

caring supporting improving together

Belfast Health and Social Care Trust Hospital Medicines Code

March 2017

Index

| 1 | Intro | oduction | 4 |
|---|-------|---|----|
| | 1.2 | Accountability arrangements | 5 |
| | 1.3 | Trust Medicines Optimisation committee | 5 |
| | 1.4 | Trust Drug and Therapeutics (D&T) Committee | 6 |
| | 1.5 | General principles | 6 |
| | 1.6 | Responsibilities of Staff | 7 |
| 2 | Proc | curement of medicines | 11 |
| 3 | Pres | scribing of medicines | 12 |
| | 3.1 | General Principles | 12 |
| | 3.2 | Prescribing of antibiotics | 18 |
| | 3.3 | Prescribing of epidurals and Patient Controlled Analgesia (PCA) | 20 |
| | 3.4 | Prescribing of unlicensed medicines | 20 |
| | 3.5 | Prescribing of a licensed medicine for an unlicensed indication (off-label prescribing) | 21 |
| | 3.6 | Prescribing of opioid medicines | 21 |
| | 3.7 | Prescribing in the outpatient setting | 22 |
| | 3.8 | Prescribing for self/family/friends | 22 |
| | 3.9 | Prescribing of lithium | 22 |
| | 3.10 | Remote prescription or direction to administer | 22 |
| | 3.11 | Verbal orders in the presence of a doctor | 22 |
| | 3.12 | Transfer of medicines related information | 23 |
| | 3.13 | Inpatient Controlled Drug (CD) prescriptions | 23 |
| | 3.14 | CD prescriptions for discharge | 23 |
| | 3.15 | Patient Group Directions (PGDs) | 24 |
| | 3.16 | Medical Gases | 24 |
| | 3.17 | Specialist medicines (Red/Amber) prescriptions | 25 |
| 4 | Adm | ninistration of medicines | 26 |
| | 4.1 | General principles | 26 |
| | 4.2 | Second check | 27 |
| | 4.3 | Administration of CDs | 28 |
| | 4.4 | Timing of administration | 28 |
| | 4.5 | Verification of patient identity | 29 |
| | 4.6 | Process for administration of medicines | 30 |
| | 4.7 | Administration of 'as required' medicines (PRNs) | 32 |
| | 4.8 | Nil by mouth | 32 |
| | 4.9 | Crushing tablets or opening capsules/administering medicines through feeding tubes | 33 |
| | 4.10 | Covert administration of medicines | 34 |

Belfast Health and Social Care Trust Medicines Code

| | 4.11 | Self or carer administration of medicines | 34 |
|---|------|--|----|
| | 4.12 | Patient's Own Drugs (PODs) | 35 |
| | 4.13 | Multidose vials | 35 |
| | 4.14 | Extravasation | 35 |
| 5 | Ord | ering, supply and receipt of pharmaceuticals | 36 |
| | 5.1 | Pharmacy Opening Hours | 36 |
| | 5.3 | Pharmacy Out of Hours Service | 37 |
| | 5.4 | Using the requisition book | 38 |
| | 5.5 | Non-stock medicines | 39 |
| | 5.6 | Тор-ир | 40 |
| | 5.7 | Resuscitation trolley | 41 |
| | 5.8 | Control of Substances Hazardous to Health (COSHH) | 41 |
| | 5.9 | Individual patient supply/Patient's Own Drug scheme | 42 |
| | 5.10 | Expiry dates of medicines | 42 |
| | 5.11 | Ordering and storage of medical gas cylinders | 42 |
| | 5.12 | Ordering Controlled Drugs (CDs) for ward stock, collection | 44 |
| | | and receipt of CDs, ordering CDs for discharge | |
| | 5.13 | Transferring medicines | 44 |
| | 5.14 | Transfer of medicines between containers | 45 |
| | 5.15 | Returns to Pharmacy and reuse | 45 |
| | 5.16 | Pharmaceutical samples | 45 |
| | 5.17 | Medicines for staff personal use | 45 |
| | 5.18 | Prescribing for self/family/friends | 46 |
| | 5.19 | Emergency cupboards | 46 |
| 6 | Pati | ent's own medicines on admission | 47 |
| | 6.2 | Patient's own CDs | 47 |
| | 6.3 | Using patient's own medicines during an inpatient stay | 47 |
| | 6.4 | Patient's Own Drug (POD) scheme | 48 |
| | 6.5 | Destruction of patient's own medicines | 48 |
| | 6.6 | Unidentified medicines | 48 |
| | 6.7 | Illicit substances | 48 |
| | 6.8 | Overdose drugs | 50 |
| 7 | Sup | plies of medicines at discharge | 51 |
| | 7.10 | Prescriptions for discharge or home leave medicines | 53 |
| | 7.11 | Handling patient's own medicines on discharge | 55 |
| | 7.12 | Discharge prescription for anticoagulants | 55 |
| | 7.13 | Oral Substitute Therapy (OST) on discharge from secondary care | 55 |
| | 7.14 | Specialist medicine therapy for administration in community | 56 |

