failure to follow this guidance will put a pharmacist's registration at risk. The pharmacist must, therefore, be prepared to explain and justify his[1] actions.

If a complaint is made against a pharmacist, the Pharmaceutical Society NI's, Fitness to Practise committee will take account of the requirements of the Code and underpinning documents, including this one. The pharmacist will be expected to justify any decision to act outside the terms set down in these documents.

ABOUT THIS DOCUMENT

The Code sets out the five mandatory principles of professional and ethical practice that a pharmacist must follow. It provides a framework for professional decision-making and it is the pharmacist's responsibility to apply the principles to daily work situations, using his professional judgement. The guidance is not meant to be exhaustive, nor can it be.

1 'Pharmacist' appears with masculine pronoun and is understood to refer to male/female gender.

Standard 1.3 of the Code states that a pharmacist must '***maintain and protect confidential information***'. In adhering to this standard, a pharmacist is expected to:

- respect the confidentiality of information, professional or otherwise, acquired in the course of professional practice or only use it for the purposes for which it is given and in compliance with current legislation.
- maintain systems which ensure security of information and take reasonable steps to prevent unauthorised access to it.
- ensure that all who have access to patient or service user's information know and maintain its confidential nature.
- ensure that confidential information is not disclosed without consent, except where legally required or permitted.

This document expands on the principles of the Code to explain the pharmacist's professional responsibilities when protecting patient privacy and the confidentiality of patient information.

A pharmacist has both a professional and legal duty to protect the privacy and confidentiality of patient information. This forms part of the general obligation to provide a service which is respectful of and actively promotes the human rights and dignity of patients.

This document does not give detailed guidance on legal requirements. The pharmacist must adhere to relevant legislative requirements set out in the Data Protection Act 1998, Human Rights Act 1998, the common law of confidentiality[2] and with any Health Service or employment policies that may apply to his work.

This guidance takes account of, and is consistent with current law in Northern Ireland.

All pharmacists should endeavour to keep themselves informed of any developments which may be relevant to their practice. Occasionally it may be necessary to ask for a professional legal opinion.

1 PROTECTION OF SERVICE USER INFORMATION

The general duty to maintain confidentiality and respect privacy is recognised by professional ethical codes which apply to health and social care staff including pharmacists and their staff and they abide by the Data Protection Act

2 The common law is the law that develops over time through the decisions of judges in particular cases. It is not included in an Act of Parliament.

1.1 ETHICAL OBLIGATIONS TO PROTECT PATIENT PRIVACY

The Department of Health, Social Services & Public Safety, Code of Practice on Protecting the Confidentiality of Service User Information clearly states that, *"The nature of the **obligation to protect confidentiality** can be expressed in terms of three core **ethical principles which underpin the law**:*

- *individuals have a **fundamental right to the privacy and confidentiality** of information related to their health and social care;*
- *individuals have a right to **control access to and disclosure of their own health and social care information** by giving, withholding or withdrawing consent;*
- *for **any disclosure** of confidential information health and social care staff should have a regard to its **necessity, proportionality and any risks attached to it[3]".***

An earlier draft of this document cited that, *"The **relationship between pharmacy staff and the service user** should be one of '**trust**'. Therefore within the relationship between a pharmacist or pharmacy staff and the patient, there exists a **tacit understanding** on the part of the patient that **private information will not be** further used or **disclosed without** the **awareness and consent** of the **patient.***

"Just as the patient has a right to self-determination in various other health and social care matters, it is in general the service-user's decision as to who should have access to personal health and social care information and how it may be used.

*"One reason for respecting confidences in health and social care is that doing so enables patients to disclose the sensitive information that staff need to provide treatment or care. **Without an assurance that confidentiality will be maintained, service-users might be less willing to disclose information,** resulting in obstacles to their effective care and negative effects for their health, for public health and for health and social care practice.*

*"**None of the arguments** stated above **lead to the conclusion that the ethical duty of confidentiality is absolute**. The confidentiality requirement exists within a wider social context in which members of staff have other duties, which may conflict with their duty of confidentiality. **In particular, they may have other ethical duties to disclose confidential information, without consent, if serious dangers are present for third parties or for the patient and where they judge that the disclosure of that information is likely to reduce or eliminate danger.** In assessing such risks and whether they outweigh the duty of confidentiality both the probability of the harm and its*

magnitude need to be considered. ***The ethical duty to disclose to prevent harm is greater when the combined weight of both the probability and the seriousness of harm to a third party or the patient are high***[4]*."*

1.2 DISABILITY DISCRIMINATION ACT 1995

Service providers are required under the Disability Discrimination Act 1995 to make reasonable adjustments to their policies, procedures and practices so that people with disabilities are not offered a service on less favourable terms than other members of society.

Human Rights legislation entitling people to privacy should also be borne in mind.

2 DUTY OF CONFIDENTIALITY STANDARDS

A patient has the right to expect that information obtained about him/her is kept confidential and is used only for the purposes for which it was given. This duty of confidentiality applies to all information obtained about a patient during the course of professional practice and extends to all members of the pharmacy team. Maintaining a patient's confidentiality is fundamental to the partnership between the pharmacist and the patient. A patient may be reluctant to seek advice from a pharmacist if he/she has concerns about the handling of confidential information.

Confidential information includes:

- personal details (including information that is not directly relevant to a patient's medical history);
- information about a patient's medication (both prescribed and non prescribed); and
- other information about a patient's medical history, treatment or care.

GOOD PRACTICE

For people with disabilities, confidentiality may be compromised if a patient finds him/herself obliged to ask a third party to read or explain information about the medication or dosage because the patient is unable to read or understand the information given to him/her.

3 DHSSPS "Code of Practice on Protecting the Confidentiality of Service User Information 29 January 2009. www.dhsspsni.gov.uk/confidentiality-code-of-practice0109.pdf
4 HSC, "Draft Code of Practice on Protecting the Confidentiality of Service User Information" 11 May 2007, Version 7.1, Page 7-8. www.dhsspsni.gov.uk/confidentiality-consultation-cop.pdf

If a pharmacist or member of staff in a pharmacy, knows or has reason to believe that a patient will not be able to read the information on packaging or patient information leaflets, he should take every step to eradicate the need for a patient to have to ask a third party to do this.

These steps will include:

- arranging for audio, large print or Braille versions of the Patient Information Leaflet to be made available to the patient as quickly as possible (e.g. through the X-PIL scheme);
- directing the patient to accessible websites or telephone information systems (e.g. the X-PIL scheme);
- writing dosage or other key information in a size and font which a patient can read;
- using compliance devices to help patients take the right medication at the right time;
- using differently sized or shaped containers for different medicines;
- taking additional time to explain the necessary information so that the patient can take it down in whatever way best suits them.

This list is not exhaustive, and the patient should always be asked which form of assistance, if any, he/she would like to receive. Please refer to www.rnib.org.uk.

3 KEEPING INFORMATION CONFIDENTIAL

3.1 DATA PROTECTION ACT (1998)

The Data Protection Act gives individuals the right to know what information is held about them. It provides a framework to ensure that personal information is handled properly.

The Act works in two ways. Firstly, it states that anyone who processes personal information must comply with eight principles, which makes sure that personal information is:

- fairly and lawfully processed;
- processed for limited purposes;
- adequate, relevant and not excessive;
- accurate and up to date;
- not kept for longer than is necessary;
- processed in line with an individual's rights;
- secure;
- not transferred to other countries without adequate protection.

The second area covered by the Act provides individuals with important rights, including the right to find out what personal information is held on computer and most paper records.

Should individuals or organisations feel they are being denied access to personal information they are entitled to, or feel their information has not been handled according to the eight principles, they can contact the Information Commissioner's Office[4 5] for help. Complaints are usually dealt with informally, but if this is not possible, enforcement action can be taken.

GOOD PRACTICE

For a patient experiencing any disability including, visual impairment, he/she will be denied his/her rights under the Data Protection Act if the eight principles contained within Act, or the means by which to raise a complaint, are not communicated to the patient in an accessible format appropriate for that patient.

Under the Data Protection Act an individual has the right to find out what personal information is held about him/her on computer or paper. For an individual with a visual impairment, information held about them on computer or on paper would need to be shown to them in an accessible format according to his/her personal choice in the event of that person making such a request.

3.2 PREVENTING INFORMATION BEING RELEASED ACCIDENTALLY STANDARDS

Accidental disclosure of information constitutes a breach of confidentiality. A pharmacist must take all reasonable steps to prevent accidental disclosure of, or unauthorised access to, confidential information. Robust procedures must be in place to protect the confidentiality of information the pharmacist receives, stores, sends or destroys. Patient identifiable information includes:

- the patient's name;
- postal address including postal code;
- date of birth;
- Health and Care number or local patient identifiable codes;

4 The Information Commissioner oversees adherence to the Data Protection Act 1998 and is also responsible for enforcing the Freedom of Information Act.
5 The Information Commissioner's Office – Northern Ireland, 51 Adelaide Street Belfast BT2 8FE Telephone: 028 9026 9380, Fax: 028 9026 9388, Email: ni@ico.gsi.gov.uk

- video footage; and
- anything else that can identify a patient either directly or indirectly such as rare diseases, drug treatments etc.

All records, registers, prescriptions and other sources of confidential information must be stored securely and be kept out of sight of patients, members of the public and any other person who should not have access to them. Security measures must be appropriate to the location where the confidential information is being stored.

The pharmacist must also take all reasonable steps to ensure appropriate levels of privacy for patient consultations so that confidential information is not overheard or accessed by others.

3.3 DISPOSAL OF PATIENT IDENTIFIABLE INFORMATION STANDARDS

Good records management and good professional practices are the essential basis of respect for the privacy of patient's information. In order to safeguard a patient's confidentiality, sources of patient-identifiable information must be disposed of in a way that prevents the information being accessible to unauthorised persons. This disposing should be done at a time consistent with an organisation's disposal schedule.

GOOD PRACTICE GUIDANCE

Disposing of patient identifiable information may involve cross-shredding, incineration, placing it in confidential waste or deleting the information with an indelible marker.

3.4 COMPUTER RECORDS STANDARDS

A patient has the right to expect that any computer record about him/her is held securely and is appropriately protected. The pharmacist is a data controller as per the Data Protection Act (1998) and must be satisfied that any system used is capable of restricting access. Suitable passwords, Personal Identification Number (PIN) or other restricted access systems must be in place. Any information stored about a person must be pertinent, accurate and up-to-date. Computers must be situated so that data cannot be seen intentionally, or by accident, by those who are not authorised to have access to it. Care must be taken in disposing of old computers to ensure that any confidential information/data is securely destroyed as far as possible.

GOOD PRACTICE GUIDANCE

- PIN numbers or passwords should not be shared and should be changed at regular intervals and on specific occasions (for example, if a member of staff terminates employment at the pharmacy).
- The level of access that various members of the pharmacy team have to a patient's records should be appropriate to their duties. For example, a member of staff who is responsible for ordering stock for the shop front will not need access to Patient Medication Records (PMRs) in the dispensary.

3.5 NOTIFICATION TO THE INFORMATION COMMISSIONER'S OFFICE (ICO)

STANDARDS

The processing of personal data, including the pharmacy PMR system, must be notified to the Information Commissioner's Office and records must be kept in accordance with relevant legislation. The ICO website provides guidance on the obligations of a data controller and specific guidance regarding the processing of health data.
(http://www.ico.gov.uk/upload/documents/library/data_protection/practical_app lication/health_data_-_use_and_disclosure001.pdf)

Unnecessary access to patient specific data must be prevented whether data is held electronically or in hard copy format. (Refer to Data Protection Act, 1998).

3.6 PHARMACY STAFF

STANDARDS

The pharmacist must ensure that all members of the pharmacy team are aware of, and demonstrate an understanding of, their duty to respect an individual's right to confidentiality and their obligations under the Data Protection Act (1998).

GOOD PRACTICE GUIDANCE

- Members of staff, where necessary, should understand that they have a duty to treat any information they receive in the course of their employment as confidential and failure to do so may result in disciplinary action. Employee contracts should include a confidentiality clause which should be signed by each member of staff. One copy should be retained on the personnel file and one copy retained by the member of staff.
- In the case of a pharmacist contacting another community pharmacy, general practice or nursing home requesting information about a

patient's medication history, only that information which is necessary to confirm patient identity and the nature of the request for a medication history should be provided. Other information such as the patient's current clinical condition should not be disclosed by the pharmacist.

3.7 STANDARD OPERATING PROCEDURES

STANDARDS

The way in which confidential information is handled must be taken into account when developing and reviewing standard operating procedures. Procedures must cover:

- who has access to confidential information and in what circumstances;
- how confidential information will be processed, used, stored and destroyed;
- disclosure of information; and
- maintenance of appropriate records of request for disclosure and details of the information disclosed.

4 DISCLOSURE OF INFORMATION

4.1 OBTAINING PATIENT CONSENT

STANDARDS

Information about a patient must not be disclosed without his/her consent other than in exceptional circumstances, or where required or permitted to by law, or by order of a Court. (See section 5 of this document). Where a patient allows the pharmacist to share information about him/her the pharmacist must make sure that the patient understands and does not object to:

- the information being released;
- the reason for the release;
- the categories of people and organisations to which the information will be released to; and
- how that information will be used.

GOOD PRACTICE

It is advisable that the pharmacist inform the patient of the nature and extent of the information to be shared and the need. In general, consent is required for the processing of sensitive personal data.

However, a patient will generally expect that information the pharmacist obtains in the course of his professional practice may be shared with other healthcare professionals or others who have a duty of confidentiality. The consent of the patient to the disclosure of information necessary for his/her care may be inferred from his/her acceptance of that care.

There may be occasions when a patient refuses to consent to particular information being shared with others providing care for him/her, for example, their general practitioner. Other than in exceptional circumstances the pharmacist must respect the patient's decision (see section 5.2 of this document). The patient must be made aware of the possible implications of not consenting to disclosure and his/her refusal to give consent must be documented.

Further information on obtaining consent can be found in the organisation's document, '*Standards and Guidance for Patient Consent*'.

4.2 RELEASING THE MINIMUM AMOUNT OF INFORMATION NECESSARY STANDARDS

When disclosing patient information, the pharmacist must release only the minimum amount of information necessary for the purpose. The pharmacist must use his professional judgement to consider the information needed to be disclosed, taking into account who is requesting the information and why.

If it is not necessary for the patient to be identified, the pharmacist must make sure that the information released by him does not inadvertently facilitate identification.

GOOD PRACTICE GUIDANCE

- Where appropriate, consideration should be given to the use of anonymised or encrypted data. [Note: anonymised/encrypted information is not considered to be confidential and its storage is not restricted in the same way as confidential information].
- In the case of a pharmacist who phones a fellow professional requesting a patient's drug information, the community pharmacist who accepts the call, must be satisfied that the individual he is speaking to, is known to him before disclosing confidential patient information (see section 5.2.2 and 5.3).

4.3 DECEASED PATIENTS STANDARDS

The confidential nature of a patient's information and the ethical obligation on pharmacy staff to respect that confidentiality remain after the death of a patient. As in life, the duty to maintain confidentiality of patient information after death is not absolute, but is subject to ethical and legal limitations. Even though the patient can no longer be harmed directly there is still a public interest in the maintenance of his/her privacy after death. A deceased patient's surviving friends and relatives might be harmed by disclosures, too, and it is they who might take action for a breach of confidentiality. {See *Lewis –v- SOS for Health [2008] EWHC 2196 QB*[6]}.

A competent patient can give or withhold consent to disclosure of information before his/her death and such wishes should be respected as they would in other circumstances. In particular, where a patient has made an explicit request before his/her death that confidential information should not be disclosed, then the patient's request should normally be upheld.

The '*Access to Health Records (Northern Ireland) Order 1993*' governs access to the health records of deceased patients.

5 RELEASING INFORMATION WITHOUT CONSENT

5.1 DECIDING TO RELEASE INFORMATION WITHOUT CONSENT STANDARDS

Confidential information must only be disclosed without consent **in exceptional circumstances or when permitted or required by law**, for example, where disclosure is by an order of the court, or where the public interest overrides the need to keep information confidential. Examples of circumstances where information may be disclosed without consent are detailed in section 5.2 of this document. Before releasing information without consent the pharmacist must, where practical or appropriate, endeavour to persuade the patient either to release information him/herself, or give permission to release it.

6 **Lewis v Secretary of State for Health [2008] EWHC 2196 (QB) (QBD)**. Under its general powers the court authorised the disclosure of the medical records of certain deceased patients to the Redfern Inquiry into human tissue analysis in United Kingdom nuclear facilities. A duty of confidentiality was capable of surviving the death of the confider. In the circumstances of the instant case, the duty of confidence had not survived the death of the confider. As to the legal foundation for authorisation, the statutory basis for authority to disclose the material sought would be rejected. The instant case was an appropriate case in which to hold that the public interest in disclosure of the material sought outweighed the other public interest, namely, that of maintaining the confidentiality of medical records and information, provided proper safeguards were put in place to ensure that no inappropriate information became public. Accordingly, disclosure of the medical records would be granted under the court's general powers.

If the pharmacist decides to reveal confidential information without obtaining consent he must be prepared to justify his decision and any action taken as a consequence of that decision.

5.2 EXCEPTIONAL CIRCUMSTANCES (INCLUDING THOSE PERMITTED OR REQUIRED BY LAW)

Information can be disclosed without patient consent in the following circumstances, including:

5.2.1 Where the patient's parent, guardian or carer has consented to the disclosure and the patient is deemed by law to be, or appears to be, incapable of consenting.

The organisation's document *Standards and Guidance for Patient Consent* provides information on determining a patient's capacity to provide consent.

Consideration should be taken of assessments already made by colleagues, for example, the patient's GP or an independent legal advisor.

5.2.2 Where disclosure of the information is to a person or body with a statutory right to require disclosure.

STANDARDS

Where the pharmacist is required to disclose information he does not have to obtain consent prior to disclosure. He must ensure that he releases the information only to an authorised person who is requesting disclosure in the performance of their statutory duties.

GOOD PRACTICE GUIDANCE

- *All reasonable efforts should be made to tell the patient that information will be released, why it is being released and to whom it is being released.*

5.2.3 Where disclosure is directed by HM Coroner, a judge or other presiding officer of a court, Public Prosecution Service in Northern Ireland, Crown Prosecution Office in England and Wales or Procurator Fiscal in Scotland.

STANDARDS

A court may order the pharmacist to release patient information without consent. If so, he must release only the minimum information needed to follow the order. In certain situations, his refusal to disclose information could result in him being found in contempt of court.

GOOD PRACTICE GUIDANCE

- *The pharmacist should, where possible, seek further legal or specialist advice in these situations.*

5.2.4 To a police officer or Health Service fraud investigation officer who provides in writing confirmation that disclosure is necessary to assist in the prevention, detection or prosecution of serious crime.

STANDARDS

There may be occasions where obtaining patient consent prior to disclosure will be inappropriate, for example, the pharmacist may receive a request for information believed to be necessary in the prevention or investigation of serious crime, in a situation where attempting to obtain consent may allow time for destruction of evidence. The request to disclose such information must be made in writing, with a clear statement of the purpose for which the information is required.

GOOD PRACTICE GUIDANCE

- *When faced with requests from the Police or a Health Service fraud investigation officer the pharmacist should consider whether there are any alternative sources for the information being requested that would not cause a breach of trust between him and the patient. The pharmacist should also discuss the matter with the person making the request and be satisfied that without disclosure, the investigation would be delayed or prejudiced.*

5.2.5 Where necessary to prevent serious injury or damage to the health of a patient, a third party or to public health.

GOOD PRACTICE GUIDANCE

- *The pharmacist should discuss with the patient the implications of continuing to undertake the activity that may cause serious injury or damage.*

5.2.6 Where disclosure is necessary for the protection of an adult or child lacking capacity.

STANDARDS

Where abuse or neglect of a person is suspected, that person's well-being is of utmost importance and ensuring this must be the pharmacist's prime concern.

GOOD PRACTICE GUIDANCE

- *The pharmacist should attempt to encourage the person to consent to disclosure; should he/she refuse the pharmacist will need to use his professional judgement to determine the best course of action.*
- *The pharmacist should consider speaking with other healthcare professionals who are also involved in the patient's care, for example, his/her general practitioner.*

The pharmacist should consult the Information Commissioner's Office[7] where he has queries about the appropriateness of disclosure in any of the above circumstances.

7 The Information Commissioner's Office – Northern Ireland, 51 Adelaide Street Belfast BT2 8FE Telephone: 028 9026 9380, Fax: 028 9026 9388, Email: ni@ico.gsi.gov.uk

CIRCUMSTANCES WHERE DISCLOSURE CAN TAKE PLACE _WITHOUT_ PATIENT CONSENT:

- where the patient's parent, guardian or carer has consented to the disclosure and the patient is deemed by law to be, or appears to be, incapable of consenting;
- where disclosure of the information is to a person or body with a statutory right to require disclosure;
- where disclosure is directed by a coroner, judge or other presiding officer of the court, Public Prosecution Service in Northern Ireland, Crown Prosecution Office in England and Wales and Procurator Fiscal in Scotland;
- to a police officer or Health Service Fraud Investigation Officer who provides in writing confirmation that disclosure is necessary to assist in the prevention, detection or prosecution of serious crime;
- where necessary to prevent serious injury or damage to the health of the patient, a third party or to public health; and
- where disclosure is necessary for the protection of a child or adult lacking capacity.

5.3 MAINTAINING RECORDS STANDARD

When the pharmacist makes a decision to disclose information without consent, he must keep an accurate record of:

- the identity/role of the person making the request;
- the reasons for releasing the information without patient consent;
- the extent to which he attempted to obtain patient consent, if at all;
- reasons for not seeking consent;
- reasons given by the patient for refusing consent;
- what information was disclosed.

If a patient refuses to provide consent in one situation the pharmacist must not assume that he/she will refuse to provide consent for disclosure in the future, in either matching or differing circumstances.

6 NORTHERN IRELAND CODE OF PRACTICE ON CONFIDENTIALITY AND DISCLOSURE OF INFORMATION STANDARDS

In January 2009, the Department of Health, Social Services and Public Safety (DHSSPS) published a Code of Practice on Confidentiality and Disclosure of Information. The aim of this Code is to support all staff who provide health and social care services in making good decisions about the protection, use and disclosure of patient information.

The Code of Practice on Confidentiality and Disclosure of Information can be viewed at: http://www.dhsspsni.gov.uk/confidentiality-code-of¬practice0109.pdf.

This, and other relevant standards or guidance on patient confidentiality, must be adhered to unless the pharmacist has good reason not to do so.

GUIDANCE THAT SUPPORTS THIS DOCUMENT

The following documents or guidance bulletins should be considered in conjunction with these standards:

- The Code – professional standards of conduct, ethics and performance for pharmacists (2016);
- Professional Standards and Guidance for Patient Consent;
- Protection of children and vulnerable adults (POCVA).

FURTHER READING

- "Guidance on NHS Code of Practice on Confidentiality" 29 October 2005, The Pharmaceutical Journal (Vol. 275) P 557 – 558.
- ACCESS to Health Records (Northern Ireland) ORDER 1993.
- The NPA Guide to Data Protection and Confidentiality in Community Pharmacy, September 2006.
- Wingfield Joy and Badcott David. Pharmacy Ethics and Decision Making. 2007. Grayslake, IL: Pharmaceutical Press 313. ISBN:9780853696896.
- Disability Discrimination Act 1995
- The Data Protection Act 1998
- The Human Rights Act 1998
- The Caldicott Principles
- Code of Practice on Confidentiality and Disclosure of Information can be viewed at: http://www.dhsspsni.gov.uk/confidentiality-code-of-practice0109.pdf
- www.psnc.communitypharmacynews/freedomofinformationact2000. July 2007
- www.psnc.communitypharmacynews/dataprotectionact1998. August 2007

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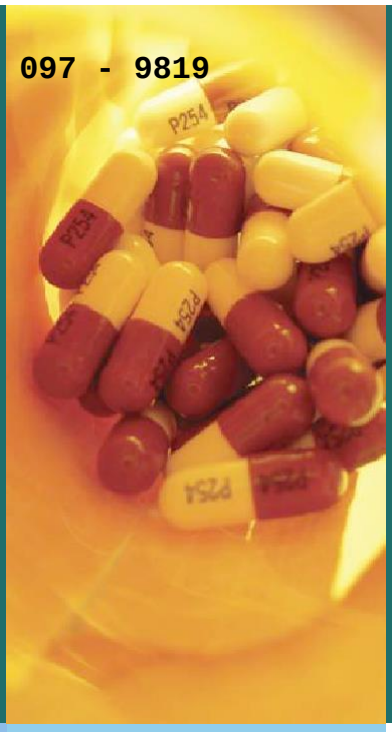

PROFESSIONAL STANDARDS AND GUIDANCE FOR THE SALE AND SUPPLY OF MEDICINES

Pharmaceutical Society of Northern Ireland

PROFESSIONAL STANDARDS AND GUIDANCE FOR THE SALE AND SUPPLY OF MEDICINES

CONTENTS

STATUS OF THIS DOCUMENT

This guidance is addressed to pharmacists but may also help patients and the public understand what they can expect when medicines are either purchased over the counter or supplied on prescription.