2 Belfast Health and Social Care Trust Medicines Code

| | 7.15 0 | Collection and delivery of discharge or home leave medicines | 56 |
|-----|---------|--|----|
| | 7.16 C | Discharge of a patient with a syringe pump | 57 |
| | 7.17 C | Dispensing of discharge prescriptions when Pharmacy is closed | 57 |
| | 7.18 0 | Checking of dispensed discharge medicines at ward level | 57 |
| | 7.19 F | Prescription Tracking System (script tracker) | 58 |
| | 7.20 T | Femporary home leave / pass medication | 59 |
| 8 | Stora | ge and security of medicines – general principles | 60 |
| | 8.18 0 | Custody and loss of medicine cupboard keys | 61 |
| | 8.19 5 | Storage and disposal of Controlled Drugs (CDs) | 62 |
| | 8.20 L | oss of medicines or unauthorised access | 62 |
| | 8.21 S | Security and storage of stationery used to order medicines | 62 |
| | 8.22 F | Pharmaceutical refrigerators | 63 |
| | | Transport of medicines | 65 |
| | 8.24 N | Medicines transport via pneumatic tube transfer system | 66 |
| 9 | Invest | tigational Medicinal Products (IMPs) | 67 |
| 10 | Medic | ation incident reporting | 69 |
| 11 | Adver | rse Drug Reaction (ADR) reporting | 71 |
| 12 | Pharn | nacy Aseptic Services | 71 |
| 13 | Defec | tive medicinal products | 72 |
| 14 | Cytote | oxic chemotherapy | 72 |
| 15 | Intrati | hecal chemotherapy | 73 |
| 16 | Oral a | anti-cancer medicines | 73 |
| 17 | Closu | re of a ward/department | 73 |
| 18 | Pharn | naceutical waste | 74 |
| 19 | Medic | cines Information | 75 |
| 20 | Gloss | ary of terms | 77 |
| Арр | endix 1 | 1 Use of Pneumatic Tube Transfer System | 80 |
| Арр | endix 2 | 2 Medicines Management Forms | 81 |
| | | Links to Medical Gas Cylinder Order Form, Form for Removal or Destruction of Unauthorised Drugs or Other Suspicious Substances, Ward Register for Illicit/Suspected Illicit Substances, Trust Pharmaceutical Samples Register, Log of Medication Supplied from Emergency Cupboard and Pharmaceutical Refrigerator Temperature Log | |

1 Introduction

- The Department of Health (Northern Ireland) requires that Trusts establish, 1.1.1 document and maintain an effective system of safe and secure medicines management. The NICE guideline 'Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes' builds on the principle of medicines management. Medicines optimisation is defined as 'a person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines. Medicines optimisation applies to people who may or may not take their medicines effectively. Shared decision-making is an essential part of evidence-based medicine, seeking to use the best available evidence to guide decisions about the care of the individual patient, taking into account their needs, preferences and values'. This Medicines Code defines the policies and procedures to be followed for medicines optimisation within Belfast Health and Social Care Trust (BHSCT) for the prescribing, administration, dispensing, monitoring, ordering, storage and transport of medicines. Its purpose is to ensure safe and effective medicines optimisation throughout BHSCT secondary care settings.
- 1.1.2 All staff employed within secondary care settings in the Trust, who are responsible for the prescribing, supply, administration, storage and transport of medicines, must adhere to the guidance contained in this Code.
- 1.1.3 Throughout the document, the senior nurse or nurse/midwife in charge is named as the responsible person for certain elements of the system. 'Patient' is the term used to refer to service users and clients in the Medicines Code.
- 1.1.4 Throughout the document, the term 'Kardex' is used to describe the Trust in-patient Medicines Prescription and Administration Record. The information given applies to all equivalent approved Trust prescribing documents, including supplementary charts and anaesthetic chart Kardexes.
- 1.1.5 Trust staff who prescribe, supply and administer medicines must practise within the current legislative requirements, their code of professional practice, this Code and any locally agreed procedures available. If necessary this Code may be supplemented by additional departmental procedures. Any such procedure must be approved by the Trust Drug and Therapeutics committee.
- 1.1.6 Those staff undertaking any procedure involving prescribing, dispensing or administering medicines must be currently registered with their professional body.
- 1.1.7 Each member of staff is accountable for their own practice and also for identifying any training needs with their line manager. A practitioner who does not fulfil this requirement must work under the direction and supervision of a registered practitioner, who will be responsible for ensuring that the person is competent to carry out the task.
- 1.1.8 This Code governs the use of all medicines within the Trust and by Trust personnel.
- 1.1.9 A medicine is defined as a substance introduced into the body, or externally applied to the body, for the purpose of:
 - treating disease;
 - preventing disease;
- 4 Belfast Health and Social Care Trust Medicines Code

- diagnosing disease;
- ascertaining the existence, degree or extent of a physiological condition;
- contraception;
- inducing general or regional anaesthesia; or,
- otherwise preventing or interfering with the normal operation of a physiological function.
- 1.1.10 Medicines supplied by Pharmacy are solely for the use of patients.
- 1.1.11 Medicines may be categorised as follows:
 - medicines and medicinal preparations which come under the provisions of the Medicines Act (1968). They include medicines used in clinical trials, unlicensed medicines, dressings, and medical gases;
 - Controlled Drugs (CDs) i.e. substances controlled under the provisions of the Misuse of Drugs Act (1971) and Regulations made under the Act.
- 1.1.12 Disinfectants, reagents (e.g. blood glucose testing strips) and other preparations not used directly to treat patients do not have to be prescribed for an individual patient. Their ordering and storage however, must comply with the relevant section of the Medicines Code.