Standard 2.1.12 of the Code states that the pharmacist must be aware of adhere to all relevant legislation, and all current standards and guidance which apply to your practice.

This document contains:

- mandatory professional standards (indicated by the word 'must' and 'have to') for all registered pharmacists;
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Serious or persistent failure to follow this guidance will put a pharmacist's registration at risk. The pharmacist[1] must, therefore, be prepared to explain and justify his actions.

If a complaint is made against a pharmacist, the Pharmaceutical Society of NI's Fitness to Practise process will take account of the requirements of the Code and underpinning documents, including this one. The pharmacist will be expected to justify any decision to act outside the terms set down in these documents.

ABOUT THIS DOCUMENT

The Code sets out five principles of ethical and professional practice that a pharmacist must follow. It provides a framework for professional decision-making and it is the pharmacist's responsibility to apply the principles to daily work situations, using his professional judgement. The guidance is not meant to be exhaustive, nor can it be.

Principles 1 and 2 of the Code state, respectively, that the pharmacist must '***Always Put the patient first'*** and must ensure ***'Provide a Safe and Quality Service'.***

1 'Pharmacist' appears with masculine pronoun and is understood to refer to male/female gender

In adhering to these principles, the pharmacist is expected to:

- promote the safe, effective and rational use of medicines, medicinal products and therapies.
- effectively control the sale or supply of medicinal and related products paying particular attention to those with a potential for abuse or dependency.
- ensure that both you and those you employ or supervise have an appropriate level of language competence or skills.
- ensure that workload or working conditions do not compromise patient care or public safety.
- make sure that your actions do not prevent others from complying with their legal or professional obligations, or present a risk to patient care or public safety.
- ensure that all professional activities undertaken by you, or under your control, are covered by appropriate professional indemnity arrangements.
- purchase medicines only from suppliers and sources known to be reputable to ensure the safety, quality and efficacy of products supplied to patients.
- ensure you have the facilities, equipment and materials necessary to provide services to professionally acceptable standards.
- take all reasonable steps to ensure that patients have safe and timely access to their medicines and pharmaceutical care, and
- obtain appropriate consent from patients for the treatment and/or professional service provided, taking particular care to act in accordance with the law where you suspect that a patient lacks or may lack capacity to consent.

This document expands on the principles of the Code, to set out the pharmacist's professional responsibilities if he is involved in the sale and supply of medicines. It is designed to meet the organisation's obligations under relevant legislation.

This document does not detail legislative requirements, but when selling or supplying medicines the pharmacist must comply with relevant legislative and contractual requirements, including Health Service terms of service where appropriate.

1 PHARMACEUTICAL STOCK STANDARDS

Patients, members of the public and other healthcare professionals are entitled to expect that medicines sold or supplied within the course of professional pharmacy practice are obtained from a reputable source, that appropriate distribution processes are followed and that the medicines are fit for the intended purpose.

The pharmacist must ensure that:

1.1 if he suspects he has been offered or supplied a counterfeit or defective medicine, this is reported to the Medicines and Healthcare products Regulatory Agency (MHRA), the Department of Health Social Services and Public Safety (DHSSPS) Inspectorate, the Pharmaceutical Society NI, the Veterinary Medicines Directorate (VMD) or the marketing authorisation holder as appropriate to the individual situation. Any such stock must be segregated from other pharmacy stock and must not be sold or supplied for the treatment of any person(s) or animal(s);

1.2 pharmaceutical stock is stored under suitable conditions, taking into consideration the stability of the drug and any manufacturers recommendations;

1.3 particular attention is paid to protection of pharmaceutical stock from contamination, sunlight, atmospheric moisture and adverse temperatures;

1.4 in cases of concern about the stability of a medicine, it must be segregated from the rest of the pharmacy stock and not sold or supplied for patient or animal use;

1.5 refrigerators used for pharmaceutical stock must be capable of storing products between 2°C and 8°C, thereby ensuring the maintenance of the "*cold chain*" and integrity of fridge lines supplied. They must be equipped with a maximum/minimum thermometer, or other suitable alternative, which is checked on each day the pharmacy is open and the maximum and minimum temperature recorded. Steps must be taken to rectify discrepancies and to appropriately dispose any pharmaceutical stock that has been subjected to temperatures outside the terms of SPC recommendations;

1.6 the labelling of all stocks of medicines in the pharmacy with batch and expiry details;

1.7 the removal of medicines from blister or foil packs only, where required, at the time of dispensing, to assist an individual patient. In so doing, the integrity of the medicine must not be impaired;

1.8 the segregation of date-expired stock from the rest of the pharmacy stock and its appropriate disposal;

1.9 the installation of procedures to reduce the risk of short dated or out-of-date stock being accidentally supplied to a patient or member of the public;

1.10 a ban on the sale or supply of products, from registered pharmacy premises, that may be injurious to a person's health, for example, tobacco products, alcoholic beverages and products intended to mask the signs of alcohol or drug consumption;

1.11 the segregation and appropriate disposal of medicines returned to the pharmacy from a patient's home, a care home or a similar institution; these medicines must not be supplied to another patient.

1.12 within the hospital setting, all medicines returned to the pharmacy department from a ward or other hospital department are examined under the direction of a pharmacist to assess their suitability for being returned to stock. This also includes ensuring patients' own medicines brought into hospital with them are not returned to pharmacy stock or supplied to another patient. (Refer to "*Use and Control of Medicines*" (DHSSPS) 2004 and the "*Duthie Report, UK.*")

2 SUPPLY OF OVER THE COUNTER (OTC) MEDICINES STANDARDS

When purchasing medicines from pharmacies patients expect to be provided with high quality, relevant information in a manner they can easily understand.

The pharmacist must ensure that:

2.1 procedures for sales of OTC medicines enable intervention and professional advice to be given whenever this can assist in the safe and effective use of medicines;

2.2 Pharmacy (P) medicines are not accessible to the public by self-selection;

2.3 for a patient or their carer who requests advice on treatment, sufficient information is obtained to enable an assessment to be made of whether self-care is appropriate, and to enable a suitable product(s) to be recommended;

2.4 if a sale is not considered suitable, the reasons for this are explained to the patient and he/she is referred to another healthcare professional where appropriate;

2.5 on supplying an OTC medicine, sufficient verbal advice is given to ensure its safe and effective use, including specific information on aspects such as safe storage, or short expiry dates;

2.6 all staff involved in the sale or supply of an OTC medicine are trained, or are undertaking the training required for their duties, and are aware of situations where referral to the pharmacist or other registered healthcare professional may be necessary;

2.7 consideration is given to the types of OTC medicines that may require the personal intervention of a pharmacist, for example, those that have recently become available without prescription, those that may be subject to abuse or misuse[2], or where the marketing authorisation for non-prescription use is restricted to certain conditions or circumstances;

2.8 all persons involved in the sale of OTC products are aware of the abuse potential of certain OTC medicines and other products including being alert to requests for large quantities and abnormally frequent requests, and knowing to refuse to make a supply where there are reasonable grounds for suspecting misuse and/or abuse;

2.9 the exercise of particular care when supplying products for children, the elderly and other special groups or individuals, or where the product is for animal use;

2.10 the sensitive handling of requests for certain medicines such as emergency hormonal contraception and the respecting of the patient's right to privacy and confidentiality;

2.11 any information provided about OTC medicines is up-to-date, accurate and reliable;

2.12 he keeps up to date with developments regarding new products and policies for health promotion and is aware of local and major national health promotion initiatives.

GOOD PRACTICE GUIDANCE

- Medicines should not be sold to children under 16 years except in exceptional circumstances.

3 SUPPLY OF PRESCRIBED MEDICINES

STANDARDS

Patients are entitled to expect the dispensing service provided to be accurate, accessible and reasonably prompt. Appropriate standard operating procedures (SOPs) must be in place for the dispensing services the pharmacist provides[3], or is responsible for.

2 For more detailed information refer to:
- Substances of Misuse. RPSGB. February 2008.
- Letter on "Sale and Supply of Medicines Liable to Abuse," by Dr Michael Mawhinney, Head of Inspection and Investigation, DHSSPSNI, posted to all registrants and dated 4 July 2008

3 It is **mandatory** for a pharmacist to have SOPs in the pharmacy covering all stages of the 'prescription journey'. Members of the National Pharmacy Association (NPA) can download a "*Guide to writing SOPs – step by step, for community pharmacists.*" Template SOPs are also available from http://www.npa.co.uk.
With the introduction of Responsible Pharmacist Regulations from 1 October 2009, the responsible pharmacist must establish (where these are not already in place) pharmacy procedures designed to ensure the safe and effective running of the pharmacy. These procedures will need to be maintained and regularly reviewed. Refer to www.psni.org.uk/responsiblepharmacist.

The pharmacist must ensure that:

3.1 adequate stock holdings are maintained;

3.2 a clinical assessment of every prescription is undertaken, by a pharmacist, to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency for the patient;

3.3 the patient receives sufficient information and advice to enable the safe and effective use of the prescribed medicine;

3.4 appropriate records of clinical interventions are maintained;

3.5 patients or their carers are informed if the patient's prescription cannot be dispensed in its entirety and are given the opportunity to take their prescription to another pharmacy;

3.6 when medication is outstanding, the patient, carer or their representative is provided with a legible note detailing the name and quantity of medicine outstanding and, where possible, informed when the balance will be available for collection. A record of the medicine owed must be kept in the pharmacy. The supply of controlled drugs must be completed within 28 days of the date of issue of the prescription or other appropriate date as indicated by the prescriber on the prescription;

3.7 a product with a marketing authorisation is supplied where such a product exists in a suitable formulation and is available, in preference to an unlicensed product or food supplement;

3.8 except in an emergency, a specifically named product is not substituted for any product without the approval of the patient or carer and the prescriber, a hospital drug and therapeutics committee, or other similar locally-agreed protocols and a record is made in the Patient Medication Record (PMR);

3.9 when providing services for drug misusers the pharmacist does not deviate from the instructions given on the prescription. Sugar and/or colour-free products have a greater potential for abuse than syrup based and coloured products and must not be dispensed unless specifically prescribed;

3.10 all solid dose and all oral and external liquid preparations are dispensed in suitable re-closable child resistant containers unless:

- the medicine is in an original pack or patient pack such as to make this inadvisable;
- the patient has difficulty in opening a child resistant container;
- a specific request is made by the patient, their carer or representative that the product is not dispensed in a child resistant container;

- no suitable child resistant container exists for a particular liquid preparation; or
- the patient has been assessed as requiring a compliance aid.

3.11 labelling of dispensed products is clear and legible, computer-generated and where appropriate includes any cautionary and advisory labelling recommended by the current British National Formulary (BNF);

3.12 appropriate systems and procedures are in place if he prepares monitored dosage systems;

3.13 reimbursement claims for Health Service or other professional services are honest and accurate;

3.14 procedures are in place to minimise the risk of dispensing errors or contamination of medicines and a record of errors and '*near-miss*' incidents must be made and practices reviewed in light of such incidents.

3.15 a patient information leaflet (PIL) is issued with a medicine at the time of dispensing.

GOOD PRACTICE GUIDANCE

- Where verbal information is provided to a patient about a prescribed medicine a record of this should be maintained, when clinically appropriate.

4 EXTEMPORANEOUS PREPARATION OR COMPOUNDING STANDARDS

This standard is not intended to cover the reconstitution of dry powders with water or other diluents.

Patients are entitled to expect that products extemporaneously prepared in a pharmacy are prepared accurately and are suitable for use.

If the pharmacist chooses to be involved in extemporaneous preparation he must ensure that:

4.1 a product is extemporaneously prepared only when there is no product with a marketing authorisation available and where he is able to prepare the product in compliance with accepted standards;

4.2 the pharmacist and any other staff involved are competent to undertake the tasks to be performed;

4.3 the requisite facilities and equipment are available and the equipment is maintained in good order to ensure that it is fit for the intended purpose;

4.4 he is satisfied as to the safety and appropriateness of the formula of the product and its suitability for the patient;

4.5 ingredients are sourced from recognised pharmaceutical manufacturers and are of an acceptable quality for use in the preparation and manufacture of pharmaceutical products, in compliance with relevant legislation;

4.6 particular attention and care is paid to substances which may be hazardous and require special handling techniques;

4.7 the product is labelled with the necessary particulars, including an expiry date and any special requirements for the safe handling or storage of the product;

4.8 if he is undertaking large scale preparation of medicinal products, all relevant standards and guidance must be followed;

4.9 records are kept for a minimum of two years. The records must include:

- the formula;
- the ingredients;
- the quantities used;
- their source;
- the batch number;
- the expiry date;
- the patient's and prescription details; and the
- date of dispensing, the personnel involved, including the identity of the pharmacist taking overall responsibility.

4.10 the manufacture of nostrums should take account of guidance issued by the organisation, DHSPPS and other professional bodies and comply with all legal requirements.

GOOD PRACTICE GUIDANCE

- Where possible, all calculations and measurements should be double-checked by a second appropriately trained member of staff.
- Where possible, try to validate the formula for the product being prescribed before dispensing from an appropriate source, for example, contact Victoria Pharmaceuticals, Royal Victoria Hospital, Belfast.

5 REPEAT MEDICATION SERVICES

STANDARDS

A repeat medication service is operated in co-operation with local prescribers, in which pharmacists will provide professional support to assist in the rational, safe, effective and economic use of medicines.

In order to provide a repeat medication service, the pharmacist must:

5.1 ensure consent is obtained from the patient or carer before requesting a repeat prescription from a surgery. The pharmacist may himself establish a patient reminder system;

5.2 ensure the pharmacy operates a patient medication record system notified to the Information Commissioner's Office[4];

5.3 ensure that an audit trail exists to identify each request and supply;

5.4 establish, at the time of each request, which items the patient or carer considers are required and ensure that unnecessary supplies are not made. At this stage the pharmacist must also use his professional judgement to decide whether concordance or other problems encountered by the patient may require early reference to the prescriber;

5.5 record all interventions in order to be able to deal with any queries that may arise. It is good practice to keep records of interventions for up to a year after the intervention occurs.

6 DELIVERY SERVICES STANDARDS

A delivery service is where the medicine is handed to the patient or their carer other than on registered pharmacy premises. When providing medicines via a delivery service the pharmacist still has a professional responsibility to ensure that patients or their carers know how to use the medication safely, effectively and appropriately and to check that they are not experiencing adverse effects or compliance difficulties.

The pharmacist must ensure that:

6.1 on each occasion a delivery service is provided he uses his professional judgement to determine whether direct face-to-face contact with the patient or their carer is necessary;

6.2 he obtains consent from the patient to provide the delivery service, confirms consent on each occasion, as appropriate, and maintains appropriate records of requests for the service;

6.3 the delivery mechanism used:

- enables the medicine to be delivered securely and promptly to the intended recipient with any necessary information to enable safe and effective use of his medicine;

4 The Information Commissioner's Office – Northern Ireland, 51 Adelaide Street, Belfast, BT2 8FE. Telephone: 028 9026 9380, Fax: 028 9026 9388, Email: ni@ico.gsi.gov.uk

- provides for any special security/storage requirements of the medicine;
- incorporates a verifiable audit trail for the medicine from the point at which it leaves the pharmacy to the point at which it is handed to the patient or their carer, or returned to the pharmacy in the event of a delivery failure;
- safeguards confidential information about the medication that a patient is taking.

GOOD PRACTICE GUIDANCE

- Wherever possible a signature should be obtained to indicate safe receipt of the medicines.
- Systems should be in place to inform a patient who is not at home that delivery was attempted.
- Refer to the HSC Board's *Guidance on Collection and Delivery services*.

7 PRESCRIPTION COLLECTION SERVICE STANDARDS

A prescription collection service encompasses any scheme where a pharmacy receives prescriptions other than directly from the patient, their carer or their representative.

When providing such a service the pharmacist must:

7.1 obtain consent to collect/receive patients' prescriptions. The request for the ongoing service must be from the patient or their carer and procedures must exist for maintaining records of the initial request for the service;

7.2 explain fully to patients, or their carers, what the service involves, including the time period required to collect/receive and dispense their prescription;

7.3 ensure that any members of staff who collect prescriptions on his behalf are acting in accordance with his directions;

7.4 take all reasonable steps to ensure patient confidentiality and the security of prescriptions;

7.5 obtain consent from the patient or carer before requesting a repeat prescription from a surgery. The pharmacist may himself establish a patient reminder system;

7.6 on receipt of prescriptions, including electronic prescriptions, be satisfied that he is authorised to collect/receive and dispense them. Any

prescription for which he does not have the authority, must be returned to the surgery for collection by the patient or carer, or be directed to the pharmacy authorised to receive it;

7.7 where more than one pharmacy is involved in supplying prescriptions a SOP must be in place with detailed governance arrangements.

8 COMPLEMENTARY THERAPIES AND MEDICINES

STANDARDS

The pharmacist must ensure that he is competent in any area in which he offers advice on treatment or medicines.

If the pharmacy sells or supplies homeopathic or herbal medicines, or other complementary therapies, the pharmacist must:

8.1 assist patients in making informed decisions by providing them with necessary and relevant information;

8.2 ensure any stock is obtained from a reputable source;

8.3 recommend a remedy only where he can be satisfied of its safety and quality, taking into account the MHRA registration schemes for homeopathic and herbal remedies. (Refer to www.mhra.org.uk).

9 EMERGENCIES

STANDARDS

There may be occasions when the pharmacist is required to assist members of the public or patients in an emergency.

In such situations the pharmacist must:

9.1 give consideration, where appropriate, to using the provision that allows pharmacists to make an emergency supply of medicines in line with the Medicines Act legislation;

9.2 give consideration to the medical consequences, if any, of not making the supply and be satisfied that his decision will not lead to patient care being compromised;

9.3 make relevant records in relation to emergency supplies in the PMR and in the '*prescription only record*' book;

9.4 advise the patient on how to obtain essential medical care where he does not consider an emergency supply to be appropriate;

9.5 assist persons in need of emergency first aid or medical treatment whether by administering first aid within his competence or by summoning assistance.

10 PATIENT GROUP DIRECTIONS (PGDS)

The legal definition of a PGD is:

'*a written instruction for the sale, supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment.*'

Guidance[1] issued along with this definition sets the overall context in which PGDs should be viewed:

'*the majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability.*'

STANDARDS

If the pharmacist is involved in the **supply and/or administration of a medicine** under a patient group direction (PGD) he must:

10.1 be satisfied that the PGD is legally valid and that it has been approved by the relevant authorising body for the organisation in which it is being used;

10.2 ensure that when supplies are made the agreed protocol is followed and the information specified in the PGD is recorded. These records must include the identity of the pharmacist assuming responsibility for each supply;

10.3 ensure that he has up-to-date knowledge relating to the clinical situation covered by the PGD, the medicine and its use for the indications specified;

10.4 ensure that PGDs are reviewed, updated and re-authorised, in line with changes to clinical practice;

10.4 ensure that he has undertaken any training required for operation of the PGD;

10.5 ensure that the staff training specified will enable safe operation of the PGD.

If the pharmacist is involved in **writing and/or approving PGDs** the pharmacist is accountable for the content and must ensure that:

10.6 he is familiar with his role and responsibilities and the advice set out in relevant guidance;

[1] NPC - December 2009: A practical guide and framework of competencies for all professionals using patient group directions accessed http://www.elmmb.nhs.uk/patient-group-direction-primary-care/ accessed 1 March 2016

10.7 only PGDs which comply with legal requirements are approved;
10.8 the appropriate people have been involved in the drafting, approving and signing of the PGD. The PGD must be signed by:

- the doctor and pharmacist involved in developing the PGD;
- the authorising body for the organisation in which it is being used.

GUIDANCE THAT SUPPORTS THIS DOCUMENT

The organisation has produced documents or guidance on the following which should be considered in conjunction with these standards:

- The Code – standards of conduct, ethics and performance for pharmacists
- Standards and Guidance for Patient Consent
- Standards and Guidance for Patient Confidentiality.

These documents can be downloaded from the organisation's website www.psni.org.uk or telephone us on 02890 326 927 for more information or a hard copy(ies).

ROYAL PHARMACEUTICAL SOCIETY

Professional Standards for Hospital Pharmacy Services

For providers of NHS and independent hospital pharmacy services including those in hospitals, mental health, community service, prison, hospice, and ambulance settings.

Endorsed by:

Pharmacyforum — Leading Promoting Supporting

UKCPA — CLINICAL PHARMACY ASSOCIATION

NPPG — Neonatal & Paediatric Pharmacists Group

INDEPENDENT CHIEF PHARMACISTS GROUP

BPNG — BRITISH PHARMACEUTICAL NUTRITION GROUP

UKMi — UK Medicines Information

CMHP

Rheumatology Pharmacists UK

British Oncology Pharmacy Association — bopa

UK Renal Pharmacy Group

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Contents

Introduction

Since 2012, the Royal Pharmaceutical Society (RPS) has published professional standards for NHS and independent (private) sector pharmacy services in hospital, mental health, private, community service, prison, hospice, and ambulance settings. They apply whether services are provided internally or outsourced. These refreshed Standards replace the 2017 version of the Professional Standards for Hospital Pharmacy Services.

A key function of a professional leadership body is to provide professional standards that are supportive and enabling, but professionally challenging. The importance of professional standards alongside regulatory standards in supporting patient safety are repeatedly emphasized (1-3). There is a clear requirement for providers of pharmacy services to use them to improve and develop services that are safe and put the needs of people first. Professional standards are consistent with and complement relevant legal framework requirements as well as the minimum standards currently required by systems regulators, professional regulators, and insurers and may be used to help inform them. Whilst they are not mandatory, they are developed and owned by the profession, and set out what constitutes 'good' in terms of practice, systems of care, and working practices. Figure 1 illustrates where RPS professional standards fit in relation to legislation, regulatory standards, other standards, policies, and procedures.

These Standards have been developed and updated to ensure with the implementation of new and increasingly integrated models of care they continue to be applicable for now and the future. They underpin a person's experience of pharmacy services and the safe, effective management of medicines within and across organisations. They aim to ensure that people using services receive a high-quality pharmacy service, from admission through to discharge across multiple care pathways and healthcare providers. This helps protect them from incidents of avoidable harm and enables them to get the best outcomes from their medicines.

They have been updated using the RPS process for the development of standards and guidance. The literature review underpinning the update can be found on the RPS website. The development and updating of the Standards have been led by the pharmacy profession with lay input. Appendix 1 contains details of who has been involved.

Figure 1.
Where RPS professional standards sit in relation to legislation, regulatory standards, other standards, policies, and procedures.

Purpose

The Standards describe quality pharmacy services or 'what good looks like'. They provide a broad framework to support pharmacy teams continually improve services, shape future services and roles, and deliver high quality care across all settings and sectors. The Standards:

- Ensure that in the design and delivery of pharmacy services people are placed at their core, allowing them to make informed decisions about their care which is joined up across the system
- Assure that procedures are in place for the safe and effective use and supply of medicines

Support strong strategic, operational, personal and clinical leadership, systems of work and ensure the right skill mix, capacity and capability to deliver pharmacy services.