1.2 Accountability arrangements

- 1.2.1 The Chief Executive of the Trust has overall responsibility for the safe and secure handling of medicines as part of the Controls Assurance Medicines Management framework.
- 1.2.2 The Head of Pharmacy and Medicines Management is responsible for maintaining the security of stocks of pharmaceuticals held in all Pharmacy departments within their authority and ensuring that systems of control operating within their area of authority are in accordance with Medicines Management Policies. The Head of Pharmacy and Medicines Management reports on these matters to the Chief Executive via the Medicines Optimisation Committee and the Director of Surgery and Specialist Services.

1.3 Trust Medicines Optimisation Committee

The Medicines Optimisation Committee is responsible for the review, analysis and monitoring of medicines management processes contributing to achievement of Trust corporate objectives through effective medicines management and in accordance with the Medicines Management Strategy. Five subgroups report to the Medicines Optimisation Committee. These are:

- a) Drug & Therapeutics (D&T)
- b) Medical Gases
- c) Medicines Risk and Safety
- d) Non-Medical Prescribing Group
- e) Immunoglobulin Assessment Panel

1.4 Trust Drug and Therapeutics (D&T) Committee

- 1.4.1 The purpose of the Trust D&T Committee is to develop Trust policies and procedures relating to safe, effective and economic use of medicines, including prescribing, administration and safe and secure handling of medicines.
- 1.4.2 The D&T Committee is accountable to the Trust Senior Management Team and the Trust Board via the Medical Director. It is responsible for promoting the safe and effective prescribing within BHSCT and across the interface with primary care. The committee is responsible for the introduction of new medicines to the Trust, supporting medicines governance, overseeing Patient Group Directions (PGDs), prescribing and other medication related policies and approval of prescription charts and protocols.
- 1.4.3 Some of this work is undertaken by D&T subcommittees, for example:
 - New Drugs sub-committee. Outcomes from this subcommittee are on the Medicines management website on the Hub. Decisions from the New Drugs sub committee apply to outpatient recommendations as well as to inpatient prescribing.
 - Antimicrobial sub-committee
 - Paediatric sub-committee
 - Psychiatry sub-committee
- 1.4.4 Policies approved by the Drug and Therapeutics committee are subsequently ratified by the Standards and Guidelines committee and finally approved for the Trust by the Policy committee and Trust Executive team.

1.5 General principles

- 1.5.1 All staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in this Code and the 'Controlled Drugs Policy'.
- 1.5.2 Senior staff, including consultants, ward or departmental sisters/charge nurses/managers are responsible for ensuring that duties are delegated to staff with appropriate knowledge and assessed as competent. Those in charge of wards and departments are responsible for ensuring that their staff, especially new employees, locum staff and agency staff, adhere to procedures in this Medicines Code, which may differ from procedures elsewhere.
- 1.5.3 The Medicines Code also applies to medical staff, nursing/midwifery staff and other healthcare professionals from other Trusts or from private practice, who are contracted to work in BHSCT on a sessional basis. Managers who contract for these services must make it explicit within written contracts that these sessional staff must follow the procedures described in this Medicines Code.
- 1.5.4 The complexity and variety of medicines, their potency and potential toxicity places an exacting responsibility on doctors, nurses and pharmacists. Errors can occur in any of the procedures relating to medicines including prescribing, dispensing, interpretation of the prescription, preparation and administration.
- Belfast Health and Social Care Trust Medicines Code

1.6 Responsibilities of staff

1.6.1 Prescribing, ordering, dispensing, storing, monitoring, administration and transport of medicines is the responsibility of various practitioners working within the organisation. Practitioners must be aware of the tasks for which they are responsible, as detailed in this section.

1.6.2 Medical staff, dentists and other authorised prescribers

- 1.6.2.1 Medical staff are responsible for the majority of prescribing of medicines for patients. They, and any other authorised prescribers, must comply with legislation, Trust policy, NI formulary, the Medicines Code and professional guidance when performing such duties.
- 1.6.2.2 All prescribers have a responsibility for prescribing in accordance with the appropriate marketing authorisation (product license) of a medicine. Where a product does not have a UK marketing authorisation, prescribing should be in accordance with an adequate body of evidence or expert opinion, and with the support of the BHSCT D&T Committee as per Trust 'Unlicensed Medicines policy'.
- 1.6.2.3 Medical students are not permitted to prescribe.
- 1.6.2.4 Prescribers must sign all prescriptions for medicines, and it is essential that the identity of the prescriber is known. A prescriber should sign and print their name on prescriptions for this purpose (including bleep number and professional registration number if applicable).
- 1.6.2.5 Non-Medical Prescribers must only prescribe in accordance with the Trust 'Non-Medical Prescribing Policy'.