Scope

The Standards cover pharmacy services, whether provided internally or outsourced, and are applicable across the full range of service providers in the NHS and independent sector. They are applicable to apply in and across these and other services:

- Hospitals (acute and non-acute)
- Mental health
- Community services
- Prison
- Hospice
- Ambulance settings

They provide a framework for safety and quality that allows:

- The whole pharmacy team to recognise, develop, and deliver the best possible outcomes from pharmacy services
- The pharmacy senior leadership team to drive continuous improvement of services and innovation
- Assurance to Chief Executives and Board members that there is adequate professional input into medicines policy making within their organisation and across partner organisations and appropriate levels and quality of pharmacy services are being provided
- Commissioners/purchasers of pharmacy services, regulators, insurers, governments, and legislators to inform and complement their own standards and outcomes
- Development of more detailed standards for other areas, for example homecare services and secure environments

USING THE STANDARDS

The Standards can be used to support benchmarking in the acute, community, mental health, and commissioning sectors. RPS has produced benchmarking metrics for acute hospitals to support consistency in the way that acute hospitals measure performance. Associated resources on the RPS website provide links to legal and regulatory frameworks, international standards, core standards required by systems regulators, as well as signposting to more detailed guidance, resources, and support tools. Individuals and organisations are encouraged to submit examples of good practice to RPS as well as further feedback on the standards (support@rpharms.com).

The Professional Standards for Hospital Pharmacy Services

STRUCTURE OF THE PROFESSIONAL STANDARDS

The standards contain 3 overarching domains:

- The person's experience
- Medicines assurance
- Delivery of the service

Within these overarching domains sit eight standards. These are further subdivided into descriptors which support attainment of a standard. An overarching standard and descriptor outcome gives an overview of what each aims to achieve. Supporting statements explain how a descriptor can be achieved.

The standards refer to people using services throughout. This is used as an umbrella term to cover the full range of those using pharmacy services across sectors and includes children and young adults, service users and clients as well as their carers.

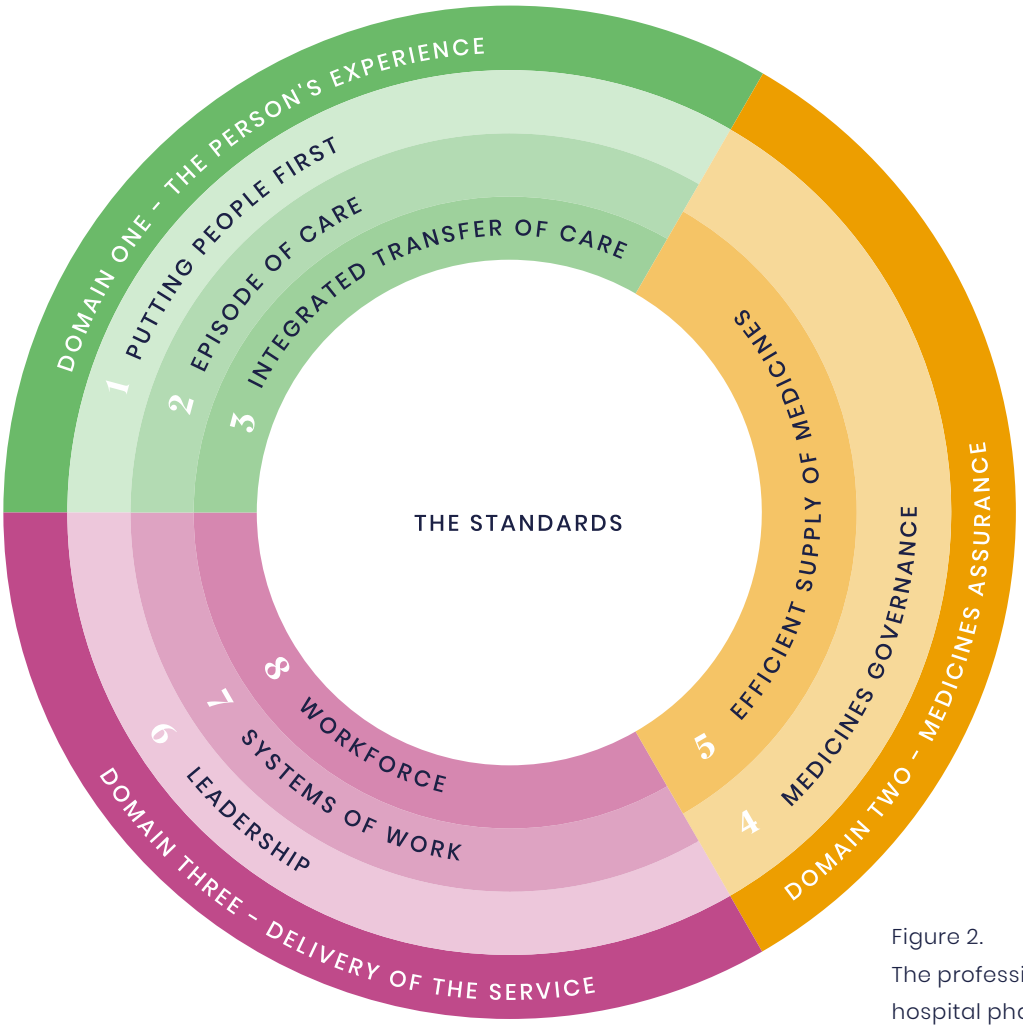

Figure 2.
The professional standards for hospital pharmacy services

Domain 1 The person's experience

Standard 1

PUTTING PEOPLE FIRST

- 1.1 Person focused services
- 1.2 Information about medicines
- 1.3 Support with effective medicines use

Standard 2

EPISODE OF CARE

- 2.1 Individual episode of care
- 2.2 Medicines related outcomes of treatment
- 2.3 Care of the person

Standard 3

INTEGRATED TRANSFER OF CARE

- 3.1 Medicines transfer at care interfaces
- 3.2 Integration

Standard 1
Putting People First

The principle of 'no decision about me, without me' underpins the design and delivery of pharmacy services ensuring that people using services can make shared decisions about their treatment and medicines. Appropriate support is provided to people to ensure effective medicines use.

DESCRIPTOR 1.1
PERSON FOCUSED SERVICES

People, their families, and circles of support are put at the heart of health, care, and wellbeing and care is focused on the needs of the individual.

The pharmacy team provide the expertise, leadership, and systems support to ensure that:

a. People are treated with compassion, dignity, and respect by all members of the pharmacy team.

b. The pharmacy team introduce themselves, their role and purpose consistently.

c. People's values, circumstances, and preferences about treatment and care are understood.

d. People are involved in decisions about the pathways under which they receive care and information (e.g., in person or remotely/virtually).

e. Views are routinely sought from people, their families, and circles of support to inform the development, improvement, and delivery of pharmacy services, ensuring people have direct input into the services that they receive.

DESCRIPTOR 1.2
INFORMATION ABOUT MEDICINES

People using services are supported to understand* the benefits and risks of medicines, their alternatives or doing nothing. People can decide about a preferred course of action based on good quality evidence-based information and their personal preferences.

**When people lack capacity, appropriate procedures should be followed, including those for deprivation of liberties, safeguarding and covert administration.*

The pharmacy team provide the expertise, leadership and systems support to ensure that services:

a. Allow people the opportunity to have meaningful discussions about their medicines, or alternative options with an appropriate pharmacy team member or other professional during a care episode and, where appropriate, after transfer to another care setting through face-to-face or virtual pharmacy services.

b. Provide people with information such as when and how to take their medicines, taking other medicines at the same time, advice about side effects, any associated costs or other relevant information in a form that they can access and understand.

c. Advise people who to contact or where to go if they need more information about their medicines, who will prescribe continuing treatment and how to access further supplies or dispose of medicines.

d. Discuss with the person information about their medicines in a form that they can understand and refer back to before discharge or transfer to another service.

e. Where appropriate, offer information in a format that is culturally sensitive or accessible to people with additional needs such as physical, sensory, or learning disabilities, and to people who do not speak or read English.

f. Partner with people and the multidisciplinary team across the system to identify, assess, and resolve barriers to actively promote and facilitate the provision of clear, understandable information about medicines.

DESCRIPTOR 1.3

SUPPORT WITH EFFECTIVE MEDICINES USE

Systems are in place to identify people who may need support, or to allow people to request support with medicines choice and use.

The pharmacy team provide the expertise, leadership, and systems support to ensure that:

a. People's beliefs, expectations about, and experiences of, taking their medicines are explored to identify those requiring support.

b. People in need of pharmacy support and pharmaceutical care planning are identified and necessary support is documented in their record. If required, further specialist input is provided by an appropriate member of the healthcare team.

c. After assessment and in partnership with the person, reasonable adjustments are made to support medication adherence.

d. Liaison with other healthcare professions or agencies within the system is undertaken where ongoing support with medicines is needed.

e. If care is transferred to another setting, people are referred or signposted to appropriate follow up or support with their medicines.

f. People are signposted to pharmacy support to improve health and wellbeing using public health services and activities when appropriate.

g. Measures to identify and support people at high risk of experiencing problems with their medicines on transfer to another care setting are in place.

Standard 2 Episode of Care

People's medicines are reviewed for accurate medication history, experiences of their medication and clinical appropriateness.

DESCRIPTOR 2.1
INDIVIDUAL EPISODE OF CARE

At pre-admission, admission, transfer, or discharge, people's medicines are reviewed to ensure an accurate and complete medication history and to identify medicines related admissions. People are encouraged to bring their own medicines to the care setting, or they are made available when needed.

The pharmacy team provide the expertise, leadership, and systems support to:

a. Reconcile people's medicines and optimise treatment to identify and avoid potential medication-related discrepancies before a planned admission.

b. Reconcile people's medicines in accordance with national guidance to avoid potential medication-related discrepancies.

c. Effectively document people's medication histories and identify medicines related admissions as part of the admission process.

d. Identify potential medicines related problems affecting discharge or transfer to another care setting so that they can be addressed to avoid risks to patient care and extending the person's episode of care.

e. Ensure people's medicines are available from the time that their next dose is needed, minimising missed doses of medicines and ensuring timely administration of critical medicines.

f. Enable people to bring their own medicines into the care setting with them; and ensure policy and procedures are available that enable staff to support appropriate self-administration of medicines.

DESCRIPTOR 2.2
MEDICINES RELATED OUTCOMES OF TREATMENT

As part of the multidisciplinary team, the pharmacy team understand people's goals and experiences of their medicines.

The pharmacy team provide the expertise, leadership, and systems support to:

a. Understand people's views, knowledge, outcomes, and experiences of their medicines.

b. Monitor people's responses to their medicines, including any unwanted effects. Appropriate action is taken where problems (potential or actual) are identified.

c. Help people to avoid and/or minimise adverse events resulting from their medicines.

d. Document and report adverse events that arise through relevant systems, appropriately managing them whilst recognising duty of candour and the need for transparency and shared learning from incidents.

e. Empower people to take an active role in the safety and effectiveness of their treatment.

DESCRIPTOR 2.3

CARE OF THE PERSON

People have their medicines clinically reviewed by pharmacy team members who play an active role in medicines management. People can access the pharmacy expertise that they need to ensure that their medicines are clinically appropriate, and their outcomes from medicines are optimised.

The pharmacy team provide the expertise, leadership, and systems support to ensure:

a. Treatment requirements are clinically reviewed to optimise outcomes from any medicine prescribed with the frequency and level of review adjusted according to individual need.

b. In partnership with the person, medicines regimens are simplified as far as possible, doses optimised, and medicines stopped when agreed it is in their best interests.

c. The pharmacy team, in partnership with the multidisciplinary team, work to ensure that medicines are available and administered on time to avoid omissions and delay in treatment. Appropriately trained pharmacy team members may also administer medicines to people independently and/or support others during medicines administration rounds.

d. Pharmacy team members are integrated into multidisciplinary teams across the organisation and provide person facing clinical services to ensure safe and appropriate medicines use for all, whatever the setting.

e. Pharmacy team members optimise treatment for people, identifying high-risk medicines and antimicrobials. Teams ensure that medicines are used in accordance with local policies and/or reflect what is recognised as good clinical practice.

f. Pharmacist prescribers are integrated into relevant care pathways and are prescribing regularly.

g. Advanced/consultant level pharmacists work in clinical specialties to maximise the availability of expert resource to other members of the multidisciplinary team for the benefit of those receiving care in that area.

Standard 3 Integrated Transfer of Care

As part of the local health and social care system, the pharmacy team ensure safe and timely transfer of information about the person and their medicines between care settings.

DESCRIPTOR 3.1
MEDICINES TRANSFER AT CARE INTERFACES

Accurate and complete information about a person's medicines is provided to the person and transferred to the health or social care professional(s) taking over care of the person at the time of transfer. Arrangements are in place to ensure a safe supply of medicines for the person and ongoing support where necessary.

The pharmacy team provide the expertise, leadership, and systems support to enable the organisation to:

a. Transfer information about a person's medicines to the professional(s) taking over care of the person in accordance with national guidance following discharge.

b. Ensure the accuracy, legibility, and timeliness of information transfer as far as practicably possible.

c. Ensure that people have access to an ongoing supply of their medicines (based on local agreement and individual need) and share information so that their medicines can be reconciled by the health professionals taking over responsibility for care.

d. Monitor, identify, and minimise delays to people's discharge or transfer due to problems in medicines being supplied.

e. Engage with people, their families, and circles of support as active partners in managing their medicines at the time of transfer. A complete list of medicines is given to the person and/or those supporting them at the time of transfer with an explanation of why they are taking them, and when and how to take them as well as a description of any changes made.

f. Communicate information about people's medicines in a way that is timely, clear, and unambiguous. It should be generated and transferred in the most effective and secure way, preferably electronically.

DESCRIPTOR 3.2
INTEGRATION

The pharmacy team, in collaboration with those across the system, strive for effective, joined up, and smooth transitions of care for people.

Within the pharmacy service, the pharmacy team:

a. Work in partnership with those across the system to ensure transitions of care are seamless for people.

b. Foster closer working relationships between pharmacy teams across all settings to ensure timely and seamless support for people.

c. Have a clear picture of pharmacy resources in their local area and use this in planning services.

d. Maximise the potential and capacity of pharmacy resources in the local area.

Domain 2 Medicines assurance

Standard 4

MEDICINES GOVERNANCE

- 4.1 Safety culture
- 4.2 Safe systems of care
- 4.3 Effective management of medicines
- 4.4 Digital technology and informatics to support medicines use
- 4.5 Support for other health and social care staff

Standard 5

EFFICIENT SUPPLY OF MEDICINES

- 5.1 Medicines procurement
- 5.2 Storage, access, and return of medicines
- 5.3 Prepared or manufactured unlicensed medicines
- 5.4 Dispensing

Standard 4 Medicines governance

Pharmacy expertise is consistently available whenever people need the service to lead the safe and effective use of medicines. The pharmacy team leads a multidisciplinary approach to safe medication practices across the organisation and within systems.

DESCRIPTOR 4.1
SAFETY CULTURE

The pharmacy senior leadership team ensure that medication safety is embedded, both within their organisation and partner organisations, including those providing outsourced services. Services are risk assessed and reviewed regularly to ensure safety.

Within the pharmacy service:

a. The Chief Pharmacist, or equivalent, has overall responsibility for medication safety and has direct access to Board support for the management of medicines safety in the organisation.

b. The organisation has a lead for medication safety with suitable experience, time, and resource, who is accountable for overview, reporting, and learning from adverse events or near misses.

c. The lead for medication safety leads on training for all pharmacy team members to embed a safety culture and ensure that medication safety is part of all job roles within pharmacy.

d. The lead for medication safety, or a nominated deputy, represents pharmacy on all high-level medicines safety and governance groups which include representation from people using services.

e. Controlled drugs are managed in line with the requirements of the Misuse of Drugs Act. Regular updates and concerns about controlled drugs are reported to the Controlled Drugs Accountable Officer.

f. The lead for medication safety, or a nominated deputy, must lead or be party to, serious incident investigations directly involving medicines or involving harm from the use of medicines.

g. Systems and processes are in place to ensure other medication incidents are identified, recorded, monitored, appropriately reported, investigated and practice changed and shared to minimise recurrence.

h. The pharmacy team actively works with, and where necessary, intervenes with prescribers, other healthcare professionals, and people using services to ensure medicines are used as safely and effectively as possible.

i. The pharmacy team, in partnership with other healthcare professionals, ensure that there are systems in place to identify trends in practice and outcomes that give rise to safety concerns.

j. Systems are in place to ensure people who have experienced a medication error are informed, apologised to, and understand any action being taken to rectify the error in line with duty of candour.

k. Shared learning is reviewed and reported at Board level on a regular basis, and shared within the organisation, professional networks, and systems.

l. Themes identified from near misses, medication errors, and systems failures related to medicines are shared with the multidisciplinary team and the whole organisation if appropriate. Action is taken to change practice to prevent or minimise the risk of reoccurrence of identified themes.

DESCRIPTOR 4.2

SAFE SYSTEMS OF CARE

The pharmacy senior leadership team lead a multidisciplinary approach that ensures all aspects of medicines use, arrangements, and processes within the organisation are safe.

Within the pharmacy service:

a. The Chief Pharmacist, or equivalent, ensures that pharmacy services operate a safety culture that aligns with organisational, national, regulatory, and professional guidance.

b. The pharmacy team lead on developing, monitoring, reporting, managing, and improving metrics relating to safe use, administration and storage of medicines.

c. The pharmacy team actively facilitates the timely implementation of medicines-related aspects of relevant national therapeutic guidance and national patient safety guidance and priorities.

d. Systems are in place to ensure appropriate and timely responses to national alerts. These include national patient safety alerts, and Medicines and Healthcare products Regulatory Agency or supplier-led defective medicines alerts and recalls, and medicines shortages.

DESCRIPTOR 4.3

EFFECTIVE MANAGEMENT OF MEDICINES

Medicines policy aims to improve outcomes both on an individual and population basis maximising safety, effectiveness, sustainability, and the value obtained from medicines use.

Within the pharmacy service:

a. The pharmacy team are integral members of a multidisciplinary group that provides a focal point for the development of medicines policy, procedures, and guidance within the organisation and across the system.

b. The pharmacy team leads the development and implementation of processes that ensure supply, prescribing, de-prescribing, monitoring, and review of medicines are safe, evidence-based, and consistent with local, regional and/or national commissioning and purchasing arrangements. This is linked to treatment guidelines, protocols, formularies, and pathways locally and across the system.

c. The environmental impact of medicines is considered when supplying, prescribing, reviewing, procuring, and disposing of medicines.

d. Horizon scanning processes enable early discussions with clinicians, local partners, and commissioners/purchasers about the financial pathways and service implications of the introduction of new medicines, new indications, or new therapeutic practices.

e. Governance arrangements, aligned to medicines regulations, are in place for the management of all medicines. This includes off-label use of licensed medicines, unlicensed medicines, radiopharmaceuticals, Investigational Medicinal Products, Advanced Therapy Medicinal Products and emerging advances in medicines and medicines technology.

DESCRIPTOR 4.4

DIGITAL TECHNOLOGY AND INFORMATICS TO SUPPORT MEDICINES USE

The pharmacy senior leadership team, in partnership with the multidisciplinary team, lead the development, implementation, integration, utilisation, optimisation and ongoing monitoring of digital technology and informatics that support medicines use across the organisation and the wider health system.

Within the pharmacy service:

a. Digital technology, including automation, is utilised to underpin and transform delivery of medicines and optimisation of therapeutic outcomes.

b. Prescribing, dispensing, referral and service data is used to drive improvements for safety, clinical efficacy, and cost effectiveness.

c. An accountable individual is fully integrated in decisions relating to the procurement, implementation, operation and development of digital technology and informatics.

d. An accountable individual works together with informatics leaders to ensure that digital systems comply with required standards and enable interoperability and commonality of language.

e. The pharmacy team have the necessary skills to maximise the use of systems and technology to support optimisation and transformation of medicines use.

f. Information generated through digital technology is used to optimise care with medicines and to support benchmarking and performance management (accommodating information governance and privacy regulations).

g. Business continuity plans are in place to ensure that any system content relating to medicines is appropriately governed and backed up. This includes looking for and managing unintended consequences of content changes or updates.

DESCRIPTOR 4.5

SUPPORT FOR OTHER HEALTH AND SOCIAL CARE STAFF

The pharmacy team support all health and social care staff who are prescribing, handling, administering, or monitoring the effects of medicines. They ensure access to relevant, up-to date evidence-based information, policies, and pharmaceutical expertise.

Within the pharmacy service:

a. The pharmacy team supports induction, and ongoing training and education in best practice use of medicines for relevant clinical and support staff across organisations and systems.

b. Pharmacy team members are accessible in, or to, clinical areas/ teams, either in person or virtually, to provide advice for other health and social care staff on the choice, use and handling of medicines.

c. Access to a Medicines Information service, who are working to national standards for medicine information, is available to health and social care teams.

d. The pharmacy team works to ensure that those who are involved with handling, administering, or monitoring medicines are supported with readily accessible information and guidance.

e. The pharmacy team works to ensure that prescribers are supported in their everyday activities with readily accessible information and guidance on medicines use.

Standard 5 Efficient Supply of Medicines

Medicines are available or can be readily made available to meet people's needs whenever there is a requirement for them.

DESCRIPTOR 5.1
MEDICINES PROCUREMENT

Medicines procurement is managed by pharmacy teams with relevant specialist expertise and knowledge in a transparent and professional way. Quality assured medicines are procured through robust and appropriate processes.

The pharmacy team provide the expertise, leadership and systems support to ensure:

a. All medicines (licensed and unlicensed) are assessed and assured to be of appropriate quality and suitable for specific patient groups.

b. Procurement decisions are informed by clinical practice and formulary systems and other medicines governance processes.

c. Medicines procurement accounts for nationally, regionally, or locally negotiated contracts and the quality, safety, and reliability of the products.

d. Contingency plans and systems are in place to manage product recalls.

e. Contingency plans and systems are in place for managing and communicating shortages of medicines to ensure continuity of care.

f. Medicines procured are safely and securely received and stored in pharmacy, in accordance with relevant professional guidance, legislation, and local policies.

DESCRIPTOR 5.2
STORAGE, ACCESS, AND RETURN OF MEDICINES

Medicines are safely and securely stored in a suitable environment. Those accessing, handling, distributing, and supplying medicines prior to administration can do so in a timely manner in line with professional guidance and local policies.

The pharmacy team provide the expertise, leadership and systems support to ensure:

a. As far as practicably possible, medicines supplies are available in the right places at the right times.

b. Supply systems ensure that clinical areas have timely access to routinely required medicines. Medicines needed urgently outside core pharmacy service hours can be obtained.

c. Policies, standard operating procedures, and systems underpin the legal, secure, and appropriate handling and storage of medicines wherever they are located.

d. Audit trails and governance processes are in place that underpin the supply, storage, and return of medicines.

DESCRIPTOR 5.3

PREPARED OR MANUFACTURED UNLICENSED MEDICINES

Any medicines custom-made by, or for, the organisation, are quality assured and appropriate for their intended use.

The pharmacy team provide the expertise, leadership and systems support to ensure:

a. Use of any type of unlicensed medicine, clinical trial medicine, Advanced Therapy Medicinal Product or radiopharmaceutical, including those that are aseptically or extemporaneously prepared, is clinically justified and used in line with regulatory requirements, adhering to the principles of risk/benefit to the person and using licensed medicines wherever possible.

b. Where possible, standardised presentations of medicines are available and used.

c. Aseptic preparation in-house or outsourced is routinely subject to internal and external audit. This is conducted in accordance with good manufacturing practice and good distribution practice.

d. Appropriate systems are in place to ensure protection of operators and products.

e. Appropriate quality assurance and control systems underpin the selection, management, and use of all unlicensed medicines, whether made in-house or outsourced.

DESCRIPTOR 5.4

DISPENSING

Medicines that are clinically appropriate are dispensed or prepared accurately, and available when needed in and out of hours. Systems and processes are risk assessed to ensure safe supply of medicines.