1.6.3 Pharmacists

- 1.6.3.1 Pharmacists are responsible for ensuring the safe, effective and economic use of medicines in the Trust. This process includes regular monitoring of prescribing to ensure appropriateness, accuracy, safety and clarity.
- 1.6.3.2 Pharmacy staff are responsible for the stock of medicines held in the Pharmacy to ensure that medicines are stored under the proper legal and environmental conditions. They are responsible for manipulation and preparation into user ready presentation and for their supply to wards and departments.
- 1.6.3.3 Pharmacy staff, where appropriate, have a responsibility to advise practitioners on the safe and secure storage of medicines in clinical areas.
- 1.6.3.4 Pharmacy is responsible for ensuring that when medicines are prescribed, supplied and administered, there is a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.
- 1.6.3.5 Pharmacy staff provide information to patients, carers, nursing/midwifery, medical and other healthcare professions with the aim of improving concordance, and the safety and effectiveness of therapy. Where advice from a member of Pharmacy staff has not been followed in respect of a patient's medicines, this should be addressed with the medical team looking after the patient. An incident form may also be completed in this situation.

| 7

- 1.6.3.6 Pharmacy is responsible for the purchase of all pharmaceuticals within the Trust.
- 1.6.3.7 Clinical pharmacists provide all the general responsibilities of a pharmacist as above but are working at ward level. They assist medical and nursing/midwifery staff ensuring safe, effective and economic use of medicines and contributing to the pharmaceutical care of patients. They can assist in ensuring accuracy of admission medicine histories as well as monitoring of therapy and discharge information.

1.6.4 Registered Nurses/Midwives

- 1.6.4.1 The nurse/midwife in charge of a ward or department is responsible for setting and monitoring the standard of administration of medicines by staff within the ward or department.
- 1.6.4.2 The nurse/midwife in charge of a ward or department is responsible for the safe custody of medicines on a ward/department and is responsible for ensuring that staff are deemed competent, have access to up to date medicines information and that Medicines Code procedures are followed correctly by ward/departmental staff.
- 1.6.4.3 The nurse/midwife in charge of a ward or department is responsible for the security of the stock of medicines held in the ward or department.
- 1.6.4.4 The nurse/midwife in charge of a ward or department is responsible for controlling access (by keys or other means) to the medicines cupboard (including Patient's Own Drugs lockers) and trolley(s). This responsibility remains with the appointed nurse/midwife in charge even if he/she decides to delegate the duty to another nurse.
- 1.6.4.5 The nurse/midwife in charge of a ward or department must ensure that medicine cupboard keys are not given over to other healthcare staff, except to a member of pharmacy staff for medicines stock management. In this instance, the nurse/midwife must confirm identity by checking the Trust photo ID of the member of pharmacy staff. If another member of healthcare staff requires medicines, it is the responsibility of the nurse/midwife in charge to access the medicines required; they must not hand over the keys to allow other healthcare staff, including medical staff and healthcare assistants, to access medicines.
- 1.6.4.6 Each registered nurse/midwife is responsible for ensuring the safe and appropriate administration of medicines and is expected to adhere to the standards as defined by the Nursing and Midwifery Council and elsewhere in this Code.
- 1.6.4.7 Trust staff who may also be in the Trust as healthcare students or bank staff may only undertake duties appropriate for the role in which they are in the Trust at any one time, whether that be their employed role or their student/bank role.

Belfast Health and Social Care Trust Medicines Code

1.6.5 Nursing/Midwifery students on pre-registration programmes

- 1.6.5.1 Nurses/midwives in training must be given every opportunity to become proficient in medicines related activities under appropriate supervision. The supervising registered nurse/midwife has responsibility for medicines related procedures at such times.
- 1.6.5.2 Prior to registration, nursing/midwifery students are not permitted to administer medicines without supervision. They may, under the direct supervision of a registered nurse/midwife, administer for the purpose of instruction and learning and sign for the administration. Where a nursing/midwifery student is involved in the administration of a medicine they are unable to provide the second check. The supervising registered nurse/midwife must countersign the medicine chart following administration of the medicine by a nursing/midwifery student. If the particular medicine needs a second check (see section 4.2), this must be carried out by a registered nurse.

1.6.6 Operating Department Practitioners (ODPs)

- 1.6.6.1 The Operating Department practitioner is a registrant with the Health and Care Professions Council (HCPC) and in theatres works in the anaesthetic, scrubbed and recovery role. They are one of the three registered staff, required as a minimum by the Association of Perioperative Practice for each theatre list. ODPs report to the theatre sister/charge nurse and are responsible to the theatre manager.
- 1.6.6.2 Their key roles are in the following areas:
- 1.6.6.2.1 Anaesthetics: Patient care and safe preparation and management of the anaesthetic equipment. This also includes preparation of medicines, including local anaesthetics and CDs. ODPs may be responsible for checking the patient into theatre and for their safe care throughout the perioperative period; their duties may also include supervision of unregistered staff. ODPs are required to adhere to all good practice guidelines in relation to the administration of medicine and be updated in these as required.
- 1.6.6.2.2 Scrubbed: They may act as the scrubbed practitioner in the same way as a Registered Nurse. This includes carrying out all swab, needle and instrument checks for a case and being accountable for this practice.
- 1.6.6.2.3 Recovery: They may be responsible for the care of a patient in the postoperative period. This care includes airway management, emergency care, blood loss management, fluid balance, administration of prescribed pain relief (including IV).
- 1.6.6.3 An ODP is authorised to hold the keys of the Medicines cupboards and to order medicines and other pharmaceutical products in the pharmacy requisition book in accordance with the BHSCT Medicines Code.
- 1.6.6.4 The ODP Must adhere to HCPC Standards of Proficiency for Operating Department Practitioners http://www.hcpc-uk.org/assets/ documents/10000514Standards_of_Proficiency_ODP.pdf and to the Trust Medicines Code.