The pharmacy team provide the expertise, leadership and systems support to ensure:

a. Before dispensing or preparation of named person supply, prescriptions are reviewed for clinical appropriateness by a pharmacist.

b. Systems are in place to prioritise dispensing to minimise the risks of omitted and delayed doses of medicines or of delayed discharge/transfer. Particular attention is paid to medicines where potential harm to the person could occur if omitted or delayed.

c. Dispensing processes make appropriate use of technology, efficient ways of working and skill mix.

d. Systems are in place to allow traceability of all dispensed medicines.

e. Medicines are labelled in line with legal requirements and professional guidance.

f. Systems are in place to identify and review the causes of near misses and dispensing errors to learn from and minimise future risk of these reoccurring. Investigations begin with an initial intent to determine systemic and human factor causes of an incident.

g. Successful patient safety improvements are shared widely within the organisation and more broadly with other healthcare providers.

Domain 3 Delivery of the service

Standard 6

LEADERSHIP

- 6.1 Strategic leadership
- 6.2 Operational leadership
- 6.3 Personal and professional leadership
- 6.4 Clinical leadership

Standard 7

SYSTEMS OF WORK

- 7.1 Systems governance
- 7.2 Research, audit, and quality improvement
- 7.3 Financial management

Standard 8

WORKFORCE

- 8.1 Workforce planning
- 8.2 Workforce development
- 8.3 Workforce quality assurance
- 8.4 Inclusion and wellbeing

Standard 6
Leadership

Pharmacy has a clear strategic vision, effective organisational processes, governance, and controls necessary to ensure people using services are safe and get the best from their medicines. This is underpinned by strong personal, professional and clinical leadership.

DESCRIPTOR 6.1
STRATEGIC LEADERSHIP

The pharmacy senior leadership team ensures that the organisation maintains a clear vision for pharmacy services, ensuring timely access to medicines as well as their optimal use across the organisation and wider healthcare system.

Within the pharmacy service, the pharmacy senior leadership team:

a. Are accountable for the quality of pharmacy services across the organisation, the quality of medicines used and ensuring that the organisation has safe and legal medicines policies and procedures.

b. There is board level sign up to the vision for pharmacy services within the organisation.

c. Provide assurance to the Board about the safe and effective use of medicines within the organisation through routine governance processes and risk management reporting.

d. Ensure the organisation has a strategy and implementation plan that has Board approval and support to ensure that people get the best outcomes from medicines which is regularly reviewed.

e. Ensure a long-term plan is in place for succession planning and workforce leadership development at all levels from trainee through to senior posts.

f. Collaborate on transformation of and innovation in service delivery to better meet people's needs, including the adoption of national initiatives and guidance, and encouraging active involvement.

g. Engage with the health community to develop a whole system approach to medicines and public health, including health inequalities, sustainability, interoperability's, emergency preparedness, resilience, and response.

DESCRIPTOR 6.2
OPERATIONAL LEADERSHIP

Pharmacy services are safe, effective, and efficiently delivered in line with organisational, regional, and national priorities and performance indicators, and the range and level of healthcare commissioned/purchased.

Within the pharmacy service:

a. The statutory role of "Chief Pharmacist" is appointed to someone within the organisation whose duty is to ensure the safe and effective running of the pharmacy service.

b. The type and level of resources required to deliver a safe, effective, and efficient service are identified and available to support the safe and secure use of medicines.

c. Agreed key performance and quality indicators are in place to enable internal and external assessment of the operational performance of pharmacy services.

d. All outsourced and shared pharmacy services, including homecare and supply functions, are performance-managed through Service Level Agreements and contract quality monitoring. Timely action is taken if services fail to meet contracted standards.

e. There are clear lines of professional and organisational responsibility established which are regularly reviewed.

f. There are effective feedback systems from people using services, staff, and anyone involved in the service is sought to ensure patient safety, continuous learning, and service improvements.

g. The pharmacy team is supported to identify and utilize opportunities for adoption, collaboration, networking and sharing of best practice internally and externally.

DESCRIPTOR 6.3

PERSONAL AND PROFESSIONAL LEADERSHIP

The pharmacy team take responsibility for their work, recognising they have a duty of care to people and to act in their best interests. They are supported to achieve this by the senior leadership team.

Within the pharmacy service:

a. Leadership at all levels across the pharmacy team is encouraged and developed.

b. Clinical supervision is an integral part of pharmacy team development.

c. The pharmacy senior leadership team lead by example through commitment, encouragement, compassion, and a continued learning approach.

d. The pharmacy senior leadership team promote a just, open, and transparent culture which recognises and values diversity of background and thought.

e. The pharmacy team behave in a candid, open and honest way encouraging diversity, equality, and inclusion.

f. All members of the pharmacy team are encouraged and empowered to raise any concerns they may have both from within the pharmacy service, and from other parts of the organisation.

g. All members of the pharmacy team feel safe and able to speak up about anything that gets in the way of delivering safe, high-quality care or affects their experience in the workplace including a clear route of escalation if unresolved.

h. All concerns are investigated and, if substantiated, dealt with at an appropriate level in line with the organizational policy.

i. All members of the pharmacy team manage conflicts of interest in line with organisational, national, regulatory, and professional guidance.

DESCRIPTOR 6.4

CLINICAL LEADERSHIP

The pharmacy team are recognised as leaders on medicines, medicines use, and innovations in medicines technology both within the organisation and across the health system.

Within the pharmacy service, the pharmacy team:

a. Provide advice, education, leadership, and support to other clinicians and support staff about safe, appropriate, and cost-effective medicines usage.

b. Ensure that their input is an integral part of the design of any service involving medicines.

c. Support the development of integrated care pathways that involve medicines as a treatment option, as well as the utilisation of pharmacy roles across systems.

d. Provide or seek leadership and education on the introduction of complex therapies, such as genomics, personalised and precision medicine in collaboration with the multidisciplinary team. The potential implications for service delivery are understood and services involving complex therapies are planned and designed around the needs of people using services.

Standard 7 Systems of work

Systems of work are in place and maintained which support the maintenance of good practice, learning from mistakes, and improvement of services whilst having clear business and financial arrangements.

DESCRIPTOR 7.1
SYSTEMS GOVERNANCE

Systems of work are established that are accountable, safe, regularly audited, and comply with relevant regulations.

Within the pharmacy service:

a. All pharmacy team members are trained in information governance to safeguard patient-identifiable information about care/medicines supplied.

b. Governance systems are in place for working with the pharmaceutical industry.

c. Working environments are planned and maintained in line with Health and Safety requirements, regulatory, and professional best practice standards.

d. Equipment and systems are maintained and operated only by appropriately trained members of the team or appropriate external contractors.

e. Standard operating procedures are in place for the delivery of all pharmacy services across the organisation.

f. Business continuity plans are developed, tested, and maintained for all services.

g. Risk registers with appropriate escalation mechanisms are maintained.

DESCRIPTOR 7.2
RESEARCH, AUDIT, AND QUALITY IMPROVEMENT

The pharmacy team actively participate and conduct research, audit, or quality improvement projects to improve outcomes of pharmacy services.

Within the pharmacy service:

a. The continuous improvement and development of pharmacy services is informed by a programme of research, audit and/or other improvement techniques/methodologies.

b. The pharmacy team is supported to develop skills to participate in, conduct, and lead research, audit, and quality improvement projects.

c. The pharmacy team is supported to identify gaps in the evidence base.

d. The pharmacy team seek opportunities for collaboration at system, regional and national level to work with academia and other research partners, including involving and engaging with patients and the public.

e. A named individual ensures there are appropriate governance mechanisms in place for conducting research, audit, and quality improvement projects.

f. Care contributions are documented and audited to demonstrate the impact of the service on patient outcomes.

DESCRIPTOR 7.3

BUSINESS AND FINANCIAL MANAGEMENT

Effective business and financial planning alongside sustainable cost improvement programmes and reporting are assessed and evaluated on a regular basis.

Within the pharmacy service:

g. A business plan incorporating finance, service, capacity, and workforce plans, linked to the organisation's corporate plan is developed, implemented, and monitored.

h. Local, regional, and national initiatives and guidance relating to medicines and pharmacy are incorporated into service planning activities.

i. Medicines use and expenditure reports are regularly interpreted and used to support budget management and monitoring of prescribing and service data.

j. The pharmacy team regularly engages with commissioners and primary care to review prescribing to deliver value across the health system.

k. Proactive horizon scanning is undertaken to identify and understand emerging transformational technologies and services and the impact of these on business and financial planning.

l. Operational performance is benchmarked against other relevant organisations using key information sources.

Standard 8
Workforce

The pharmacy team has the right skill mix, capability, and capacity to provide safe, quality services to people whilst being supported to maintain their personal development and health and wellbeing.

DESCRIPTOR 8.1
WORKFORCE PLANNING

The pharmacy team has appropriate levels of staff available to deliver a safe, high-quality service now and in the future.

Within the pharmacy service:

a. Workforce data is collected and analysed, with trends identified and acted upon. This is linked to the organisational strategic workforce plan.

b. The pharmacy senior leadership team maximise the use of systems, such as digital rostering, to inform optimum use of pharmacy staff resource dependent on hospital workflow.

c. The training pipeline secures sustainable numbers within all parts of the pharmacy team through collaboration with local commissioners.

d. Imbalances in supply and demand for pharmacy staff are understood and corrective measures put in place considering quality, accessibility and acceptability for people using services and the organisation.

e. Succession planning arrangements are in place and are linked to workforce training and personal development plans.

f. Modelling is undertaken to predict future workforce requirements.

DESCRIPTOR 8.2
WORKFORCE DEVELOPMENT

The pharmacy team is supported to develop new skills and attributes to meet the needs of people using services, their families, and circles of support across the health and social care system.

Within the pharmacy service:

a. Workforce development is included in the pharmacy strategic plan. This is linked to the organisational strategic workforce plan.

b. Workforce development takes a needs-based approach focusing on future service needs and new models of care, and engaging with local service planners, education commissioners and members of the multi-disciplinary team.

c. Skill mix is reviewed across the pharmacy and wider clinical team considering changing demographics, advances in technology, and the effective use of available and future staff resources.

d. All staff are given appropriate training to their role to ensure they can provide a safe and effective service.

e. Roles are designed that support models of integrated care that enable collaboration across the wider multi-disciplinary team in all sectors.

f. The outcomes of workforce development plans deliver cost-effective use of staff practising at their highest skill level.

g. The development of advanced pharmacy roles achieves the right balance between generalists and specialists necessary to meet the needs of people and the organisation.

DESCRIPTOR 8.3

WORKFORCE QUALITY ASSURANCE

Operational policies, procedures, and plans are in place to ensure that the pharmacy workforce is managed and appropriately resourced to support service quality, productivity, and safety.

Within the pharmacy service:

a. All members of the pharmacy team are clear about their role and responsibilities and aware of their level of performance and competency as part of a robust annual appraisal, and performance and talent review process. Personal development plans highlight appropriate professional, managerial and leadership frameworks, tools, and assessments.

b. Staffing levels are reviewed and set to ensure the delivery of safe services. The senior leadership team determines levels locally taking account of national guidance where it exists.

c. A culture of continuous learning is apparent, and all members of the pharmacy team acknowledge their role as learners, educators, and trainers. Tutors, mentors, and supervisors are trained appropriately and meet any relevant standards and guidance.

d. Continued learning and professional/personal development opportunities are provided for all members of the pharmacy team.

e. Pharmacists, pharmacy technicians and non-registered pharmacy staff have access to early years vocational training and development programmes and support.

DESCRIPTOR 8.4

INCLUSION AND WELLBEING

The pharmacy team has a culture of belonging which champions inclusive and authentic leadership, challenges inclusion and diversity barriers and promotes positive mental health and wellbeing.

Within the pharmacy service, the pharmacy team:

a. Champion an inclusive, diverse culture of belonging by treating their team with kindness and respect, ensuring the diverse voices of colleagues are represented, heard, valued, and included in decision making.

b. Commit to better understand and respect each other's backgrounds, experiences, beliefs, boundaries, and choice. They support all to be their authentic self when at work.

c. Understand their own personal biases and look to be an ally for under-represented groups.

d. Have zero tolerance for any form of discrimination, bullying or harassment and can raise concerns without fear of repercussions.

e. Collect and understand workforce data relating to equality and diversity and have an action plan to address any identified inequalities.

f. In partnership with the senior leadership team commit to providing a healthy work-life balance for the pharmacy team through encouraging them to take their full allocation of breaks and flexible working options where appropriate.

g. Feel empowered to look after their own mental and physical health and wellbeing and can speak up when work expectations and demands are too much.

h. Are actively aware of what support is provided for wellbeing and how to access it.

Glossary

ACCOUNTABLE INDIVIDUAL
An operational leader who ensures that organizational requirements are reflected in operational frameworks, procedures and plans.

ADVANCED THERAPY MEDICINAL PRODUCTS
Advanced therapy medicinal products (ATMPs) are medicines for human use that are based on genes or cells. ATMPs can be classified into four main groups: gene therapy medicines; somatic-cell therapy medicines; tissues-engineered medicines; and combined ATMPs.
www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000294.jsp

CHIEF PHARMACIST
A statutory term and duty under the Rebalancing medicines legislation and pharmacy regulation to allow pharmacy professionals working in hospital pharmacy services to rely on the defences of section 63 and 64 of the Medicines Act.

CIRCLE OF SUPPORT
One or more people who support an individual on a regular basis. This could be in a paid or unpaid capacity. They support a person to make their own decisions about their life.

CLINICAL SUPERVISION
A formal process of professional support and learning that enables individual practitioners to develop knowledge and competence, assume responsibility for their own practice, and enhance patient protection and safety of care in a wide range of situations. It is an activity that brings two or more professionals together in order to reflect upon and review clinical practice.

DEPRIVATION OF LIBERTIES
The Deprivation of Liberty Safeguards is the procedure prescribed in law when it is necessary to deprive of their liberty a resident or patient who lacks capacity to consent to their care and treatment in order to keep them safe from harm.
www.scie.org.uk/mca/dols/at-a-glance

DUTY OF CANDOUR
Health professionals must be open and honest with patients when things go wrong. This is also known as 'the duty of candour'.
www.pharmacyregulation.org/news/professional-duty-of-candour-joint-health-regulators-statement

INFORMATICS AND CLINICAL INFORMATICS
Informatics is a general term used to refer to biomedical informatics and its many areas of application and practice (e.g. bioinformatics, clinical informatics, public health informatics). Clinical informatics involves the capture, communication and use of data and clinical knowledge to support health professionals.

INTEROPERABILITY
With new models of care emerging and evolving, there is a clear need for more effective information sharing between care settings, organisations and geographies, as well as between professionals and citizens, to optimise patient outcomes and quality of care. Interoperability describes the ability of IT systems across health and care to exchange and make use of information.

MEDICATION ERRORS
Any unintended or unexpected incident, which could have or did lead to harm for one or more people receiving NHS care. Medication errors are any 'patient safety incident' (PSI) where there has been an error in the process of prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines. These PSIs can be divided into two categories: errors of commission or errors of omission. The former include, for example, wrong medicine or wrong dose. The latter include, for example, omitted dose or a failure to monitor, such as international normalised ratio for anticoagulant therapy.

NAMED INDIVIDUAL
Someone who is responsible for setting overall framework and policy standards across a specific healthcare setting

PERSON
Used as an umbrella term to cover the full range of people using pharmacy services across sectors this includes children and young adults, service users and clients as well as their carers.

PHARMACY TEAM
Pharmacy team encompasses all staff working in the delivery of pharmacy services.

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Appendix 1 Acknowledgements

Task and finish group for the 2022 review		*Also members of RPS HEAG
NAME	ROLE/AFFILIATION	REPRESENTING
Rob Duncombe*	Chair of T&F Group Chief Pharmacist, The Royal Marsden	HEAG
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NORTHERN IRELAND

CLINICAL PHARMACY STANDARDS

2013

Review date 2015

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Review Date: 2015

CONTENTS

Introduction

Clinical pharmacy relates to the safe, effective and economic use of medicines and contributes to the 'patient care journey' at all stages.

It is the practice of pharmacy in a multidisciplinary healthcare team directed at achieving patient treatment goals by ensuring

- The maximisation of the effectiveness and tolerability of drug treatment and minimisation of drug toxicity in individual patients
- That the correct patient receives the optimum dose of the most appropriate medicine for a specific condition via a rational dosage form and regimen over an appropriate time period
- The promotion of good prescribing practice
- That untoward effects and interactions of medicines are identified, resolved and where possible prevented
- Involvement in educating and advising patients on medicines and healthcare
- Monitoring of medicine therapy
- Involvement in prescriber education
- Involvement in research
- Provision of advice on the clinical use of medicines
- Cost effective drug utilisation
- That the quality use of medicines is promoted through other activities as appropriate

The ethos of clinical pharmacy is that pharmacists provide the standard of pharmaceutical care they would want themselves to receive. The pharmacist develops through experience, training and personal development the attitude, knowledge, skills, relationships and professional responsibilities necessary to provide an effective and efficient clinical pharmacy service. The pharmacist acts as the patient's advocate with respect to the use of medicines.

Clinical pharmacy services have been shown to:

- Identify clinically important drug-related problems
- Reduce the incidence of clinically important drug-related problems
- Improve patient education and concordance
- Improve prescribing
- Improve clinical outcomes
- Improve cost-effectiveness
- Reduce length of hospital stay

Clinical pharmacy is an integral component of medicines management.

The principle objective of this document is to improve the clinical pharmacy contribution to patient care through the development of a structured, systematic approach to clinical pharmacy practice.

Standards on the individual components of a clinical pharmacy service have been developed. These standards need to be supported by local standard operating procedures (SOPs) specific to individual trusts. Appendix 1 contains sample procedures for some of the standards that individual trusts can use to develop their own SOPs.

These standards are a working document owned by the Pharmacy Service of the five Health and Social Care Trusts in Northern Ireland. They will be regularly reviewed, built upon and expanded to ensure that they continue to be fit for purpose.

STANDARD 1
Medicine History Interview and Medicines Reconciliation

Basic Standard Requirements

An accurate medicine history is obtained on admission to hospital.

A pharmacist/ trained accredited technician in drug history taking shall obtain a medicine history from all patients and/ or their carers on admission. Where this is not possible for all patients, a pharmacist/ trained accredited technician in drug history taking shall verify the medicine history obtained by another healthcare professional. A pharmacist shall use the drug history to undertake medicines reconciliation.

1.1 A local SOP exists of how to take a medicine history and how to complete medicines reconciliation.

1.2 The SOP states where the medicine history is recorded and how medicines reconciliation is documented.

1.3 A medicine history is documented or verified by a pharmacist/ trained accredited technician as soon as possible after admission to hospital, ideally within 24 hours.

1.4 The medications are reconciled by a pharmacist as soon as possible after admission to hospital, ideally within 24 hours.

1.5 The medicine history includes:

- current and recently prescribed medicines
- over the counter medicines
- clinical trial medicines
- unlicensed medicines
- herbal and homeopathic remedies
- Chinese remedies or any other alternative remedies
- recreational drug use, smoking status, alcohol consumption, using appropriate professional judgment where appropriate

1.6 The medicine history documents relevant recent vaccination history where applicable. This will depend on the age and presenting complaint of the patient.

1.7 The medicine history documents any known previous adverse drug reactions.

1.8 The medicine history documents any known allergies / sensitivities including non drug allergies/ sensitivities. The type of reaction is documented when known.

1.9 The patient's current therapy is assessed in light of the patient's presenting condition for appropriateness and alterations made if necessary in conjunction with medical staff.

Advanced requirements

1.10 Any possible drug related admissions are identified and recorded.

1.12 Any history of previous or current non-concordance with therapy is documented.

1.12 It is documented where the medicine history is obtained. At least two sources are used. Sources include:

- The patient and/ or their carer
- The patient's own drugs (PODs)
- The patient's GP practice/ emergency care summary
- The community pharmacy the patient uses at least 75% of the time
- The admitting hospital when a transfer has occurred

When a source other than the patient or his/her PODs is used a written format of the medicine history should be obtained. When this is not possible the information may be obtained verbally. The patient's identity is confirmed by his/her name, address and date of birth. The pharmacist requests the information about the patient's prescribed medicines. If there is any uncertainty of a medicine's name the pharmacist should ask for it to be spelt out. The pharmacist should read back the verbal information they have received to the other member of staff to confirm accuracy. Where possible the verbal transfer of information should be followed within 24 hours with written information. This should be reviewed to ensure that the verbal transfer has taken place correctly

Why it is important

The goal of the medicine history interview is to obtain information on drug use that may assist in the overall care of the patient. Pharmacists with their broad knowledge of a wide range of drugs and dose forms and their uses are the most competent healthcare professionals to undertake this task. The information gathered can be used to:

- Undertake medicines reconciliation to ensure that the medicines prescribed on admission correspond to those the patient was taking before admission. This is done by comparing the medicine history with the prescription chart(s) and investigating and recording discrepancies. Any inaccuracies should be corrected. If a prescribing or administration

incident has occurred this must be reported and the patient appropriately managed.

- Verify medicine histories taken by other staff and provide additional information where appropriate
- Document allergies, sensitivities and adverse reactions and nature and date of reaction where known
- Screen for drug interactions
- Screen for adverse effects
- Assess patient medicine concordance
- Assess the rationale for prescribed drugs
- Assess the evidence of drug abuse
- Appraise drug administration techniques
- Examine the need for medicine aids
- Document patient initiated medicines and patient initiated changes to prescribed medicines

The medicine history interview enables pharmacists to:

- Establish a direct relationship with the patient and explain their role in patient care
- Understand the patient's needs and desired outcome
- Obtain medicine related information
- Commence preliminary education and reinforce the principles of the quality use of medicines
- Identify any problems with current medicines as perceived by the patient
- Use the information obtained to form the basis of an ongoing pharmaceutical care plan

Medicine History Interview and Medicines Reconciliation

An accurate medicine history is obtained on admission to hospital.
A pharmacist/ trained accredited technician in drug history taking shall obtain a medicine history from all patients and/ or their carers on admission. Where this is not possible for all patients, a pharmacist/ trained accredited technician in drug history taking shall verify the medicine history obtained by another healthcare professional. A pharmacist shall use the drug history to undertake medicines reconciliation.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Medicine History Interview and Medicines Reconciliation	**Y**	**N**	**N/A**			
1.1 A local SOP exists of how to take a medicine history and how to complete medicines reconciliation.	☐	☐	☐			
1.2 The SOP states where the medicine history is recorded and how medicines reconciliation is documented.	☐	☐	☐			
1.3 A medicine history is documented or verified by a pharmacist/ trained accredited technician as soon as possible after admission to hospital, Ideally within 24 hours.	☐	☐	☐			
1.4 The medications are reconciled by a pharmacist as soon as possible after admission to hospital, ideally within 24 hours.	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Medicine History Interview and Medicines Reconciliation	**Y**	**N**	**N/A**			
1.5 The medicine history includes: • current and recently prescribed medicines • over the counter medicines • clinical trial medicines • unlicensed medicines • herbal and homeopathic remedies • Chinese remedies or any other alternative remedies • recreational drug use, smoking status alcohol consumption, using professional judgement where appropriate.	☐	☐	☐			
1.6 A vaccination history is documented where applicable. This will depend on the age and presenting complaint of the patient.	☐	☐	☐			
1.7 The medicine history documents any known previous significant adverse drug reactions.	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Medicine History Interview and Medicines Reconciliation	**Y**	**N**	**N/A**			
1.8 The medicine history documents any known allergies / sensitivities including non drug allergies / sensitivities. The type of reaction is documented when known.	☐	☐	☐			
1.9 The patient's current therapy is assessed in light of the patient's presenting condition for appropriateness and alterations made if necessary in conjunction with medical staff.	☐	☐	☐			
1.10 Any possible drug related admissions are identified and recorded.	☐	☐	☐			
1.11 Any history of previous or current non-concordance with therapy is documented.	☐	☐	☐			
1.12 The sources used to obtain the medicine history are documented. More than one source should be used.	☐	☐	☐			

STANDARD 2
Medicine Therapy Monitoring (Pharmaceutical Care)

Basic Standard Requirements

Pharmacists provide medicine therapy monitoring routinely to all patients. Where this is not possible criteria shall exist to identify patients who would benefit most from medicine therapy monitoring. This criteria includes:

- Patients taking 4 or more regular medicines
- Patients taking a high risk drug e.g.
  - Angiotensin-converting enzyme inhibitors/ Angiotensin-11 receptor antagonists
  - Antidepressants (including lithium)
  - Beta blockers
  - Clopidogrel
  - Digoxin
  - Diuretics
  - Insulin/ oral hypoglycaemics
  - Methotrexate
  - NSAIDs
  - Opiates
  - Prednisolone
  - Anticoagulants/ Warfarin,
  - Anti-infectives
  - Antiparkinson drugs
  - Antiepileptics
  - Clozapine
  - Potassium
  - Any medicine deemed a critical medicines where timeliness of administration is crucial

  This is not an exhaustive list
- Patients who have been readmitted to hospital within 6 months of previous discharge

2.1 A local SOP exists for medicine therapy monitoring and methods of prioritising patients e.g. MEWS score.

2.2 The pharmacist assesses the patient's pharmaceutical needs and identifies the patient's pharmaceutical care issues.

2.3 The pharmacist formulates a pharmaceutical care plan that:

- prioritises the patient's pharmaceutical care issues
- identifies the desired outcomes for the patient
- proposes pharmaceutical actions and a monitoring strategy to achieve the desired outcomes

- is recorded as an action plan if appropriate of 1 to 2 points in the patient's medical notes

2.4 The pharmacist implements, monitors and reviews the pharmaceutical care plan.

Why it is important

Pharmaceutical care is 'The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life'. The goal of medicine therapy monitoring is to optimise medicine therapy for the individual patient and involves:

- Collation and interpretation of patient specific information continuously throughout a patient's admission using sources such as medical notes, laboratory results etc.
- Identification of a patient's pharmaceutical care issues
- Identification of desired therapeutic outcomes the pharmacist intends to achieve for a patient in relation to their pharmaceutical care issues
- Review of medicine therapy
- Formulation and implementation of a monitoring strategy to measure progress towards the desired outcomes
- Review of outcomes
- Modification of patient management if required
- Help prevent omitted or delayed doses especially of critical medicines.