1.6.7 Independent sector

- 1.6.7.1 An Independent Sector (IS) company is responsible for ensuring that IS staff are familiar with key BHSCT medicines management policies e.g. Medicines code and CD policy. IS staff must operate in accordance with the BHSCT Medicines Code, BHSCT Controlled Drugs policy and other policies relevant to the area of practice. IS nursing staff must comply with NMC Medicines Management guidelines.
- 1.6.7.2 The delegated nurse in charge should either be a member of the nursing team for the area or an existing BHSCT employed registered nurse. As a minimum a CD check must be completed in theatre/ward areas before commencing activity and when the activity is completed.
- 1.6.7.3 IS Prescribers must prescribe in accordance with the NI Formulary.

2 Procurement of medicines

- 2.1 Refer also to Trust policy for medicines procurement and purchasing for safety.
- 2.2 Medicines may only be purchased or acquired by a pharmacist or member of pharmacy staff acting under the delegated authority of the Head of Pharmacy and Medicines Management. All procurement of medicines must comply with public procurement policy and strategy. This will be achieved by ensuring:
- 2.2.1 UK licensed products are always used in preference to unlicensed products.
- 2.2.2 All new medicines within the Trust must be approved for use by the New Drugs sub-committee of the D&T Committee. Consideration must be given to the recurring financial cost of a medicine and when necessary, commissioner approval must be sought after D&T approval.
- 2.2.3 All Investigational Medicinal Products must be delivered directly to, and managed by, Pharmacy (See section 9).
- 2.3 Medicines must be supplied to wards and departments by the Pharmacy department. This is essential to ensure an appropriate audit trail exists and to ensure that all medicines are assessed before use in the Trust.
- 2.4 All Trust staff must comply with the Trust 'Policy on Interfacing with the Pharmaceutical Industry'. This includes the management of samples of medicinal products which must be issued through Pharmacy (Appendix 2).
- 2.5 Shortages of medicines can occur for various reasons e.g. manufacturing problems. Shortages will be communicated to the relevant clinical areas. An action plan will be implemented for a major shortage of medicines after consultation with the relevant parties.
- 2.6 Medicines should be prescribed from the selection of pharmaceuticals available as ward stock. A printed list is available at medicine cupboards for convenience. Prescribing by junior medical staff is limited by the NI Formulary.
- 2.7 Medicines newly prescribed outside the NI Formulary may only be prescribed by senior medical staff.
- 2.8 A patient may be admitted to the hospital on a medicine, on which they have been stabilised for chronic conditions such as Parkinson's disease, epilepsy etc. If Pharmacy do not stock this medicine the treatment should not be changed unless the time involved in obtaining supplies compromises the patient's care. To ensure the patient continues to receive their medicine, the patient's own medication can be used provided an assessment, by appropriately trained staff, has been made on the quality of medicine before administering. Medicines brought in by the patient should only be used when they can be positively identified, meet defined quality criteria and are appropriately labelled. If the treatment is for a condition for which the patient has been admitted, medication review is reasonable.

3 Prescribing of medicines

3.1 General principles

- 3.1.1 Prescribers must comply with the relevant legislation when writing prescriptions. The guidance to which they must adhere is given in the BNF under 'General Information and Prescription Writing'. It is good practice to physically see the patient when prescribing or reviewing their medicines.
- 3.1.2 Prescribers must write clearly in ink and print the medicine name. Illegible prescriptions must be rewritten before a medicine can be administered and thus may delay the patient receiving medication. Nurses are entitled to refuse to administer medicines which are improperly or illegibly prescribed.
- 3.1.3 A new Kardex must be used at the start of each admission. If a patient goes home on weekend leave, the Kardex may continue to be used following the weekend leave.
- 3.1.4 Where a regional Kardex (e.g. for adult, acute patients) is in use and the patient's addressographs and patient identity band both state the Health and Care number, then the Kardex can be used across the Trust.
- 3.1.5 If a patient has transferred from another Trust with a regional Kardex, a Kardex for their BHSCT admission must be written. If, however, arrangements have been agreed between specialties in different Trusts, then the Kardex that is transferred with the patient may be used in the receiving hospital.
- 3.1.6 All medicines must be prescribed on the Kardex. This includes any medicines prescribed on additional charts e.g. fluid balance chart, syringe driver chart, Patient Controlled Analgesia (PCA) and epidural observation charts or warfarin prescription chart/discharge form. These medicines must be prescribed in the main body of the Kardex with the dose instructions 'as per chart' as shown:

| MARFAR | IN | | Start date | 0600 | | | | |
|---|----------------|------------|------------|-------|--|--|--|--|
| Dose As perchat | Route | Frequency | Stop date | 1000 | | | | |
| Special Instructions/Indication | | | Signature | 12.00 | | | | |
| Medicines Recond | iliation (cire | :le) | Supply | 1400 | | | | |
| Pre-admission Increased dose Decreased New Sign A Das Kor Prof. no. 973 W77 | | Pharmacist | 1800 | | | | | |
| Print A DOCTOR | | 0001 | Thurmuciac | 2200 | | | | |