Medicine therapy monitoring encompasses a number of clinical pharmacy activities simultaneously including:

- Medicine History Interview and Medicines Reconciliation (Standard 1)
- Prescription monitoring and review (Standard 3)
- Adverse drug reaction management (Standard 4)
- Prevention, detection, assessment & management of drug interactions (Standard 5)
- Therapeutic drug monitoring (Standard 6)

Medicine Therapy Monitoring

Pharmacists provide medicine therapy monitoring routinely. Criteria shall exist to identify patients who would benefit most from medicine therapy monitoring.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Medicine Therapy Monitoring	**Y**	**N**	**N/A**			
2.1 A local SOP exists for medicine therapy monitoring and methods of prioritising patients e.g. MEWS score.	☐	☐	☐			
2.2 The pharmacist assesses the patient's pharmaceutical needs and identifies the patient's pharmaceutical care issues.	☐	☐	☐			
2.3 The pharmacist formulates a plan for pharmaceutical care. This need not be a separate document.	☐	☐	☐			
2.4 The pharmacist implements, monitors and reviews the pharmaceutical care plan.	☐	☐	☐			

STANDARD 3
Prescription Monitoring and Review

Basic Standard Requirements

Patients' prescription charts are monitored and reviewed in conjunction with the patient's medical notes and relevant medical laboratory results by a pharmacist at regular intervals. The recommended intervals are:

- Acute wards — once daily
- Intermediate stay wards — once weekly
- Rehabilitation wards, community hospital wards — once weekly
- Long stay psychiatric/ learning difficulties — once a month

3.1 A local SOP exists for prescription monitoring and review.

3.2 Patients' prescription charts are monitored and reviewed by a pharmacist as soon as possible after admission, ideally within 24hours. Where possible the patient should be present.

3.3 Prescription monitoring and review is repeated at regular intervals as defined above throughout the patient's admission.

3.4 The patient's administration record is reviewed to determine non-administration and to resolve any issues e.g. patient nil by mouth, swallowing difficulties.

3.5 Pharmacists endorse prescriptions to add clarity to the original prescription, if applicable.

3.6 Pharmacists initial and date a medication on the kardex once clinically checked.

3.7 A local SOP exists for prescription endorsement by pharmacists.

3.8 If a medication incident or a near miss has occurred it is reported according to the local policy/ procedure for reporting medication incidents or near misses.

3.9 Any queries regarding the prescription are resolved with the prescriber.

3.10 If a new allergy/ sensitivity is identified during the patient's admission, this is documented in the patient's medical notes with the nature of the reaction and the patient's prescription chart is amended as appropriate.

3.11 A written annotation of these discussions is made in the patient's medical notes or pharmacy records/ profiles as appropriate.

Advanced requirements

3.12 A pharmacist reviews all prescriptions for 'high risk' drugs (except in emergency situations) before the first dose is dispensed or administered.

Examples of high risk drugs include:

- Angiotensin-converting enzyme inhibitors/ Angiotensin-11 receptor antagonists
- Antidepressants (including lithium)
- Beta blockers
- Clopidogrel
- Digoxin
- Diuretics
- Insulin/ oral hypoglycaemics
- Methotrexate
- NSAIDs
- Opiates
- Prednisolone
- Anticoagulants/ Warfarin,
- Anti-infectives
- Antiparkinson drugs
- Antiepileptics
- Clozapine
- Potassium
- Any medicine deemed a critical medicines where timeliness of administration is crucial

This is not an exhaustive list

Why it is important

The purpose of prescription monitoring and review is to optimise the patient's drug therapy. This includes ensuring that the right patient receives the right drug at the right dose by the right route at the right time. Through prescription monitoring and review the pharmacist identifies problems or opportunities for optimising treatment and medicine related problems are minimised. Outcomes of treatment are reviewed and the patient's response to therapy is evaluated.

Prescription Monitoring and Review

Patients' prescription charts are monitored and reviewed by a pharmacist at regular intervals.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Prescription monitoring and review	**Y**	**N**	**N/A**			
3.1 A local SOP exists for prescription monitoring and review.	☐	☐	☐			
3.2 Patients' prescription charts are monitored and reviewed by a pharmacist as soon as possible after admission, ideally within 24hours. Where possible the patient should be present.	☐	☐	☐			
3.3 Prescription monitoring and review is repeated at regular intervals throughout the patient's admission	☐	☐	☐			
3.4 The patient's administration record is reviewed to determine non-administration and to resolve any issues	☐	☐	☐			
3.5 Pharmacists endorse prescriptions to add clarity to the original prescription, if applicable.	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Prescription monitoring and review	**Y**	**N**	**N/A**			
3.6 Pharmacists initial and date a medication on the kardex once clinically checked.	☐	☐	☐			
3.7 A local SOP exists for prescription endorsement by pharmacists.	☐	☐	☐			
3.8 If a medication incident or a near miss has occurred it is reported according to the local policy/ procedure for reporting medication incidents or near misses.	☐	☐	☐			
3.9 Any queries regarding the prescription are resolved with the prescriber.	☐	☐	☐			
3.10 If a new allergy/ sensitivity is identified during the patient's admission, this is documented in the patient's medical notes with the nature of the reaction and the patient's prescription chart is amended as appropriate.	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Prescription monitoring and review	**Y**	**N**	**N/A**			
3.11 A written annotation of these medication related discussions is made in the patient's medical notes / charts or pharmacy records/ profiles as appropriate.	☐	☐	☐			
3.12 A pharmacist reviews all prescriptions for 'high risk' drugs (except in emergency situations) before the first dose is dispensed or administered.	☐	☐	☐			

STANDARD 4
Prevention, detection, assessment and management of adverse drug reactions

Basic Standard Requirements

The World Health Organisation defines an adverse drug reaction as 'any response to a drug which is noxious, unintended and occurs at doses used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function'.

The following groups of patients are at increased risk of an adverse drug reaction:

- Patients taking multiple drug therapy
- The older patient
- Neonates and the newborn
- Patients with renal disease
- Patients with liver disease
- Intercurrent disease e.g. the increased incidence of adverse reactions to co-trimoxazole in AIDS patients
- Women – adverse drug reactions are more common in women than men
- Race and genetic polymorphism – this may account for alterations in the handling of drugs and their end-organ effects.
- Patients taking a high risk drug
  - Angiotensin-converting enzyme inhibitors/ Angiotensin-11 receptor antagonists
  - Antidepressants (including lithium)
  - Beta blockers
  - Clopidogrel
  - Digoxin
  - Diuretics
  - Insulin/ oral hypoglycaemics
  - Methotrexate
  - NSAIDs
  - Opiates
  - Prednisolone
  - Anticoagulants/ Warfarin,
  - Anti-infectives
  - Antiparkinson drugs
  - Antiepileptics
  - Clozapine
  - Potassium
  - Any medicine deemed a critical medicines where timeliness of administration is crucial

  This is not an exhaustive list

Pharmacists contribute to the prevention, detection, assessment, management and reporting of adverse drug reactions (ADRs).

4.1 A local SOP exists for the monitoring and reporting of ADRs.

4.2 Patients at risk of an ADR are identified and monitored.

4.3 Medicines with high incidence of adverse reactions or that are known to cause serious adverse reactions are closely monitored.

4.4 Admission of a patient to hospital due to an adverse drug reaction is documented in the patient's medical notes.

4.5 ADRs are discussed with the multidisciplinary team and documented in patients' medical notes or the patient's prescription chart according to local guidance to prevent re-exposure.

4.6 The following ADRs are reported using the Yellow Card Scheme:

- All serious suspected adverse reaction to established medicines and vaccines
  Serious reactions include those that are:
  - fatal
  - life-threatening
  - disabling
  - incapacitating
  - congenital abnormality
  - involve hospitalisation
  - and/ or are medically significant
- All adverse reactions (including those considered to be non-serious) suspected to be associated with black triangle medicines
- All suspected adverse reactions that occur in children associated with either established or new medicines and vaccines

4.7 GPs are notified on discharge by the doctor or pharmacist of significant ADRs their patients have experienced, when appropriate to prevent re-exposure.

Advanced requirements

4.8 Community pharmacists are notified by the pharmacist of significant ADRs their patients have experienced, when appropriate to prevent re-exposure.

4.9 Patients who have experienced serious reactions are provided with written information and 'alert cards' if available. (Medic alert jewellery is available from www.medicalert.co.uk.)

Why it is important

Pharmacists play an important role in the prevention, detection, assessment, management and reporting of adverse drug reactions (ADRs). Emphasis should be on the prevention of ADRs and on the prevention of re-exposure in patients who have already experienced an ADR.

Prevention, Detection, Assessment and Management of Adverse Drug Reactions.

Pharmacists contribute to the prevention, detection, assessment, management and reporting of adverse drug reactions (ADRs).

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Adverse Drug Reactions	**Y**	**N**	**N/A**			
4.1 A local SOP exists for the monitoring and reporting of ADRs.	☐	☐	☐			
4.2 All patients at risk of an ADR are monitored.	☐	☐	☐			
4.3 Medicines with high incidence of adverse reactions or that are known to cause serious adverse reactions are closely monitored.	☐	☐	☐			
4.4 Admission of a patient to hospital due to an adverse drug reaction is documented in the patient's medical notes	☐	☐	☐			
4.5 ADRs are discussed with the multidisciplinary team and documented in patients' medical notes or the patient's prescription chart according to local guidance to prevent re-exposure.						
4.6 Appropriate ADRs are reported using the Yellow Card Scheme	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Adverse Drug Reactions	**Y**	**N**	**N/A**			
4.7 GPs are notified on discharge by the doctor or pharmacist of significant ADRs their patients have experienced, when appropriate to prevent re-exposure.	☐	☐	☐			
4.8 Community pharmacists are notified by the pharmacist of significant ADRs their patients have experienced, when appropriate to prevent re-exposure.	☐	☐	☐			
4.9 Patients who have experienced serious reactions are provided with verbal information and if available written information or 'alert cards'.	☐	☐	☐			

STANDARD 5
Prevention, Assessment and Management of Drug Interactions

Basic Standard Requirements

A drug interaction occurs when the effects of one drug are changed by the presence of another drug, food, drink or by some environmental chemical change.

Pharmacists monitor for potential and existing drug interactions when monitoring and reviewing patient's medicine therapy.

5.1 A local SOP exists for the prevention, assessment and management of drug interactions.

When reviewing patients drug therapy pharmacists:

5.2 Identify patients at risk of drug interactions and suggest suitable methods of management.

5.3 Inform the prescriber and other appropriate healthcare professionals when drugs that have a clinically significant drug interaction are prescribed.

5.4 Details of known clinically significant interactions are documented in the patient's medical notes.

5.5 Interactions with adverse consequences are reported according to the organisation's incident reporting policy. Appropriate action is taken to avoid recurrence.

Why it is important

Drug interaction can cause enhanced action, reduced efficacy, increased incidence of adverse effects or misinterpretation of laboratory tests.

Prevention, Assessment and Management of Drug Interactions

Pharmacists monitor for potential and existing drug interactions when monitoring and reviewing patient's medicine therapy.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Prevention, assessment and management of drug interactions	**Y**	**N**	**N/A**			
5.1 A local SOP exists for the prevention, assessment and management of drug interactions.	☐	☐	☐			
5.2 Pharmacists identify patients at risk of drug interactions and suggest suitable methods of management	☐	☐	☐			
5.3 Pharmacists inform the prescriber and other appropriate healthcare professionals when a known clinically significant drug interaction is prescribed.	☐	☐	☐			
5.4 Details of known clinically significant interactions are documented in the patient's medical notes.	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Prevention, assessment and management of drug interactions	**Y**	**N**	**N/A**			
5.5 Interactions with adverse consequences are reported according to the organisation's incident reporting policy. Appropriate action is taken to avoid recurrence.	☐	☐	☐			

STANDARD 6
Therapeutic Drug Monitoring

Basic Standard Requirements

Pharmacists to optimise therapy for medicines where there is a known, close relationship between serum concentration and therapeutic effect and adverse effect use therapeutic Drug Monitoring (TDM).

6.1 A local SOP exists for therapeutic drug monitoring. The SOP details
- how to request monitoring
- lists those drugs that require TDM
- how to identify patients who will benefit from TDM

6.2 Pharmacists ensure optimal dosage selection for maximum therapeutic benefit and minimum adverse effects.

6.3 Pharmacists offer guidance on timing of samples, dose adjustment and monitor relevant laboratory results and resultant therapeutic effects.

Advanced requirements

6.4 Pharmacists will specialise in TDM in appropriate clinical fields.

Why it is important

Before undertaking TDM the desired therapeutic outcome must be identified, the target serum concentration of a particular medicine may be dependant on the desired clinical outcome.

TDM may also be used to assess a patient's concordance with treatment.
TDM should only be undertaken in conjunction with clinical review of the patient. This includes:

- Physical signs and clinical symptoms.
- Therapeutic appropriateness of the drug therapy.
- Therapeutic duplication in drug therapy.
- Appropriateness of the route and method of administration.
- Patient concordance with the prescribed treatment.
- Potential and actual drug interactions.
- Clinical and laboratory test results.

Therapeutic Drug Monitoring

Therapeutic Drug Monitoring is used by pharmacists to optimise therapy for medicines where there is a known relationship between serum concentration and therapeutic effect.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Therapeutic Drug Monitoring	**Y**	**N**	**N/A**			
6.1 A local SOP exists for therapeutic drug monitoring. The SOP details • how to request monitoring • lists those drugs that require TDM • how to identify patients who willl benefit from TDM	☐	☐	☐			
6.2 Pharmacists ensure optimal dosage selection for maximum therapeutic benefit and minimum adverse effects	☐	☐	☐			
6.3 Pharmacists offer guidance on timing of samples, dose adjustment and monitor relevant laboratory results and resultant therapeutic effects.	☐	☐	☐			
6.4 Pharmacists will specialise in TDM in appropriate clinical fields.	☐	☐	☐			

STANDARD 7
Prevention, identification, management and reporting of medication incidents

Basic Standard Requirements

Pharmacists contribute to the prevention, identification, management and reporting of medication incidents.

7.1 A local SOP exists for the prevention, identification, management and reporting of medication incidents.

7.2 Pharmacists work in collaboration with medical, nursing, midwifery and other relevant staff groups in the prevention, identification, management and reporting of medication incidents.

7.3 All identified medication incidents are reported according to the organisation's incident reporting policy.

7.4 The reporting of medication incidents by other professional staff is promoted.

7.5 The systems approach to medication incident management is supported and promoted.

7.6 Policies that support the safe use of medicines are implemented and adhered to.

Advanced Requirements

7.7 Medication related risk is proactively identified and managed within the area of clinical responsibility.

7.8 Medication incident data is submitted for regional collation.

Why it is important

Medication incidents are the most preventable cause of patient harm. Pharmacists have an integral role in protecting patients by promoting the safe use of medicines. A medication incident is defined as any preventable medication related event that could have or did lead to patient harm, loss or damage. Medication incidents may occur at any stage of the medication use process - prescribing, dispensing or administration and as part of clinical pharmacy activity. It is important that all medication incidents are reported, irrespective of whether the event reached the patient or caused harm, to ensure that opportunities for learning are not overlooked.

Prevention, identification, management and reporting of medication incidents

Pharmacists contribute to the prevention, identification, management and reporting of medication incidents.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Medication Incidents	**Y**	**N**	**N/A**			
7.1 A local SOP exists for the prevention, identification, management and reporting of medication incidents	☐	☐	☐			
7.2 Pharmacists work in collaboration with medical, nursing, midwifery and other relevant staff groups in the prevention, identification, management and reporting of medication incidents.	☐	☐	☐			
7.3 All incidents identified by a pharmacist are reported according to the organisation's incident reporting policy.	☐	☐	☐			
7.4 The reporting of medication incidents by other professional staff is promoted.	☐	☐	☐			
7.5 The systems approach to medication incident management is supported and promoted.	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Medication Incidents	**Y**	**N**	**N/A**			
7.6 Policies that support the safe use of medicines are implemented and adhered to.	☐	☐	☐			
7.7 Medication related risk is proactively identified and managed within the area of clinical responsibility.	☐	☐	☐			
7.8 Medication incident data is submitted for regional collation.	☐	☐	☐			

STANDARD 8
Multidisciplinary Working

Basic Standard Requirements

Where appropriate the pharmacist shall attend ward rounds and clinical meetings as a member of the healthcare team.

8.1 A local SOP exists for the participation of pharmacists in ward rounds and clinical meetings. This includes description of the pharmacist's role and how they use their clinical and communication skills.

8.2 Pharmacists participate routinely in ward rounds and multi-disciplinary clinical meetings where they can have the most impact and gather the most relevant information.

8.3 Pharmacists on ward rounds:

- Provide evidence based medicines information.
- Promote rational medicine therapy.
- Influence prescribing at the time of decision making.
- Identify pharmaceutical care issues
- Act as the patient's advocate

Why it is important

Participation in ward rounds:

- will give the pharmacist an improved understanding of the patient's clinical details, treatment plan and desired outcomes
- allow the pharmacist to provide pharmaceutical information regarding the patient's medicine therapy at the point of prescribing
- optimises prescribing of medicines medicine treatment by the pharmacist influencing therapy selection, implementation of therapy and monitoring of therapy
- improves discharge planning

Multidisciplinary Working

Where appropriate the pharmacist shall attend ward rounds and clinical meetings as a member of the healthcare team.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Multidisciplinary Working	**Y**	**N**	**N/A**			
8.1 A local SOP exists for the participation of pharmacists in ward rounds and clinical meetings. This includes description of the pharmacist's role and how they use their clinical and communication skills.	☐	☐	☐			
8.2 Pharmacists participate in ward rounds and multi - disciplinary clinical meetings where they can have the most impact and gather the most relevant information *	☐	☐	☐			
8.3 Pharmacists on ward rounds:						
8.3.1 Provide medicines information *	☐	☐	☐			
8.3.2 Promote rational medicine therapy *	☐	☐	☐			
8.3.3 Influence prescribing at the time of decision making *	☐	☐	☐			
8.3.5 identify pharmaceutical care issues *	☐	☐	☐			

*This is measured by pharmacist activity and intervention data

STANDARD 9
Provision of Medicines Information Advice by Pharmacists

Basic Standard Requirements

Pharmacists have a responsibility to provide appropriate, evidence based timely information and advice on medicine-related matters to meet the requirements of healthcare providers and patients and/ or their carers.

9.1 A local SOP exists for the provision of medicines information by pharmacists.

9.2 Pharmacists ensure medicine selection follows local guidelines, formulary, regional contracts, pharmacoeconomic reviews and availability where applicable.

9.3 All pharmacists should be trained to respond to medicines information needs in a systematic & timely method. This can be undertaken by completing the United Kingdom Medicines Information (UKMi) rolling training programme.

9.4 Pharmacists are able to provide accurate, relevant and evidence based medicines information.

9.5 Pharmacists are aware of, and understand how to use the available medicines information resources.

9.6 Pharmacists use the experience and resource of a medicines information department when appropriate.

9.7 Pharmacists providing medicines information and advice are competent in interpersonal communication techniques.

9.8 Enquiries associated with immediate patient care requirements are given priority.

9.9 Pharmacists keep up to date with changes in medicinal products and therapeutic advances.

9.10 The information provided should be in a form appropriate for the situation and personnel involved i.e. phone/email, formal letter etc.

9.11 The advice given should be documented in an appropriate place i.e. the patient's medical notes and/or the Medicines Information enquiry form.

Advanced requirements

9.12 Pharmacists are proactively involved in medicines information through:

- Provision of education and training
- Published medication advice

Why it is important

The involvement of pharmacists in the provision of medicines information advice is to contribute to patient care and optimise drug therapy. It is essential for the safe and effective use of medicines in patients

A variety of medicines information and advice activities may be provided.

These include:

- Providing medicines information/ advice to healthcare providers, patients and carers
- Establishing and maintaining an evidence based formulary, prescribing guidelines which also consider safety, cost and patient factors
- Developing and participating in medicines governance activities e.g. medicine incident reporting
- Providing information about adverse drug reactions
- Developing policies and procedures relating to medicines
- Developing methods of changing patient and healthcare provider behaviour to optimise medicine use
- Publishing newsletters and patient information on medicine use to educate patients, carers and healthcare providers Information should be shared between different hospitals to avoid duplication of effort.
- Drug use evaluation
- Educating healthcare providers on medicine related policies and procedures
- Providing continuing education to other healthcare professionals
- Educating pharmacy students, pre-registration pharmacists and junior pharmacists
- Advising on the legal and ethical considerations regarding unlicensed medicines and the use of licensed medicines outside their product licence
- Developing and maintaining an active research and audit programme

The information or advice provided may be initiated by the pharmacist e.g. from the findings of drug therapy monitoring or be in response to an enquiry from a healthcare provider, patient or carer.

Medicines information may be particularly helpful for drugs:

- That are unlicensed newly marketed or about which there is little available information

- That are associated with specific requirements which if not followed may adversely affect the patient
- Of which individual healthcare providers have limited experience

Pharmacists need to be aware of their own limitations and when to refer back to the local or regional Medicines Information.

Provision of Medicines Information and Advice by Pharmacists

Pharmacists have a responsibility to provide appropriate, evidence based, timely information and advice on medicine-related matters to meet the requirements of healthcare providers and patients and/or their carers.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Provision of Medicines Information and Advice	**Y**	**N**	**N/A**			
9.1 A local SOP exists for the provision of medicines information by pharmacists.	☐	☐	☐			
9.2 Pharmacists ensure medicine selection follows local guidelines, formulary, regional contracts, pharmacoeconomic reviews and availability where applicable.	☐	☐	☐			
9.3 All pharmacists should be trained to respond to medicines information needs in a systematic & timely method. This can be undertaken by completing the UKMi rolling training programme	☐	☐	☐			
9.4 Pharmacists provide accurate, relevant and evidence based medicines information. (This is measured by MI enquiry records)	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Provision of Medicines Information and Advice	**Y**	**N**	**N/A**			
9.5 Pharmacists are aware of and understand the available medicines information resources. (This is measured by MI enquiry records)	☐	☐	☐			
9.6 Pharmacists use the experience and resource of a medicines information department when appropriate.	☐	☐	☐			
9.7 Pharmacists providing medicines information and advice are appraised in relation to interpersonal communication techniques. (This is measured by peer review)	☐	☐	☐			
9.8 Enquiries associated with immediate patient care requirements are given priority. (This is measured by MI enquiry forms)	☐	☐	☐			
9.9 Pharmacists keep up to date with changes in medicinal products and therapeutic advances. (This is measured from pharmacist CPD records)	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Provision of Medicines Information and Advice	**Y**	**N**	**N/A**			
9.10 The information is provided in a form appropriate for the situation and personnel involved. (This is measured by an MI pharmacist assessing the pharmacist's competency during training or assessment of a random sample of completed MI enquiries by an MI pharmacist)	☐	☐	☐			
9.11 The advice given should be documented in an appropriate place i.e. the patient's medical notes and/or the Medicines Information enquiry form.	☐	☐	☐			
9.12 Pharmacists are proactively involved in medicines information through: • Provision of education and training • Published medication advice	☐	☐	☐			

Please note this is not a standard for Medicines Information Departments

STANDARD 10
Discharge

Basic Standard Requirements

The pharmacist ensures that all medicines prescribed at discharge are clinically accurate and appropriate. The patient is dispensed a supply of their prescribed medicines and is provided with accurate, up-to date information about their medicines. Accurate and up-to date information of a patient's medicines at discharge is safely and effectively communicated to primary care healthcare professionals.

10.1 A local SOP exists for the responsibilities of the pharmacist at discharge.

10.2 The pharmacist is actively involved in discharge planning.

10.3 Prior to discharge, the pharmacist reviews the current pharmaceutical care plan, anticipates any potential pharmaceutical care issues and liases with primary care and if appropriate the Pharmacist Interface Network to ensure arrangements are in place for continuity of care. This should be recorded as clinical activity performed by the pharmacist.

10.4 The pharmacist checks that all the medicines prescribed at discharge are clinically accurate and appropriate

10.5 Pharmacists clinically check the written or electronic information to primary care healthcare professionals when the patient is discharged detailing:

- Current medicines.
- Changes to medicine and the reason for the change.
- Information needed to continue supply of medicine within primary care.
- Monitoring requirements e.g. warfarin

A copy of this information is filed in the patient's medical notes or within pharmacy.

10.6 The pharmacist/ accredited checking pharmacy technician (ACPT) ensures that the patient is dispensed an appropriate quantity of medicines according to local guidance.

10.7 The pharmacist ensures that the patient is educated on prescribed medicines as appropriate and receives reinforcement of the need to adhere to the prescribed treatment, especially where there is a risk or previous history of non concordance (standard 11)

Advanced requirements

10.8 If a patient is discharged outside of pharmacy opening hours the discharge is followed up by a pharmacist by the next working day after discharge.

Why it is important

Discharge planning prevents hospital discharge being delayed due to medicines not being available. One stop dispensing and the reuse of patients own drugs schemes can be used to help discharge planning. However policies and procedures need to be put in place to ensure that patient safety is maintained.

Liaison with primary care healthcare professionals will ensure continuity of prescribed medicines and their supply. It also allows appropriate monitoring of new or altered medicines to be performed.

Special problems e.g. concordance issues, medicine aids, patient education can also be communicated.

Discharge

The pharmacist ensures that all medicines prescribed at discharge are clinically accurate and appropriate. The patient is dispensed a supply of their prescribed medicines and is provided with accurate, up-to date information about their medicines. Accurate and up-to date information of a patient's medicines at discharge is safely and effectively communicated to primary care healthcare professionals.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Discharge	**Y**	**N**	**N/A**			
10.1 A local SOP exists for the responsibilities of the pharmacist at discharge.	☐	☐	☐			
10.2 The pharmacist is actively involved in discharge planning.	☐	☐	☐			
10.3 Prior to discharge, the pharmacist reviews the current pharmaceutical care plan, anticipates any potential pharmaceutical care issues and liases with primary care and if appropriate the Pharmacist Interface Network to ensure arrangements are in place for continuity of care. This should be recorded as clinical activity performed by the pharmacist.	☐	☐	☐			
10.4 The pharmacist checks that all the medicines prescribed at discharge are clinically accurate and appropriate	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Discharge	**Y**	**N**	**N/A**			
10.5 Pharmacists clinically check the written or electronic information to primary care healthcare professionals when the patient is discharged detailing: •Current medicines. •Changes to medicine and the reason for the change. •Information needed to continue supply of medicine within primary care. •Monitoring requirements e.g. warfarin A copy of this information is filed in the patient's medical notes or within pharmacy.	☐	☐	☐			
10.6 The pharmacist / ACPT ensures that the patient is dispensed an appropriate quantity of medicines according to local guidance.	☐	☐	☐			
10.7 The pharmacist ensures that the patient is educated on prescribed medicines as appropriate and receives reinforcement of the need to adhere to the prescribed treatment, especially where there is a risk or previous history of non concordance	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Discharge	**Y**	**N**	**N/A**			
10.8 If a patient is discharged outside of pharmacy opening hours the discharge is followed up by a pharmacist by the next working day after discharge.	☐	☐	☐			

STANDARD 11
Patient Medicine Education

Basic Standard Requirements

Medicine education services shall be provided to patients or their carers where appropriate. If this is not possible categories of patients where maximal benefit is likely should be identified.

11.1 A local SOP exists for patient medicine education. The SOP identifies patients who would benefit most from medicine education. These include:

- Patients with serious and/or unstable disease states
- Patients admitted to hospital due to an iatrogenic cause
- Patients receiving specific medicines e.g. drugs with a narrow therapeutic index such as warfarin
- Patient started on a novel device e.g. inhaler device, insulin device, use of oral syringe
- Patients taking investigational medicine
- Patients treated with complex drug regimens
- Patients on four or more regular medicines
- Patients whose established medicines have been altered including new medicines, changed doses, discontinued drugs
- Elderly patients
- Paediatric patients and their guardians
- Patients identified as non-intentional non-concorders rather than those choosing not to concord on the basis of informed judgement
- Patients with language or reading difficulties
- Patients with impaired vision or hearing difficulties
- Patients with mental health problems and/ or learning difficulties
- Patients with dexterity problems

11.2 Pharmacists provide medicine education services to all patients. Where this is not possible patients who would benefit most from medicine education are identified.

11.3 Pharmacists ensure patients receive a PIL on discharge and have access to a PIL on request during admission according to European Legislation.

11.4 Patients are provided with verbal information in a form they can understand.

11.5 Where other health care professionals provide patient medicine education pharmacists should guide and advise as appropriate.

11.6 Pharmacists are involved in multidisciplinary patient education e.g. cardiac rehab, respiratory rehab, falls rehab where resources have been secured.

11.7 Medicine education should be documented in the patient's medical or multidisciplinary notes.

Advanced requirements

11.8 Patients are provided with written information in a form they can understand.

Why it is important.

The goal of patient medicine education is to provide information directed at encouraging safe and appropriate use of medicine thereby improving therapeutic outcomes. Pharmacists have a responsibility to provide sufficient information and education to ensure patients and/or their carers have the knowledge, skills and facilities to use their medicines and appliances appropriately. Pharmacists should encourage patients to seek further information on their medications if required..

Patient Medicine Education

Medicine education services shall be provided to all patients. If this is not possible categories of patients where maximal benefit is likely should be identified.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Patient Medicine Education	**Y**	**N**	**N/A**			
11.1 A local SOP exists for patient medicine education	☐	☐	☐			
11.2. Pharmacists provide medicine education services to all patients. Where this is not possible patients who would benefit most from medicine education are identified	☐	☐	☐			
11.3 Pharmacists ensure patients receive a PIL on discharge and have access to a PIL on request during admission according to European Legislation	☐	☐	☐			
11.4 Patients are provided with verbal information in a form they can understand	☐	☐	☐			
11.5 Where other health care professionals provide patient medicine education pharmacists should guide and advise as appropriate	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Patient Medicine Education	**Y**	**N**	**N/A**			
11.6 Pharmacists are involved in multidisciplinary patient education e.g. cardiac rehab, respiratory rehab, falls rehab where resources have been secured.	☐	☐	☐			
11.7 Medicine education is documented in the patient's medical or multidisciplinary notes	☐	☐	☐			
11.8 Patients are provided with written information in a form they can understand	☐	☐	☐			

STANDARD 12
Continuing Professional Development for Pharmacists

Basic Standard Requirements

Pharmacists must maintain and update their clinical and pharmaceutical knowledge relative to their sphere of practice through active participation in continuing professional development (CPD), in-service training and formal postgraduate diploma and degree courses.

Examples of CPD include formal courses and work shadowing.

12.1 Pharmacists participate in and record at least 30 hours of Continuing Professional Development (CPD) each year.

12.2 Pharmacists training needs are identified through self-assessment, peer review, professional audit and performance appraisal. These needs should then be met by participation in educational activities including:

- Attainment of postgraduate qualifications
- Attendance and contribution at relevant clinical meetings and conferences relevant to his/ her sphere of practice
- Participation in a recognised continuing education programme
- Review of relevant literature
- Participation in education programmes for pharmacists.

12.3 Pharmacists training needs and how these are met must be documented.

12.4 Pharmacists starting practice in a ward or department, which is unfamiliar to them are provided with an orientation and training programme, which is competency based. This programme is tailored to the experience and practice of the pharmacist and is co-ordinated by a suitably experienced pharmacist.

12.5 Education and training outcomes of pharmacists are reflected in practice and improvement in the quality of pharmaceutical care e.g. CPD cycles and how they impact on patient safety.

12.6 Where there is a defined role, pharmacists are trained as non medical prescribers in accordance with local procedure /practice.

12.7 A standard induction programme for clinical pharmacy practice exists with a written record of competence of each component to ensure consistency of training

12.8 Pharmacist competencies are reviewed on an ongoing basis for each area they work in

Why it is important

As advocates of best practice, the Pharmaceutical Society of Northern Ireland has introduced continuing professional development as a professional requirement from 1st June 2005 for all pharmacists registered in Northern Ireland as part of a system of good clinical governance. Pharmacists are required to undertake at least 30 hours of continuing professional development each year.

'Revalidation is a mechanism that allows health professionals to demonstrate that they remain up-to-date and can demonstrate that they continue to meet the requirements of their professional regulator' (Department of Health, 2008. Principles for revalidation: report of the working group for non-medical revalidation; Professional Regulation and Patient Safety Programme).

The report of the working group outlines the key principles for the development of non-medical revalidation proposals. Principle 5 is 'Continuing Professional Development', which is defined as the process by which individual registrants keep themselves up to date with healthcare developments in order to maintain the highest standards of professional practice. The report states that CPD should be seen as an integral part of revalidation and may provide supporting evidence that a practitioner submits to the regulatory body. From June 2013 CPD is a statutory requirement for registration with the Pharmaceutical Society of Northern Ireland.

Part 2 of the RPSGB Code of Ethics and its Appendix on 'Standards of Professional Performance' require that pharmacists must continually review the skills and knowledge required for their field of practice, identifying those skills or knowledge most in need of development or improvement and audit their performance as part of the review.

Participation in CPD allows the pharmacist to develop professionally and to provide a quality service.

Continuing Professional Development of Pharmacists

Pharmacists must maintain and update their clinical and pharmaceutical knowledge relative to their sphere of practice through active participation in continuing professional development (CPD), in-service training and formal postgraduate diploma and degree courses.
Examples of CPD include formal courses and work shadowing.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
CPD	**Y**	**N**	**N/A**			
12.1 Pharmacist participate in and record at least 30 hours of Continuing Professional Development (CPD) each year.	☐	☐	☐			
12.2 Pharmacists training needs are identified through self-assessment, peer review, professional audit and performance appraisal.	☐	☐	☐			
12.3 Pharmacists training needs and how these are met are documented.	☐	☐	☐			
12.4 Pharmacists starting practice in a ward or department, which is unfamiliar to them are provided with an orientation and training programme, which is competency based. This programme is tailored to the experience and practice of the pharmacist and is co-ordinated by a suitably experienced pharmacist.	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Education and Training	**Y**	**N**	**N/A**			
12.5 Education and training outcomes of pharmacists are reflected in practice and improvement in the quality of pharmaceutical care e.g. CPD cycles and how they impact on patient safety.	☐	☐	☐			
12.6 Where there is a defined role, pharmacists are trained as non medical prescribers in accordance with local procedure /practice.	☐	☐	☐			
12.7 A standard induction programme for clinical pharmacy practice exists with a written record of competence of each component to ensure consistency of training	☐	☐	☐			
12.8 Pharmacist competencies are reviewed on an ongoing basis for each area they work in	☐	☐	☐			

STANDARD 13
Resources

Basic Standard Requirements

Appropriate resources must be available for the provision of a clinical pharmacy service and to provide CPD opportunities for pharmacists irrespective of their working patterns.

The following resources are recommended:

13.1 Access to up-to-date medicines information and medical literature as suggested by the UKMi (United Kingdom Medicines Information national network)

13.2 Information technology facilities

13.2 Appropriate work space and environment as per Health Estates Acute Hospital – Standard Data Sheet T0125HEA Medicines Management and T0601HEA Clean Utility

13.4 Support and resources for involvement in CPD activities, training and research

13.5 Appropriate staffing levels and structure (Standard 14).

13.6 Access to patient specific information

Why it is important

Recommended resources allow the efficient provision of a clinical pharmacy service.

Resources

Appropriate resources must be available for the provision of a clinical pharmacy service and to provide CPD opportunities for pharmacists irrespective of their working patterns.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Resources	**Y**	**N**	**N/A**			
13.1 Pharmacists have access to up-to-date medicines information and medical literature	☐	☐	☐			
13.2 The pharmacy department has information technology facilities	☐	☐	☐			
13.3 The pharmacy department/ ward team has appropriate work space and environment as per Estates Acute Hospital standard data sheets T0125HEA and T0601HEA	☐	☐	☐			
13.4 Pharmacists are provided with support and resources for involvement in CPD activities, training and research	☐	☐	☐			
13.5 The pharmacy department has appropriate staffing levels and structure (Standard 14).	☐	☐	☐			
13.6 Pharmacists have access to adequate patient specific information	☐	☐	☐			

STANDARD 14
Staffing Levels and Structure

Basic Standard Requirements

Staffing levels and structure are in place to provide patient-focused pharmaceutical care.

14.1 Adequate staff levels are established and maintained to provide a continuous and consistent clinical pharmacy service (Table 1).

14.2 Adequate support staff levels are available to perform non-clinical functions (Table 1).

Why it is important

Staffing structure will be determined by the size and type of hospital, bed occupancy, local management and local resources. General guidance with bed type and pharmacist and technician ratios is shown in table 1.

Staffing Levels and Structure

Staffing levels and structure are in place to provide patient-focused pharmaceutical care.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Staffing Structure and Levels	**Y**	**N**	**N/A**			
14.1 Adequate staff levels are established and maintained to provide a continuous and consistent clinical pharmacy service	☐	☐	☐			
14.2 Adequate support staff levels are available to perform non-clinical functions	☐	☐	☐			

Table 1: Clinical Pharmacy Staffing Levels to Provide a Clinical Pharmacy Service

Hospital Area	Pharmacist Ratio	Technician Ratio	Reference
General Medicine Cardiology Oncology Inpatients Haematology Inpatients Other comparable specialities	Pharmacist time per admission 102 minutes	Technician time per admission 83 minutes	NI timings 2012 (appendix 2)
General Surgery Orthopaedics	Pharmacist time per admission 80 minutes	Technician time per admission 64 minutes	NI timings 2012 (appendix 2)
Gynae	Pharmacist time per admission 67 minutes	Technician time per admission 51 minutes	NI timings 2012 (appendix 2)
Paediatrics	Pharmacist time per admission 36 minutes	Technician time per admission 14 minutes	NI timings 2012 (appendix 2)
Acute Elderly Care	Pharmacist time per admission 160 minutes	Technician time per admission 141 minutes	NI timings 2012 (appendix 2)
Acute Psychiatry	Pharmacist time per admission 181 minutes	Technician time per admission 84 minutes	NI timings 2012 (appendix 2)
Maternity			Further work needed
ENT			Further work needed
Long stay Psychiatric Long stay learning difficulties Long stay Elderly Care Other comparable specialities			Further work needed
ICU / HDU†	0.05-0.1 wte pharmacist for each single level 3* bed and for every two level 2† beds	0.1technician per bed/ cot station	NHS Modernisation Agency 2002
Neonatal	10-20minutes per cot per day		British Association of Perinatal Medicine 2010
Accident and Emergency	1 pharmacist per 100,000 attendances	1 technician per 100,000 attendances	Further work needed using conversion rates

Hospital Area	Pharmacist Ratio	Technician Ratio	Reference
Cystic Fibrosis Patients HIV Patients Other comparable specialities	0.3 pharmacist per 50 registered patients	0.3 technician per 50 registered patients	Further work needed
Pharmacy led Clinics (based on half day clinic session and half day preparation/ follow up)	0.2 pharmacist per clinic	-	Further work needed
Specialist Teams	0.5 pharmacist per team	-	Further work needed
Clinics - STD	0.1 pharmacist per 1000 patient visits	-	Further work needed
Renal replacement therapy	1 wte pharmacist per 250 RRT patients		National Renal Workforce Planning Group 2002 Further work needed re renal clinics and pre dialysis patients
Renal transplant	1 wte pharmacist per 60 transplants per annum		National Renal Workforce Planning Group 2002

†Level 2 Patients requiring more detailed observations or interventions including support for a single failing organ system or post-operative care and those 'stepping down' from higher levels of care.

*Level 3 Patients requiring advanced respiratory support alone or basic respiratory support together with the support of at least two organs systems. This level includes all complex patients requiring support for multi-organ failure.

STANDARD 15
Documentation

Basic Standard Requirements

Pharmacists activities that contribute to patient care shall be appropriately documented

15.1 Contribution to patient care may be documented in the patient's medical notes when appropriate according to local policy. However written documentation should not replace verbal communication. This may include:

- Medicine history and medicines reconciliation
- Response to patient specific questions from other members of the healthcare team
- Recommendations for medicines optimisation
- Recommendations for laboratory monitoring
- ADR assessment and management recommendations
- Potential drug interactions
- Patient education details
- Medicine Information enquiries

This is not an exhaustive list

15.2 Pharmacists clinical activity, workload and interventions are documented according to local SOPs

15.3 Pharmacists interventions are documented and classified according to locally agreed procedures

15.4 Medicine related incidents are documented and reported according to local medicine incident reporting policy and procedure (Standard 7)

15.5 Any other activity that improves the quality of patient care is documented e.g. medicines information supplied

15.7 Documentation is retained according to local guidelines

Why it is important

Any activity undertaken by a pharmacist that affects patient care should be documented making a permanent record of the pharmacist's concerns, actions and recommendations.

When making an entry in patient medical, nursing or multidisciplinary notes the pharmacist should:

- Write in photocopiable ink
- Designate the entry
- Date and time the entry
- Follow a SOAP SEQUENCE
  - ❖ Subjective relevant patient details
  - ❖ Objective clinical findings
  - ❖ Assessment of the situation/ problem
  - ❖ Proposed management plan
- Limit comments to recommendations to allow discussion
- Document any discussion with medical or nursing staff
- Only use approved abbreviations
- Sign the entry, print name and designation beside signature and provide bleep number or contact number if applicable

Any entry in a patient's notes is a legal record.

Workload and clinical activity documentation can be used to provide evidence of the effect of clinical pharmacy services on patient care. It can also be used to obtain adequate resources for continuity of service.

Intervention recording and classification of the type of intervention allows the outcome of pharmacists' clinical activities to be qualified and quantified.

Medicine incidents are documented to allow investigation of the incident as appropriate, a review of processes to occur to prevent recurrence and can be used as a source of learning (standard 7).

Documentation

Pharmacists activities that contribute to patient care shall be appropriately documented

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Documentation	**Y**	**N**	**N/A**			
15.1 Contribution to patient care is documented in the patient's medical notes when appropriate	☐	☐	☐			
15.2 Pharmacists clinical workload and activity is documented according to local SOPs	☐	☐	☐			
15.3 Pharmacists interventions are documented and classified according to locally agreed procedures	☐	☐	☐			
15.4 Medicine related incidents are documented according to local medicine incident reporting policy and procedure	☐	☐	☐			
15.5 Any other activity that improves the quality of patient care is documented	☐	☐	☐			
15.6 Documentation is retained according to local guidelines	☐	☐	☐			

STANDARD 16
Quality of Clinical Pharmacy Services

Basic Standard Requirements

A continuous quality improvement system shall exist to assess and assure the quality of the clinical pharmacy service.

16.1 Pharmacists are involved in ongoing quality improvements that may be used to assure the quality of the clinical pharmacy service. These include:

- Clinical audit
- Peer review
- Benchmarking
- Review of workload statistics
- Review of interventions
- Review of medication incidents
- Education and training
- Compliance with regional and national directives
- Formal research
- Horizon scanning

16.2 Quality improvements are shared with other Trusts in Northern Ireland , and the United Kingdom and internationally. This may be done through publications and presentations at local and national and international conferences.

Why it is important

Quality may be described as a level of excellence that gives user satisfaction and ensures that a product or service is fit for the purpose intended.

Quality of Clinical Pharmacy Services

A continuous quality improvement system shall exist to assess and assure the quality of the clinical pharmacy service.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Quality of Clinical Pharmacy Services	**Y**	**N**	**N/A**			
16.1 Pharmacists are involved in ongoing quality improvements	☐	☐	☐			
16.1.1 Pharmacists are involved in clinical audit	☐	☐	☐			
16.1.2 Pharmacists are involved in peer review	☐	☐	☐			
16.1.3 Pharmacists are involved in benchmarking	☐	☐	☐			
16.1.4 Pharmacists are involved in production of workload statistics	☐	☐	☐			
16.1.5 Pharmacists are involved in review of interventions	☐	☐	☐			
16.1.6 Pharmacists are involved in review of medication incidents	☐	☐	☐			
16.1.7 Pharmacists are involved in education and training of pharmacists and other healthcare professionals.	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Quality of Clinical Pharmacy Services	**Y**	**N**	**N/A**			
16.1.8 Pharmacists comply with regional and national directives	☐	☐	☐			
16.1.9 Pharmacists are involved in formal research	☐	☐	☐			
16.2 Quality improvements are shared with other Trusts in Northern Ireland, the United Kingdom and internationally. This may be done through publications and presentations at local, national and international conferences.	☐	☐	☐			

STANDARD 17
Health Promotion

Basic Standard Requirements

Pharmacists are involved in health promotion to promote good health and prevent disease by helping individuals change attitudes to health damaging behaviour and encourage individuals to change their lifestyle.

17.1 Pharmacists provide health education information so that patients can make informed choices in their lifestyle and behaviour e.g. fitness and diet

17.2 Pharmacists increase awareness of current issues in health promotion e.g. participate in national and local health campaigns

17.3 Pharmacists participate in disease prevention strategies, reducing the risk of developing preventable illness or progression of disease by adopting a healthier approach e.g. smoking cessation programmes, vaccination programmes

17.4 Pharmacists contribute to health protection initiatives through education and ensuring that treatment is optimised to prevent further deterioration in health e.g. cardiac, respiratory and falls rehab classes, production and adherence to safe systems of work, policies and procedures for the storage, handling, administration and disposal of medicines

Why it is important

The World Health Organisation defines health as ‘a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity’.

Health promotion refers to any measure designed to achieve health and prevent disease and is concerned with influencing health choices. It involves health education, disease prevention and health protection.

Pharmacists can reduce the risk of preventable disease by assisting in the prevention of adverse drug reactions and minimising the risk of developing known or dose related adverse drug reactions

Health Promotion

Pharmacists are involved in health promotion to promote good health and prevent disease by helping individuals change attitudes to health damaging behaviour and encourage individuals to change their lifestyle.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Health Promotion	**Y**	**N**	**N/A**			
17.1 Pharmacists provide health education information so that patients can make informed choices in their lifestyle and behaviour	☐	☐	☐			
17.2 Pharmacists increase awareness of current issues in health promotion	☐	☐	☐			
17.3 Pharmacists participate in disease prevention strategies, reducing the risk of developing preventable illness or progression of disease by adopting a healthier approach	☐	☐	☐			
17.4 Pharmacists contribute to health protection initiatives by educating and ensuring that treatment is optimised to prevent further deterioration in health	☐	☐	☐			

STANDARD 18
Pharmacoeconomic Evaluation of the use of Medicines

Basic Standard Requirements

Pharmacists are involved in the pharmacoeconomic evaluation of the use of medicines to ensure that medicines are used appropriately, safely, effectively and economically.