- 3.1.7 Intravenous infusions should be prescribed on the reverse of the fluid balance chart. Where an intravenous infusion contains a medicine, the medicine must also be prescribed on the Kardex.
- 3.1.8 The 'additional charts in use' section on the front of the Kardex must also be ticked as appropriate.
- 3.1.9 Nutritional products should not be prescribed on the Kardex. Medicines are clearly indentified by having GSL, P or POM printed on the outer packaging.
- 3.1.10 All additional charts, whether additional Kardexes or supplementary charts, should be attached to the Kardex.
- 12 Belfast Health and Social Care Trust Medicines Code

- 3.1.11 Whenever possible, only one Kardex should exist at any one time for any patient. When more than one Kardex is required due to a large number of prescribed items, subsequent Kardexes must indicate clearly the existence of other charts e.g. 1 of 2 etc.
- 3.1.12 The Kardex should be reviewed by medical staff as part of routine medical review, for example at ward rounds, by nursing staff at administration rounds and by pharmacists in accordance with the Northern Ireland Clinical Pharmacy Standards.
- 3.1.13 The following information must be included on every Kardex:
- 3.1.14 Date Every entry must be dated. This start date must be carried forward to any rewritten prescription chart. Any change of dose or frequency of administration is regarded as a new prescription and must be rewritten with a new start date. The date of admission must also be recorded.
- 3.1.15 Patient's full name, date of birth or age and Health and Care number must be on every Kardex and on each page of the Kardex. Where an addressograph is used, it should be checked that it is the correct addressograph for that patient.
- 3.1.16 When completing patient details on the Kardex, the prescriber must record the following:
- 3.1.17 Patient's consultant
- 3.1.18 Ward and hospital site
- 3.1.18.1 Weight in kilograms (if medication dose is related to patient weight). In paediatrics all medication doses relate to a child's weight; it is therefore essential that the child's current weight (in kilograms) is recorded on the Kardex.
- 3.1.18.2 The nurse looking after the patient must record weight on the Kardex.
- 3.1.19 Height in metres (if medication dose is related to body surface area).
- 3.1.20 Allergy/medicine sensitivities must be clearly indicated on the Kardex and any other prescription chart with an indication of the type of reaction. A medicine allergen must be recorded by generic (approved) name. The type of reaction, e.g. rash, and when it occurred must also be recorded, where known, for each medicine allergen. This entry on the Kardex must be signed and dated as shown:

| This sect | gies / Medic ion must be complete exceptional circumst | ed before prescribin | ivities ng and administration | | | | | |
|----------------------------------|--|-----------------------------|----------------------------------|--|--|--|--|--|
| Date of Reaction | Medicine/allergen | Type of reaction (eg. rash) | Signature/ designation/date | | | | | |
| 5 9 12 | PENICILLIN | | 1-0-stv | | | | | |
| or | | | | | | | | |
| No known allergies (Please tick) | | | | | | | | |
| Signature | / Designation: | | Date: | | | | | |

- 3.1.21 If there are no known medicine sensitivities/allergies then the prescriber must sign and date 'No known allergies' section of the allergy box.
- 3.1.22 Medicines should not be prescribed or administered if the allergy box is incomplete (unless in an emergency).
- 3.1.23 The approved name of a medicine should be used whenever possible in accordance with the Trust 'Policy for appropriate use of the generic names of medicines'. Some medicines must be prescribed by brand names. Abbreviations for medicine names must not be used.
- 3.1.24 Dosage form must be specified e.g. tablets; liquid; injection; inhaler. The dose should be clearly stated in metric units (e.g. 250mg) or the number of dosage units where appropriate.
- 3.1.25 'Microgram' and 'nanogram' must be spelt out in full and not abbreviated to 'mcg', 'µg' or 'ng'.
- 3.1.26 Quantities less than 1g should be written in milligrams e.g. '500mg', not '0.5g'. Quantities less than 1mg should be written as micrograms e.g. '100 micrograms', not 0.1mg.
- 3.1.27 Avoid 'trailing zeros' in prescribing i.e. prescribe as '2mg' and not '2.0mg'. As appropriate, medicines must be prescribed using 'leading zeros' i.e. '0.5 units' instead of '.5 units'.
- 3.1.28 'Units' or 'international units' must be written out in full and not abbreviated to 'u' or 'iu'.
- 3.1.29 Roman numerals may cause confusion that could lead to medication errors and should not be used.
- 3.1.30 Where a loading dose of a medicine is prescribed, the same prescriber should also prescribe the maintenance dose.
- 3.1.31 Variable doses/times can be written as shown:

| 10 - BENEL POPA | Start date | 06 ⁰⁰ USUD |
|---|------------|-----------------------|
| Dose Route Frequency Five Time | Stop date | |
| Special instructions/Indication | Signature | 1200 1300 |
| SEE SPECIFIC TIMES Medicines Reconciliation (circle) | Supply | 1400 |
| Pre-admission dose Increased Decreased New Stgn 4 Prof. no. G734377 | Pharmacist | 1800 1900 |
| Print ADOCTOR Bleep 0001 | | 2200 |