18.1 Pharmacists evaluate medicine expenditure and usage on a monthly basis to:

- Identify medicine usage issues and trends
- Identify high cost medicines
- Identify high usage medicines
- Identify whether there is an underspend, overspend or that expenditure is within budget.
- Highlight reasons for deviation from budget expenditure

18.2 There is a close working relationship between the finance department and pharmacy department whereby expenditure evaluation is explained to the finance department, requests for funding for medicine use are agreed and future cost pressures identified.

18.3 Pharmacists are involved in evaluating medicine use e.g. prescribing pattern audits and interpreting and reporting the evaluation findings to the Drug and Therapeutics Committee to recommend changes in medicine use practice

Why it is important

Pharmacoeconomic evaluation of the use of medicines is a multidisciplinary structured, ongoing, organisationally authorised, quality assurance process designed to ensure that medicines are used appropriately, safely, effectively and economically. It is complemented by:

- effective, concurrent drug therapy monitoring by pharmacy staff
- continuous education on appropriate drug use and
- assessment of patient outcome.

Pharmacoeconomic Evaluation of the use of Medicines

Pharmacists are involved in the pharmacoeconomic evaluation of the use of medicines to ensure that drugs are used appropriately, safely, effectively and economically.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Pharmacoeconomic evaluation of the use of medicines	Y	N	N/A			
18.1 Pharmacists evaluate medicine expenditure and usage on a monthly basis	☐	☐	☐			
18.1.1 Pharmacists identify medicine usage issues and trends	☐	☐	☐			
18.1.2 Pharmacists identify high cost medicines	☐	☐	☐			
18.1.3 Pharmacists identify high usage medicines	☐	☐	☐			
18.1.4 Pharmacists identify whether there is an underspend, overspend or that expenditure is within budget	☐	☐	☐			
18.1.5 Pharmacists highlight reasons for deviation from budget expenditure	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Pharmacoeconomic evaluation of the use of medicines	Y	N	N/A			
18.2 There is a close working relationship between the finance department and pharmacy department whereby expenditure evaluation is explained to the finance department, requests for funding for medicine use are agreed and future cost pressures identified.	☐	☐	☐			

STANDARD 19
Pharmacist Clinics

Basic Standard Requirements

Pharmacist clinics are managed by pharmacists with appropriate knowledge, experience and training.

19.1 A local SOP exists to guide practice for pharmacist clinics.

19.2 A defined role for the pharmacist is determined in consultation with medical staff and other relevant health professionals.

19.3 The pharmacist completes a training package and/ or induction programme to work in the clinic. If appropriate the pharmacist is a trained non medical prescriber (Standard 20).

19.4 Criteria exist to aid the appropriate referral of patients to medical staff and other health professionals.

19.5 Pharmacists maintain their specialist clinical knowledge in their field of practice.

19.6 Criteria exist to identify patients who require regular review.

19.6.1 The pharmacist regularly attends multidisciplinary team meetings linked to the area of practice.

19.8 The pharmacist's contribution to patient care is documented in the patient's medical notes and if appropriate communicated with the multidisciplinary team and relevant primary health care professionals.

Why it is important

Pharmacists manage clinics in various fields of practice. Examples include:

- Renal
- Cystic Fibrosis
- Pain
- Anticoagulation
- Diabetes
- Pre-operative assessment
- Respiratory
- HIV
- Oncology/ haematology

Pharmacist clinics encompasses a number of clinical pharmacy activities simultaneously including:

- Medicine History Interview and Medicines Reconciliation (Standard 1)
- Prescription monitoring and review (Standard 3)
- Adverse drug reaction management (Standard 4)
- Prevention, detection, assessment & management of drug interactions (Standard 5)
- Therapeutic drug monitoring (Standard 6)
- Patient medicine education (Standard 11)
- Pharmacoeconomic evaluation of the use of medicines (Standard 18)

Pharmacist Led Clinics

Pharmacist led clinics are managed by pharmacists with appropriate knowledge, experience and training.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Pharmacist led clinics	**Y**	**N**	**N/A**			
19.1 A local SOP exists to guide practice for pharmacist led clinics	☐	☐	☐			
19.2 A defined role for the pharmacist is determined in consultation with medical staff and other relevant health professionals	☐	☐	☐			
19.3 The pharmacist completes a training package and/ or induction programme to work in the clinic. If appropriate the pharmacist is a trained non medical prescriber	☐	☐	☐			
19.4 Criteria exist to aid the appropriate referral of patients to medical staff and other health professionals	☐	☐	☐			
19.5 Pharmacists maintain their specialist clinical knowledge in their field of practice	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Pharmacist led clinics	**Y**	**N**	**N/A**			
19.6 Criteria exist to identify patients who require regular review	☐	☐	☐			
19.7 The pharmacist regularly attends multidisciplinary team meetings linked to the area of practice	☐	☐	☐			
19.8 The pharmacist's contribution to patient care is documented in the patient's medical notes and if appropriate communicated with the multidisciplinary team and relevant primary health care professionals.	☐	☐	☐			

STANDARD 20
Non medical Prescribing (Pharmacist)

Basic Standard Requirements

Pharmacists who work as non medical prescribers must have completed appropriate training and have their Trust's support to work within their field of practice.

Pharmacists who work as supplementary or independent prescribers:

20.1 Have at least 2 years post registration experience.

20.2 Have completed supplementary and/ or independent prescribing training, including 12 days supervised practice.

20.3 Are on the Trust's prescribing register.

20.4 Are annotated as a supplementary or independent prescriber on the register of the Pharmaceutical Society of Northern Ireland.

20.5 Have the agreement of a consultant in their field(s) of practice.

20.6 Keep up to date and participate in CPD in their field of practice as part of their 30 hours of annual CPD.

20.7 Supplementary prescribers work within an agreed patient-specific clinical management plan with the patient's agreement.

20.8 Maintain and develop the appropriate skills of a non medical prescriber.

20.9 Are aware of their own limitations and when to refer to the patient's consultant.

Why it is important

In 1999, the Review of Prescribing, Supply and Administration of Medicines led by Dr June Crown suggested the introduction of a new form of prescribing to be undertaken by non-medical health professionals after a diagnosis had been made and a Clinical Management Plan drawn up for the patient by a doctor. Among the healthcare professionals named as prospective supplementary prescribers were pharmacists.

Supplementary prescribing is a voluntary prescribing partnership between an independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.

In May 2006 following extensive consultation and advice from the Committee of Safety of Medicines, The Prescription Only Medicines Order (POM Order), which is UK wide legislation, was changed to allow independent prescribing by suitably trained nurses and pharmacists. Further changes to the HPSS Primary Medical Services Regulations in Northern Ireland in August 2006 allowed the provisions in the POM Order to be applied in the context of HPSS services thus enabling suitably trained pharmacists in Northern Ireland to practice as independent prescribers. The definition of pharmacist independent prescribing is:

'…a practitioner (e.g. doctor, dentist, nurse, pharmacist) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing.'

Non Medical Prescribing (Pharmacists)

Pharmacists who work as non medical prescribers must have completed appropriate training and have their Trust's support to work within their field of practice.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Non Medical Prescribing (Pharmacists)	**Y**	**N**	**N/A**			
Pharmacists who work as supplementary or independent prescribers:						
20.1 Have at least 2 years post registration experience	☐	☐	☐			
20.2 Have completed supplementary and/ or independent prescribing training, including 12 days supervised practice	☐	☐	☐			
20.3 Are on the Trust's prescribing register	☐	☐	☐			
20.4 Are annotated as a supplementary or independent prescriber on the register of the Pharmaceutical Society of Northern Ireland	☐	☐	☐			
20.5 Have the agreement of a consultant in their field(s) of practice	☐	☐	☐			
20.6 Keep up to date and participate in CPD in their field of practice as part of their 30 hours of annual CPD	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Non Medical Prescribing (Pharmacists)	**Y**	**N**	**N/A**			
Pharmacists who work as supplementary or independent prescribers:						
20.7 Supplementary prescribers work within an agreed patient-specific clinical management plan with the patient's agreement	☐	☐	☐			
20.8 Maintain and develop the appropriate skills of a supplementary or independent prescriber	☐	☐	☐			
20.9 Are aware of their own limitations and when to refer to the patient's consultant	☐	☐	☐			

STANDARD 21
Communication

Basic Standard Requirements

Pharmacists use communication skills to build more effective relationships with patients and other health professionals.

21.1 Pharmacists identify and respond to key pharmaceutical care issues requiring follow up.

21.2 Pharmacists communicate key pharmaceutical care issues to the necessary health professionals in primary and secondary care.

Why it is important

Communication is central to all aspects of professional health care and promotion. It includes the following skills:

- Specialised knowledge
- Practical skills
- Social and interpersonal skills
- Rapport
- Agenda setting
- Information collection/ management
- Active listening
- Addressing feelings
- Reaching common ground.

Communication

Pharmacists use communication skills to build more effective relationships with patients and other health professionals.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Communication	**Y**	**N**	**N/A**			
21.1 Pharmacists identify and respond to key pharmaceutical care issues requiring follow up	☐	☐	☐			
21.2 Pharmacists communicate key pharmaceutical care issues to the necessary health professionals in primary and secondary care	☐	☐	☐			

STANDARD 22
Self Administration of Medicines

Basic Standard Requirements

Patients may undertake routine self administration of their medicines where a specific local procedure approved by the Trust's Drug and Therapeutics Committee is in place.

22.1 A local SOP approved by the Trust's Drug and Therapeutics Committee exists for patient self administration of medicines.

22.2 Suitable patients are assessed for self administration by a designated member of staff who has undergone appropriate training.

22.3 Patients consent to self administer their medicines after receiving education, information and details of their responsibilities whilst self medicating.

22.4 Patients have immediate access to GTN sprays for the relief of angina pain and beta adreno-receptor agonist bronchodilator inhalers.

22.5 Medicines other than immediate access medicines are stored securely to prevent misuse by others.

22.6 A record of the dose and frequency of self administered medicine is made on the inpatient drug administration chart.

Why it is important

Self administration of medicines by patients has many benefits including:

- Helping patients achieve/ maintain a greater degree of independence during their stay
- Identifying concordance issues prior to discharge
- Improving patients' knowledge of prescribed medicines
- Promoting drug administration at the most appropriate time

Self Administration of Medicines

Patients may undertake routine self administration of their medicines where a specific local procedure approved by the Trust's Drug and Therapeutics Committee is in place.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Self administration of medicines	**Y**	**N**	**N/A**			
22.1 A local SOP approved by the Trust's Drug and Therapeutics Committee exists for patient self administration of medicines	☐	☐	☐			
22.2 Suitable patients are assessed for self administration by a designated member of staff who has undergone appropriate training	☐	☐	☐			
22.3 Patients consent to self administer their medicines after receiving education, information and details of their responsibilities whilst self medicating	☐	☐	☐			
22.4 Patients have immediate access to GTN sprays for the relief of angina pain and beta adreno-receptor agonist bronchodilator inhalers	☐	☐	☐			
22.5 Medicines other than immediate access medicines are stored securely to prevent misuse by others	☐	☐	☐			

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Self administration of medicines	**Y**	**N**	**N/A**			
22.6 A record of the dose and frequency of self administered medicine is made on the inpatient drug administration chart	☐	☐	☐			

STANDARD 23
Reuse of Patient's Own Medicines

Basic Standard Requirements

Patient's own medicines used during inpatient care are both safe and fit for purpose.

23.1 A local SOP exists for the reuse of patient's own medicines.

23.2 Patient's own medicines are securely stored in a locked medicine cupboard, individual patient locker or cabinet or locked in a medicines trolley.

23.3 Patient's own medicines are not used as part of inpatient treatment or as discharge medication unless they have been approved by a designated member of staff who has undergone appropriate training.

23.4 Patient's own medicines are only administered or supplied to the individual patient to whom they belong in accordance with a valid prescription.

Why it is important

Spoonful of Sugar advocated the reuse of patient's own drugs. Some of the advantages are:

- Identification of medicine related problems on admission
- reduced confusion for patient's on discharge in that they only have one supply of each prescribed medicine thus preventing accidental overdose
- medicines discontinued during inpatient hospital stay can be disposed of preventing patient's continuing to take a medication they are no longer prescribed.

Reuse of Patient's Own Medicines

Patient's own medicines used during inpatient care are both safe and fit for purpose.

Indicators	Audit Result			Comments Action to be taken	Target Date	Completed
Reuse of Patient's Own Medicines	**Y**	**N**	**N/A**			
23.1 A local SOP exists for the reuse of patient's own medicines	☐	☐	☐			
23.2 Patient's own medicines are securely stored in a locked medicine cupboard, individual patient locker or cabinet or locked in a medicines trolley	☐	☐	☐			
23.3 Patient's own medicines are not used as part of inpatient treatment or as discharge medication unless they have been approved by a designated member of staff who has undergone appropriate training	☐	☐	☐			
23.4 Patient's own medicines are only administered or supplied to the individual patient to whom they belong in accordance with a valid prescription	☐	☐	☐			

Appendix 1

Sample Procedures

Procedure for Medicine History Interview and Medicines Reconciliation

- Determine the ability of the patient to communicate appropriately
- Choose a suitable environment that allows privacy and confidentiality for the patient and minimises the risk of interruption and distraction
- Establish the identity of the patient
- Introduce yourself
- Explain the purpose of the interview
- Respect the patient's right to decline an interview
- Adopt a physical position that allows the interview to take place comfortably and effectively
- In the event that the patient is not involved in the administration and management of their medicine the interview should be continued with the relevant person(s) e.g. relative or carer, after obtaining consent from the patient if possible.

The nature of the medicine history interview will depend on the individual patient. Questions must be relevant to the specific patient and tailored to obtain the necessary information. A standardised form should be used to record the information obtained. At the end of the interview this form should be signed and dated by the pharmacist/ trained accredited technician in drug history taking who has taken the medicine history and be filed in the patient's medical notes and/ or form part of the patient's pharmaceutical care plan. Open-ended questions should be used to seek information on the following:

- Prescription medicine use including all forms e.g. inhaled, topical, injections
- Non-prescription medicine use
- Self-initiated medicines and other types of health products used e.g. complementary alternative medicine
- Concordance with therapy including practical problems such as opening bottles
- Allergies/sensitivities (date and nature of reaction), previous adverse drug reactions and their manifestations
- Social drug use e.g. alcohol, tobacco
- Illicit drug use using professional judgement when appropriate
- Immunisation status when appropriate
- Community pharmacies visited
- Are the medicines supplied in a monitored dosage system
- Recent changes to medicine

Assess the patient's understanding and attitude to their therapy. Open-ended questions should be used to seek information on the following if necessary:

- The patient's perception of the purpose and effectiveness of the medicine(s)
- The dose and dose schedule used

- The duration of therapies used
- A general impression of the likelihood that the patient has used the medicine as prescribed
- The reason(s) for discontinuation or alteration of medicine(s)
- The storage of the medicine(s) e.g. fridge items
- Any problems with the medicine therapy

At the conclusion of the interview:

- Summarise the important information for the patient
- Ask the patient if they have any concerns or questions about their medicine and address these if appropriate
- Encourage the patient to provide further information that may be recalled after the interview. To facilitate this it may be necessary to provide a contact name and telephone number
- Explain when the next opportunity for discussion with a pharmacist will arise

Documentation and information that may assist the medicine history includes:

- Current hospital medicine administration record
- Current medicine record from general practitioner (printed or obtained via telephone from GP surgery). Check for both repeat and acute issues and for any recent information that may not yet have been updated on the GP computer records.
- Current medicine record from community pharmacist (printed or obtained via telephone from community pharmacist)
- Referral letter from general practitioner or other source e.g. nursing home, another hospital
- Previous hospital prescriptions e.g. discharge prescriptions, outpatient prescriptions
- Current admission details (medical and nursing notes)
- The patient's own medicine list
- The patients own drugs brought into hospital

At least two sources of information should be used

If a reliable medicine history cannot be obtained from the patient, relative or carer, community healthcare professionals should be contacted e.g. general practitioner, community pharmacist, nursing home staff. It should be documented on the medicine history form where the medicine history has been obtained.

After the interview the information obtained should be used to resolve any medicine-related problems. The medicine history should be compared with the current hospital medicine administration record and any discrepancies resolved. The prescriber should be contacted if appropriate and a medication incident form completed. Patients should be educated about alterations to their medicines where necessary.

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MEDICINE HISTORY INTERVIEW TOOL

Patient name: DOB: Address: Hosp. No. (Attach addressograph)	GP name: Address: Community Pharmacist: Address:

Patient able to communicate appropriately: Y/N
Patient manages & administers own medicines at home: Y/N
If NO who manages and administers patients medicines at home? ……
Monitored dose system: Y/N

Allergies/ Previous adverse reactions Nature of reaction(s)	Recent vaccination history

Does the patient have a known history of alcohol abuse/ misuse? Y/N
If YES give details:……

Does the patient have a known history of drug abuse/ misuse? Y/N
If YES give details:……
Does patient smoke? Y/N

Drugs on Admission:

Drugs prescribed by doctor:				
Drug name & form	Strength, dose, frequency, formulation	Information source[1]	Patient concordant and medicines stored correctly	Supply at home[2]
			Y/N	
			Y/N	
			Y/N	
			Y/N	

(Continued overleaf)

Any additional information:

Key: 1. **GP** – General Practitioner **P** – Patient **C** – Relative/ Carer **CP** – Community Pharmacist **NH** – Nursing Home **O** – Other (please specify) 2. **H** – Home **W** – Ward **D/C** – Discontinued medicine

Drugs on Admission:

Drugs prescribed by doctor continued:				
Drug name & form	Strength, dose, frequency	Information source$_1$	Patient concordant and medicines stored correctly	Supply at home$_2$
			Y/N	
			Y/N	
			Y/N	
			Y/N	
			Y/N	
			Y/N	
			Y/N	

Non prescription medicine/ self-initiated medicine (including homeopathic & herbal medicine)				
			Y/N	
			Y/N	
			Y/N	
			Y/N	
			Y/N	

Drug related admission: Y/N
If YES give details:……
……

Follow up required:

Pharmacist's/ Technician Name:…….(Please print)

Signature: …… Date:……

Procedure for Prescription Monitoring and Review.

The patient's prescription should be reviewed in conjunction with the patient, the administration record, the patient's notes, the medicine history and relevant laboratory test results. All current and recently prescribed drugs should be reviewed. This may include routine medicine, variable dose drugs, intravenous therapy, single dose drugs, anaesthetic records, epidural medicine or other analgesics. A patient may have several different prescription charts at any one time e.g. multiple prescription charts, supplementary sheets such as anticoagulant chart, fluid balance chart and all of these must be reviewed. Recent consultations, clinical tests and procedure results, observation results, treatment plans, daily progress and information elicited from the patient should be taken into account when determining the appropriateness of prescribed drugs. Prescription monitoring and review should include:

- Checking that the prescription is written according to legal and local requirements. The patient's identification information must be clear and complete. The patient's allergy and sensitivity status must be complete and correct. It must be updated if the patient develops a new allergy or sensitivity during admission
- Ensuring that the prescription is complete and unambiguous, appropriate terminology is used and that drug names and units are not abbreviated. The prescription chart should be annotated for clarification if required
- A new prescription is written when current treatment is altered
- Detecting medicines prescribed to which the patient is allergic, hypersensitive or intolerant.
- Ensuring the prescription is appropriate with respect to:
    - The patient's previous medicine
    - Patient specific considerations e.g. pregnancy, nil by mouth
    - Drug dosage and dosage schedule with respect to age, renal function, liver function
    - Route, dosage form and method of administration
- Checking for medicine duplication
- Checking for actual or potential medicine interactions or incompatibilities
- Ensuring that administration times are appropriate e.g. with respect to food, other medicines, procedures
- Checking the administration records to ensure that medicine is administered as prescribed
- Ensuring that the prescription clearly indicates the times of drug administration. Prescriptions for drugs that are not prescribed on a 24hour basis must indicate the frequency and if appropriate the day of administration
- Ensuring that the duration of therapy is appropriate e.g. antibiotics, analgesics
- Ensuring that the prescription is cancelled when drug therapy is intended to cease and that this is signed and dated

- If appropriate, follow up any non-formulary drug orders and recommend a formulary equivalent if required
- Ensuring that appropriate therapy monitoring is implemented
- Ensuring that all medicine is prescribed according to the patient's medical condition e.g. if a patient is prescribed an opiate has a laxative been prescribed
- Reviewing medicines for cost effectiveness
- Endorsing prescriptions with clarifying information e.g. dilution/ administration rates for intravenous infusions, times of administration, generic drug names and allergies/ sensitivities as appropriate
- Evaluate prescription(s) as a whole e.g. do as required medicines have an implication on regular medicines
- Evaluating the patients response to therapy
- Identifying medicine related problems. These include:
  - Untreated indications – the patient has a medical problem that requires medicine therapy but is not receiving a medicine for that indication
  - Missing medicines e.g. patient prescribed a rate controlling medicine for atrial fibrillation but not prescribed an anticoagulant or antiplatelet
  - Inappropriate drug selection – the patient has a medicine indication but is taking the wrong medicine. The patient's treatment should be current best practice
  - Subtherapeutic dosage – the patient has a medical problem treated with too little of the correct medicine
  - Failure to receive medicine – the patient has a medical problem as the result of not receiving a medicine
  - Overdosage – the patient has a medical problem being treated with too much of the correct medicine
  - Actual or potential adverse drug reactions or effects
  - Drug interactions – the patient has a medical problem that is the result of a drug-drug, drug-food or drug-test interaction
  - Medicine use with no medical indication
  - Lack of understanding of the medicine therapy by the patient
  - Failure of the patient to adhere to the medicine regimen

Consultation with the prescriber to discuss and agree any suggested and necessary changes must be undertaken as soon as practical. Prescription charts should be altered or rewritten as soon as possible. Consultation and intervention in patient care should be documented in the patient's medical notes and pharmacy records where appropriate.

If a problem requires urgent resolution and the prescriber is not available the prescriber or a member of the medical team should be contacted by the pharmacist immediately e.g. by bleep or phone and the problem with suggested solutions explained.

The pharmacist must follow up on consultations to ensure that problems are resolved.

Procedure for the prevention, detection, assessment and management of adverse drug reactions

In preventing and detecting ADRs pharmacist should:

- Identify and monitor patients most susceptible to ADRs. For example
  - Older patients
  - Paediatric patients
  - Those with multiple diseases
  - Patients treated with a large number of drugs
  - Patients treated with medicines known to have a high incidence of adverse effects. Avoid use of these medicines where an equally effective and safer alternative exists or ensure they are used appropriately to minimise the risk.
  - Patients treated with medicines associated with serious adverse effects
  - Patients treated with medicines with a narrow therapeutic index
  - Patient treated with medicines with potential for multiple interactions
  - Patients with compromised drug handling ability e.g. altered absorption, distribution, metabolism or excretion
  - Patients with compromised ability to take or use medicines e.g. dysphagic patients

- Check that patients are not exposed to unnecessary risk e.g. drug use with no indication, disregard for stated warnings, special precautions, contra-indications
- Check that there are no drug interactions with prescribed medicine, over the counter medicine, food or drink
- Ensure patients receive cautionary and advisory labels and education on the correct use, storage and disposal of their medicine at discharge
- Educate patients to recognise ADRs and what action to take should they experience an ADR
- Encourage patients to report ADRs
- Encourage medical and nursing staff to report ADRs
- Identify patients who have had previous ADRs, intolerance or hypersensitivity to a particular drug or class of drugs
- Monitor patients on black triangle or unlicensed medicines
- Detect ADRS through routine drug therapy monitoring e.g. extra-pyramidal symptoms caused by metoclopramide
- Monitor patients for delayed ADRs with both established and newer medicines

When an ADR is suspected all possible sources of information should be considered. These include:

- Patient details
  - Age, sex, ethnic background, weight and height
  - Diagnosis and other relevant co-morbidities prior to reaction
  - Previous exposure to suspected medicine(s) or related medicine(s)
- Medicine details, including non-prescription drugs, alternative treatments and recently ceased medicines
  - Name, dose, route of administration
  - Manufacturer, batch number
  - Time and date commenced
  - Date and time discontinued (if applicable)
  - Indication for use
- Adverse drug reaction details
  - Description of reaction
  - Time, onset and duration of reaction
  - Complications and outcomes
  - Treatment of reaction and outcome of treatment
  - Relevant investigation results
  - Post mortem result

Correlation of a suspected medicine with an adverse drug reaction may be:

- Certain. Whereby:
  - There is a clear association between medicine administration and the reaction
  - The results of investigations confirm that there is a relationship between the administration of the medicine and the reaction
  - The reaction recurs when the patient is re-exposed to the medicine
  - The reaction is commonly known to occur with the suspected medicine
- Probable. Whereby:
  - The reaction is known to occur with the suspected medicine and there Is a possible association between the reaction and medicine administration
  - The reaction resolves or improves upon stopping the suspected medicine and other medicine remains unchanged
- Possible. Whereby:
  - An alternative explanation for the reaction exists
  - More than one medicine is suspected
  - Recovery occurs after stopping more than one medicine
  - The association of the reaction with the medicine administration is unclear
- Doubtful. Whereby:
  - Another cause is more likely to have accounted for the reaction

When a reaction has occurred the decision whether to continue treatment with the suspected medicine depends on the likelihood of the suspected medicine causing the reaction and the clinical significance of the reaction.

Pharmacists may make recommendations on treatment options or recommend alternative treatment.

When managing an ADR the following needs to be considered:

- The condition of the patient
- The risks and benefits associated with continuing therapy with a medicine known to have caused an adverse drug reaction
- The efficacy and safety of alternative treatments
- Prophylactic use of other drugs to prevent future adverse reactions

A suspected ADR should be appropriately documented by the pharmacist. This includes:

- Documentation of the date and nature of the reaction in the patient's medical notes
- Documentation in allergy/ sensitivity section of patients prescription chart if appropriate
- Notification of Medical staff, including GP and original prescriber
- Medication Incident form
- Reporting all adverse reactions for black triangle drugs and any serious adverse reactions for established drugs to the Committee on Safety of Medicines (CSM) using the Suspected Adverse Drug Reaction form (yellow card system)
- The medical staff should inform the patient and/ or their carer of the ADR.

Procedure for the Prevention, Assessment and Management of Drug Interactions.

Pharmacists should regularly monitor for potential and existing drug interactions. This is important during:

- Medicine history interview and medicines reconciliation.
- Prescription monitoring and review.
- Commencement of a new medicine.
- Cessation of a medicine.
- Therapeutic drug monitoring

Pharmacists need to maintain an up-to-date knowledge of common and clinically significant drug interactions. They also need to be able to access up-to-date medicines information sources dealing with drug interactions.

When managing a drug interaction the following factors must be considered:

- Details of the interacting agents e.g. date of commencement.
- Therapy monitoring details e.g. laboratory results.
- Possible other causes e.g. renal impairment.

Recommendations to manage an interaction may include:

- Switching to an alternative agent.
- Monitoring the patient without altering therapy.
- Dose adjustment of the interacting agent(s).
- Altering the dosing schedule.
- Changing the route of administration.
- Stopping one or both of the interacting medicines.

All suspected drug interactions with adverse sequelae should be discussed with medical staff and documented appropriately. The patient should be notified to prevent future recurrence of the same interaction.

Patients or their carers should be counselled about the current use of agents that may adversely interact with medicines the patient has already been prescribed.

Procedure for Therapeutic Drug Monitoring

Therapeutic Drug Monitoring (TDM) is used by pharmacists to optimise therapy for medicines where there is a known, close relationship between serum concentration, therapeutic affect and adverse effect.

TDM may be indicated in the following patients:

- Patients with renal impairment
- Patients with hepatic impairment
- Patients undergoing dialysis or haemofiltration
- Patients with uncompensated cardiac dysfunction e.g. oedema associated with heart failure
- Patients with severe airways disease
- Patients with diabetes
- Obstetric patients
- Older patients
- Paediatric patients
- Neonatal patients
- Obese/ undernourished patients
- Burns patients
- Cystic fibrosis patients
- Surgical patients e.g. management of patients on lithium going for surgery
- Patients showing signs of toxicity e.g. digoxin
- Patients unresponsive to therapy to check for therapeutic levels e.g. theophylline
- Overdose patients
- Patients treated with a drug with a narrow therapeutic index
- Patients treated with a drug with a high incidence of adverse effects
- Patients treated with a drug associated with clinically significant interactions

Accurate sampling is necessary to relate the measured serum concentration to therapeutic effect. Time of sampling, time of last dose and duration of current treatment must be recorded.

When interpreting results the following should be considered:

- Drug/ dose/ formulation/ schedule
- Method of administration
- Indication for treatment
- Indication for TDM
- Target serum concentration levels
- Duration of current treatment

- Time of last dose
- Time of sampling
- Prior drug monitoring
- Relevant laboratory results
- Concordance
- Administration
- Clinical status of patient and recent progress
- Renal and hepatic function, cardiac status, age, weight etc
- Fluid balance
- Pharmacokinetic and pharmacodynamic properties of drug and patient factors that may influence these
- Concurrent medicines
- Concurrent disease
- Environmental factors e.g. smoking

Results of TDM must be reported in a timely manner and recommended action and future monitoring requirements indicated.

When appropriate, recommendations should be documented in the patient's medical notes and pharmacy records.

Procedure for Multidisciplinary Working.

Before participating in a ward round the pharmacist must prepare by monitoring and reviewing all patients' prescriptions in conjunction with medical notes and relevant laboratory test results if possible prior to the ward round. This allows the pharmacist to:

- Gain knowledge of the medicine and disease states likely to be encountered on the ward round.
- Consider the aspects of the patient's medicine therapy likely to be discussed.
- Organise questions to ask to address issues the Clinical Pharmacist wants to raise
- Prepare the patient pharmaceutical care issues they wish to raise with medical staff.

Appropriate communication skills must be used when discussing medicine related problems with other healthcare professionals, the patient and their family.

The ward round provides the opportunity to:

- Contribute information regarding the patient's medicine therapy e.g. suggestions for monitoring.
- Investigate unusual medicine orders or doses
- Assimilate additional information about the patient, which may be relevant to their medicine therapy e.g. social circumstances
- Detect ADRs and interactions.
- Participate in discharge planning.

At the end of the ward round or clinical meeting the pharmacist follows up any outstanding issues including:

- Responding to any enquiries generated.
- Communicating changes in medicine therapy to relevant personnel and patient.
- Completing necessary documentation e.g. discharge information, medication incident forms
- Considering the impact of changes to the pharmaceutical care plan and adapting the care plan as required.
- Discussing changes to therapy with the patient and other healthcare professionals if appropriate.
- Organise timely writing of discharge prescription

Procedure for the provision of Medicines Information Advice by Pharmacists

The exact reason for the request and all relevant patient information surrounding the enquiry should be established to ensure that the answer provided is appropriate e.g. the diagnosis, test results, goal of treatment, age, weight. The urgency of the request should be established.

The request may be dealt with at the time of the enquiry if the pharmacist is confident that the information is accurate and sufficient.

If the enquiry requires research

- Systematically retrieve evidence-based information using the resources and expertise available including medicine information pharmacists or other specialists in the field
- If further consultation is required discuss patient specific details with a medicines information pharmacist or other specialists in the field
- Evaluate and interpret the information retrieved
- Formulate a response which meets the specific needs of the enquirer
- Communicate the response in a written or verbal form as appropriate
- Document the request, information sources and response
- If appropriate follow up the response to determine if the response supplied contributed to patient care or if further information is required
- Advise the enquirer if further relevant information becomes available
- Document in patient notes if appropriate

Medicines information enquiries should be recorded and filed according to local policy in an easily retrievable manner to allow access by other users and to prevent duplication.

Procedure for Discharge

The pharmacist ensures that all medicines prescribed at discharge are clinically accurate and appropriate. A transcription check is carried out between the prescription chart and the discharge prescription to ensure that there are no errors or omissions.

Whenever possible discharge medicines should be dispensed as early as possible prior to discharge to prevents hospital discharge being delayed. This may involve one stop dispensing and the reuse of patients' own medicines according to local policy.

The patient is dispensed an agreed labelled quantity of their medicines according to local policy.

The patient is educated about their medicines and is given written, accurate up-to date information about their medicines.

The pharmacist may liaise with other healthcare professionals to ensure arrangements are in place for continuity of care.

The healthcare professionals the pharmacist may liaise with include:

- General Practitioner
- Community Pharmacist
- District Nurse
- Practice Nurse
- Community Psychiatric Nurse
- Nursing/residential home
- Interface Pharmacist
- Intermediate care teams
- Out of hours services
- Specialist community nurses i.e. tissue viability nurse

.Accurate and up-to date information of a patient's medicines at discharge is safely and effectively communicated to primary care healthcare professionals. The information communicated should include :

- Current medicines.
- Changes to medicine and the reason for the change.
- Information needed to continue supply of medicine within primary care.
- Monitoring requirements

Communication with primary care professionals may be

- Verbal (by telephone)
- Written
- Electronic
- Fax
- email

Patient's confidentiality and personal wishes must be respected. The name and contact number of the hospital pharmacist should be made available to the primary care healthcare professional.

All patients will benefit from liaison between primary and secondary care. Where resources do not permit this, patients who would benefit the most should be identified. These patients include:

- The elderly.
- Patients with psychiatric illnesses.
- Patients on complex medicine treatments.
- Patients taking 4 or more regular medicines
- Patients taking a high risk drug
  - Angiotensin-converting enzyme inhibitors/ Angiotensin-11 receptor antagonists
  - Antidepressants (including lithium)
  - Beta blockers
  - Clopidogrel
  - Digoxin
  - Diuretics
  - Insulin/ oral hypoglycaemics
  - Methotrexate
  - NSAIDs
  - Opiates
  - Prednisolone
  - Anticoagulants/ Warfarin,
  - Anti-infectives
  - Antiparkinson drugs
  - Antiepileptics
  - Clozapine
  - Potassium
  - Any medicine deemed a critical medicines where timeliness of administration is crucial

  This is not an exhaustive list
- Patients who have been readmitted to hospital within 6 months of previous discharge
- Patients unaware/unsure of their medicine history
- Patients discharged on 'red/amber' drugs e.g. IV antibiotics to be administered in primary care.

If a patient is discharged outside of pharmacy opening hours the discharge is followed up by a pharmacist within 24 hours of discharge. The discharge prescription should be checked for clinically accuracy, appropriateness and to ensure that there are no errors or omissions. Any discrepancies should be resolved, the patient, GP and community pharmacist contacted to correct any erroneous information.

Procedure for Patient Medicine Education

Medicine education may be necessary at different times:

- During an outpatient clinic visit
- On admission, beginning with the medicine history interview
- Throughout an inpatient stay
- Immediately prior to discharge or at discharge

Patient understanding of their medicine and retention of information is optimised if education occurs during the patient's hospital admission as well as at discharge. Education should be reinforced at every available opportunity. If it is apparent that the patient will not be able to self-medicate on discharge the education and education needs of the carer must be met.

Choose a suitable environment that allows privacy and confidentiality for the patient and minimises the risk of interruption and distraction. The mode of presentation will depend on the patient's needs, the person being counselled and the timing of education. Education can incorporate the use of various techniques:

- One to one discussions
- Group teaching
- Use of information resources e.g. consumer product information
- Audiovisual and educational displays

The primary steps in education are to:

- Identify the patient
- Introduce yourself
- Explain the purpose and expected length of the session
- Obtain the patient's agreement to participate
- Adopt a suitable physical position to enable education to take place comfortably and effectively
- Assess the patient's knowledge about their health problems and medicines and their physical and mental capability to use the medicines appropriately. Assess the patient's literacy and numeracy skills.
- Ask the patient open ended questions about their perception of the purpose of each medicine, what the patient expects and ask the patient to describe how he or she will use the medicine.
- If there are multiple medicines, organise the drugs in a logical sequence and provide a written or printed medicine list as a concordance aid. This should be signed and dated by the pharmacist.
- Utilise other education aids when appropriate e.g. large print labels, plain closures.

Using effective communication methods counsel the patient and/or carer regarding relevant aspects of their drug regimen. Tailor the information to the needs of the patient. Assess the ability of the patient to understand the information to be imparted. Employ the expertise of an interpreter if necessary. Ensure a carer fully understands if the patient does not. Consider modified education strategies for patients with cognitive or perceptual problems or for those treated with medicine that may impair the ability to remember.

Information that should be discussed during an education session includes:

- The generic and trade name of the drug, physical description and strength
- The intended purpose and expected action of treatment
- Information on how and when to take the medicine
- Any special directions or precautions about taking the drug
- Common side effects that may be encountered, ways in which to minimise them and action that is required if such side effects occur
- Details of medicine ceased and its relationship to new medicine
- Details of medicine altered in any way
- Any techniques for self-monitoring of therapy
- Appropriate storage requirements
- Relevant drug-drug (including non-prescription), drug-food, drug-disease, drug-alcohol and drug-test/procedure interactions
- Demonstrate the assembly and use of administration devices e.g. inhalers and spacer devices
- The number of days treatment that is supplied, the duration of treatment that will be required and the means to obtain further supplies taking into account unlicensed medicines , Red/Amber medicines etc
- The action to be taken in the event of a missed dose
- Consumer product information as appropriate
- Proper disposal of contaminated or discontinuation medicines and used administration devices
- A printed or written signed and dated medicine list as required
- Details of medicines dispensed on discharge

During the education session the pharmacist should determine whether the patient is willing to use a medicine and whether they intend to do so.

At the end of the education session:

- Summarise the significant information for the patient
- Assess the patient’s understanding e.g. ask the patient to repeat the information given
- Ensure the patient has all the relevant information
- Supply medicine aids as necessary
- Ask the patient if they have any questions or if there is any information they did not understand

- Answer the patient's questions and clarify any information they did not understand
- Encourage the patient to contact the hospital or community pharmacist if there are any difficulties regarding their medicine. Provide a contact name and telephone number
- If the patient is in a repeat dispensing scheme the pharmacist shall inform the community pharmacist and GP of changes to the patient's medication
- Document in the patient's medical, multidisciplinary notes or pharmaceutical care plan that education has occurred and that a suitable level of understanding has been achieved by the patient or carer to facilitate concordance

Based on the assessment of the patient's understanding determine if any follow-up is required. This may include:

- Further education sessions e.g. referral to their community pharmacist for further education
- Liaison with other healthcare professionals may be necessary to supervise the administration of medicine
- Communication of relevant strategies or perceived problems to the necessary healthcare workers either verbally or in writing

Appendix 2

Northern Ireland Timings

The time to complete specific clinical tasks was collected across the five trusts in Northern Ireland and an average time for each task calculated.

General Medicine

Pharmacist time spent on a standard medical patient

Medicines Reconciliation on Admission	28mins
Inpatient Monitoring (based on LOS* 6.54days)	5.23 x 6.54 = 34mins
Medicines Reconciliation at Discharge + Prep	35mins
Discharge Counselling	5mins
Total	**102mins per patient**

Technician time spent on a standard medical patient

Drug History on Admission	5mins
Stocking OSD drawer on Admission	10mins
Inpatient Kardex Review (based on LOS* 6.54days)	5.186 x 6.54 = 34mins
Discharge Prep and check	34mins
Total	**83mins per patient**

Surgical wards (including Trauma & Orthopaedics)

Pharmacist time spent on a standard surgical patient

Medicines Reconciliation on Admission	25.5mins
Inpatient Monitoring (based on LOS* 4.72days)	5.23 x 4.72 = 25mins
Medicines Reconciliation at Discharge + Prep	24mins
Discharge Counselling	5mins
Total	**79.5mins per patient**

Technician time spent on a standard surgical patient

Drug History on Admission	5mins
Stocking OSD drawer on Admission	10mins
Inpatient Kardex Review (based on LOS* 4.72days)	5.18 x 4.72 = 24.5mins
Discharge Prep and check	24mins
Total	**63.5mins per patient**

Gynae wards

Pharmacist time spent on a standard gynae patient

Medicines Reconciliation on Admission	25.5mins
Inpatient Monitoring (based on LOS* 2.4days)	5.23 x 2.4 = 12.5mins
Medicines Reconciliation at Discharge + Prep	24mins
Discharge Counselling	5mins
Total	**67mins per patient**

Technician time spent on a standard gynae patient

Drug History on Admission	5mins
Stocking OSD drawer on Admission	10mins
Inpatient Kardex Review (based on LOS* 2.4days)	5.18 x 2.4 = 12mins
Discharge Prep and check	24mins
Total	**51mins per patient**

Paediatrics

Pharmacist time spent on a standard paediatric patient

Medicines Reconciliation on Admission	4mins
Inpatient Monitoring (based on LOS* 3.54days)	6.16 x 3.54 = 21.8mins
Medicines Reconciliation at Discharge + Prep	6.6mins
Discharge Counselling	3mins
Total	**36mins per patient**

Technician time spent on a standard paediatric patient

Dispensing of discharge	14mins
Total	**14mins per patient**

Acute Elderly Care

Pharmacist time spent on a standard acute elderly care patient

Medicines Reconciliation on Admission	28mins
Inpatient Monitoring (based on LOS* 17.72days)	5.23 x 17.72 = 92mins
Medicines Reconciliation at Discharge + Prep	35mins
Discharge Counselling	5mins
Total	**160mins per patient**

Technician time spent on a standard acute elderly care patient

Drug History on Admission	5mins
Stocking OSD drawer on Admission	10mins
Inpatient Kardex Review (based on LOS* 17.72days)	5.186 x 17.72 = 92mins
Discharge Prep and check	34mins
Total	**141mins per patient**

Acute Psychiatry

Pharmacist time spent on a standard mental health patient

Medicines Reconciliation on Admission	18mins
Inpatient Monitoring (based on LOS* 27days)	3.425 x 27= 92mins
Care plan meeting (based on LOS* 27 days/ 4 weeks)	12.5 x 4 =50mins
Medicines Reconciliation at Discharge + Prep	16mins
Discharge Counselling	5mins
Total	**181mins per patient**

Technician time spent on a standard mental health patient

Inpatient Monitoring (based on LOS* 27days)	2.625 x 27 = 71mins
Dispensing of discharge	13mins
Total	**84mins per patient**

*LOS = average length of stay for all Trusts in Northern Ireland for financial year 2011/12

The figures do not take into account other tasks that are performed on the ward e.g.
3 monthly Controlled Drug Checks
Medicine Information requests
Therapeutic Drug Monitoring
Antibiotic Audits
Follow up of clinical queries with medical staff
Addressing supply issues
Anticoagulant counselling
University student accompanied ward visits
Developing guidelines

Glossary

Clinical Pharmacy	A discipline concerned with the application of pharmaceutical expertise to help maximise drug efficacy and minimise drug toxicity in individual patients.
Concordance	The patient and the prescriber agree therapeutic decisions that incorporate their respective views, including patient support in medicine taking as well as prescribing communication.
GP	General Practitioner
Medicines	Drug and dressing treatments that may be taken orally, by injection, topically, inhalation, rectally.
Medicine history	Details of a patient's current and recently discontinued medicines, along with details of any drug allergies or sensitivities.
Medicines Management in hospitals	The way that medicines are selected, procured, delivered, prescribed, dispensed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care.
Medicines Reconciliation	The NPSA definition of medicines reconciliation: • collecting information on medication history (prior to admission) using the most recent and accurate sources of information to create a full and current list of medicines (for example, GP repeat prescribing record supplemented by information from the patient and/or carer), and • checking or verifying this list against the current prescription chart in the hospital, ensuring any discrepancies are accounted for and actioned appropriately, and • communicating through appropriate documentation, any changes, omissions and discrepancies.
Pharmaceutical Care Plan	One or more pharmaceutical care issues for an individual patient, together with the desired outcome(s) and the action(s) planned to achieve the outcome(s).
Pharmaceutical Care	The pharmaceutical contribution to patient care.

Yellow Card Scheme	The scheme is run by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Commission on Human Medicines (CHM) to collect information from anybody, healthcare professionals and the general public, on suspected side effects or adverse drug reactions (ADRs) from a medicine.

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AN ROINN
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

MÄNNYSTRIE O
Poustie, Resydènter Heisin an Fowk Siccar

Subject:

Misappropriation of Patients' Monies – Implementation of Controls

Circular Reference: HSS (F) 45/2009

21 July 2009

For Action by:

Chief Executive & Director of Finance of each HSC Trust, Special Agency, NDPB, HSC Board, Business Services Organisation;
Directors in Public Health Agency and Head of Operations and Head of Development & Corporate Services in the Patient & Client Council;
HSC Heads of Internal Audit

Related documents:

Residential Care Homes – Minimum Standards
HSS (F) 13/2007

Summary of Contents:

The purpose of this circular is to remind organisations of the mandatory controls that should be in place in respect of the handling of patients' monies in both statutory and private Care Homes and requires your urgent attention.

Status of Contents:
Action

Implementation:
Immediate

Enquiries:

Any enquiries about the contents of this Circular should be addressed to:

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MAHI - STM - 097 - 9985

BACKGROUND

The Department has recently been notified of two incidents where there has been misappropriation of patients' monies, one in respect of Trust patients in a private care home and the other in a Trust facility. The purpose of this guidance is to remind you of your responsibility in relation to ensuring that patients' interests are safeguarded. In particular it is important to ensure that basic controls are operating successfully and that these controls are reviewed on a regular basis. It is essential that Accountable Officers ensure that the following controls are operating in both Care Homes and Trust facilities and that they are in compliance with extant Departmental guidance.

CONTROLS

- **Supervision –** appropriate systems of supervision should be put in place to safeguard patients' funds;

- **Authorisation of Withdrawals from Bank Accounts** – withdrawals of patients' monies should be countersigned by at least two appropriate officers;

- **Monitoring of Expenditure –** regular detailed monitoring of patients' expenditure and bank deposit balances should be undertaken and reviewed regularly through the Audit function;

- **Review of Individual Bank Account Balances –** examination and consideration of excessive withdrawals of monies from individual bank accounts should take place and patients spending patterns monitored;

- **Reconciliations –** reconciliations of individual bank deposit account balances should be evidenced and recorded at least quarterly;

- **Private Patient Property Cash withdrawal books/ records** - Regular checks should be undertaken to ensure that forms are being appropriately completed, that the correct nominated officer is authorising the cash withdrawal and where larger cash withdrawals
  are made that there is a record of the specific need. Books should regularly be retained for inspection.

- Checks on authorising signatures for cash withdrawals on Patients' Private Property

Forms should be undertaken for evidence of alteration;

- HSC Trust Managers are reminded of the need to regularly review residents' expenditure for reasonableness where their Trust monies are managed by Private Home staff.

MANDATORY DEPARTMENTAL GUIDANCE

In addition, your attention is drawn to the existing mandatory Departmental guidance which can be accessed through the following links:-

Residential Care Homes – Minimum Standards
http://www.dhsspsni.gov.uk/care_standards_-_residential_care_homes.pdf

HSS (F) 13/2007 – Financial Governance Model for New HSS Trusts
http://www.dhsspsni.gov.uk/hss_f_13-2007.pdf

Patients and Clients' Property can be found in chapter 28 of the Standing Financial Instructions http://www.dhsspsni.gov.uk/sos_res__del_of_p_sfis_mar_07.pdf

REGULATION AND QUALITY IMPROVEMENT AUTHORITY (RQIA)

RQIA, the independent health and social care regulator and quality improvement body for Northern Ireland is responsible for monitoring and inspecting the availability of health and social care services and encouraging improvements in the quality of these through its programmes of inspections and reviews; e.g. it is responsible for inspecting all residential, nursing and children's homes in Northern Ireland on a regular basis.

RECOMMENDATIONS

Accountable Officers should review existing controls operating in Care Homes and Trust facilities to satisfy themselves that these controls are in place and that they are in compliance with extant Departmental guidance. Independent assurance should be obtained periodically as to the effectiveness of the operation of such controls and compliance with Departmental guidance.

RQIA will determine compliance with the mandatory regulations and continue to look for evidence that standards are being met in all Care Homes.