3.1.32 The route of administration must be clearly stated. The table below indicates acceptable abbreviations for various routes of administration. Instructions indicating specific sites of administration e.g. 'the left ear' may be required.

| PO | Oral by mouth | PR | Per Rectum |
|-----|---------------|------|-----------------|
| TOP | Topical | PV | Vaginal |
| INH | Inhalation | IV | Intravenous |
| IM | Intramuscular | SC | Subcutaneous |
| NEB | Nebulised | PEG | Per gastrostomy |
| NG | Nasogastric | BUCC | Buccal |
| SL | Sublingual | TD | Transdermal |

- 3.1.33 Other routes of administration must be written in full.
- 3.1.34 The frequency of administration is indicated by circling the pre-printed time on the Kardex. Where a different time is required, this must be entered in the column beside the pre-printed times. The frequency box in each medicines entry must also be completed.
- 3.1.35 Acceptable abbreviations for frequency are:

| Once daily | od | Twice daily | bd |
|-------------------|------------|------------------|------------|
| Three times daily | tds or tid | Four times daily | qds or qid |
| Every morning | mane | Every night | nocte |

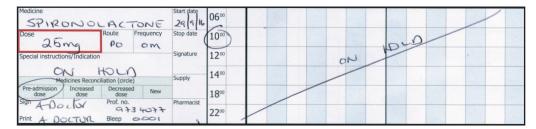
3.1.36 If the frequency is other than daily e.g. weekly methotrexate, it should be prescribed by writing 'weekly' and documenting the day of the week it is to be given in the special instruction section. The administration section of the Kardex should be annotated to ensure that a weekly dose only can be administered. An example of how this should be done is shown as follows:

| Medicine METINDTREXATE Dose 15mg Special instructione/Indication METINDTREXATE Start date Frequency Stop date NEEA Signature | |
|--|-----------------|
| OWCE A WEELL ON TUESDAY Supply | - 1400 |
| Pre-admission Increased Decreased New | 1800 |
| Sign ADOLTU Prof. no. 973 WH Pharmacis Print DOLTUR Bleep 0001 | 22 [∞] |

3.1.37 The indication for the medicine should also be included.

3.1.38 Medicines reconciliation

- 3.1.38.1 Medicines reconciliation 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 whereby every time a patient is transferred from one healthcare setting to another, accurate and reliable information about the patient's medication is transferred at the same time. This enables healthcare professionals responsible for the care to be able to match-up the patient's previous medication list with their current medication list; thereby enabling timely, informed decisions about the next stage in the patient's medicines management journey. The BHSCT Medicines reconciliation policy is available here.
- 3.1.38.2 For each regular or 'when required' medicine, changes made to therapy during hospital stay are indicated as follows:
- 3.1.38.2.1 On admission, refer to the patient's documented medication history, reconcile the medicines on the Kardex and circle 'pre-admission dose', increased or decreased dose or 'new medicine' accordingly.
- 3.1.38.2.2 During patient stay, ensure any subsequent changes are similarly indicated and document why in the medical notes.
- 3.1.38.2.3 At discharge, ensure information on medicine changes (including those started and stopped during the admission) is sent to the GP.
- 3.1.38.3 If a medicine is being held it should be entered on the Kardex as shown:



3.1.39 'As required' prescriptions

3.1.39.1 The majority of medicines will be prescribed and administered on a regular basis. However some medicines may only be needed occasionally or in certain specific circumstances. 'As required' prescriptions should be written as shown below.

| PARACETAMOL | Start date | Date |
|--|------------------------|---------------------|
| Dose 1 9 Route Frequency PD Q DS Special instructions/Indication Max dose in 24h | Stop date Signature | Time 24 hr clock |
| Medicines Reconciliation (circle) Pre-admission Increased Decreased New | Supply | Dose Route |
| dose dose dose dose rot. no. Print A DOLTUR Bleep DOOL | Pharmacist | Given by |

3.1.39.2 The circumstances in which the 'as required' medication may be given should be stated, e.g. 'for severe agitation', 'for pain' etc.

16 Belfast Health and Social Care Trust Medicines Code

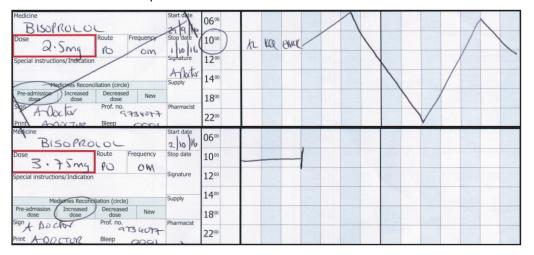
- 3.1.39.3 The minimum interval between doses and the reason for administration must be clearly specified.
- 3.1.39.4 Maximum dose in 24 hours should also be stated.
- 3.1.39.5 All 'as required' prescriptions must be reviewed regularly by a doctor as determined by clinical need. To avoid accumulation of 'as required' prescriptions, the following guidelines should be observed:
- 3.1.39.6 Before discharge, the prescriber must review hospital only medicines e.g. night time sedation.
- 3.1.39.7 Care must be taken not to duplicate medicines that are being taken regularly, e.g. compound analgesics containing paracetamol. It is important to look at regular medication, as required section and the once only section before prescribing an additional medicine.

3.1.40 'Once only' medicines

3.1.40.1 The times for administration of 'once only' medicines should be stated using the 24 hour clock.

3.1.41 Discontinuation of treatment

3.1.41.1 When an individual item on the prescription chart is no longer required or the dose or frequency has changed, the prescriber should discontinue it by crossing it off the chart, and entering the stop date and their signature in the appropriate boxes on the chart as shown. The prescriber should also cancel the remainder of the administration record to ensure that the medicine is not given after the intended stop date.



- 3.1.41.2 Changes to prescriptions are not permitted. If a change to an entry on a Kardex is required, the item must be discontinued, dated, signed and a new entry made.
- 3.1.41.3 When a medicine has been discontinued, the reasons for discontinuation should be documented in the medical notes. Availability of this information at discharge should assist with medicines reconciliation and improve the quality of discharge information relating to medicines sent to the GP.

- 3.1.41.4 Rewriting prescription charts Prescription charts must be re-written by a doctor when no more spaces are available for new entries or when the condition of the Kardex has deteriorated eg pages detaching.
- 3.1.41.5 If more than one chart is in use, and all currently prescribed items would fit on fewer charts, then the chart must be rewritten. The prescriber should complete the rewritten section on the Kardex. The previous Kardex must be filed in the patient's notes.

3.1.42 Signature of prescriber

3.1.42.1 Each prescription item must be validated by the full signature of a registered medical practitioner or authorised prescriber. The prescriber must print their name (including a bleep number if applicable and professional registration number) at the last entry they make in a section of the Kardex.

3.1.43 Pharmacist endorsements on the Kardex

The ward pharmacist should initial and date the 'pharmacist' box in each medicine entry on the Kardex to indicate that they have screened the prescription for accuracy and appropriateness. Pharmacy staff should also initial the 'supply' box to record details of non stock supply.

3.2 Prescribing of Antimicrobials

3.2.1 Prudent antibiotic prescribing

- 3.2.1.1 To reduce emergence of multi resistant organisms and Clostridium difficile associated diarrhoea:
- 3.2.1.2 De-escalate to narrow spectrum from broad spectrum empirical regimens based on cultures where possible.
- 3.2.1.3 Avoid clindamycin, cephalosporins and fluoroquinolones outside guideline limitations.
- 3.2.2 A Start Smart then Focus approach is recommended for all antibiotic prescriptions. This means:
- 3.2.2.1 Do not start antimicrobial therapy unless there is clear evidence of infection
- 3.2.2.2 Take a thorough drug allergy history.
- 3.2.2.3 Initiate prompt effective antibiotic treatment within one hour of diagnosis (or as soon as possible) in patients with severe sepsis or life-threatening infections. Avoid inappropriate use of broad-spectrum antibiotics.
- 3.2.2.4 Comply with local antimicrobial prescribing guidance.
- 3.2.2.5 Document clinical indication (and disease severity if appropriate), drug name, dose and route on drug chart and in clinical notes*
- 3.2.2.6 Include review/stop date or duration.
- 3.2.2.7 Obtain cultures prior to commencing therapy where possible (but do not delay therapy).
- 18 Belfast Health and Social Care Trust Medicines Code

- 3.2.2.8 Prescribe single dose antibiotics for surgical prophylaxis where antibiotics have been shown to be effective.
- 3.2.2.9 Document the exact indication on the drug chart (rather than stating long term prophylaxis) for clinical prophylaxis.
- 3.2.3 Then 'Focus' this means:
- 3.2.3.1 reviewing the clinical diagnosis and the continuing need for antibiotics at 48*-72 hours and documenting a clear plan of action - the 'antimicrobial prescribing decision'.
- 3.2.3.2 When reviewing, consider these five 'antimicrobial prescribing decision' options:
- 3.2.3.2.1 Stop antibiotics if there is no evidence of infection.
- 3.2.3.2.2 Switch antibiotics from intravenous to oral.
- 3.2.3.2.3 Change antibiotics ideally to a narrower spectrum or broader if required.
- 3.2.3.2.4 Continue and document next review date or stop date.
- 3.2.3.2.5 Outpatient Parenteral Antibiotic Therapy (OPAT).
- 3.2.3 It is essential that the review and subsequent decision is clearly documented in the clinical notes and on the drug chart where possible e.g. stop antibiotic

* Due to advances in rapid diagnostics it may be possible to review prior to 48 hours after first dose.

- 3.2.4 When prescribing:
- 3.2.4.1 Document in the medical notes and on the kardex the indication, drug prescribed, dose, frequency, route and planned duration or review date as shown:

| Medicine Check allergy PIPERALILLIN TAZOBACTAM | Start date | 06** | AB | ky o | the | / | / | 1 | / | / | | 1 |
|--|------------|--------|----------|----------|-----|---|----|----|---|---|-----|---|
| Dose 4.54 Route Frequency | / | 1000 | / | | N | | / | | | N | /// | 1 |
| Special instructions | Signature | 1200 | 1 | 1 | ш | / | / | ш | | ш | /// | 1 |
| What infection are you treating? | Supply | (1400) | A3 00 | the | Z | / | /. | N | / | N | /// | 1 |
| Cultures sent Yes No Remember blood culture | | 1800 | 1 | | ш | | / | | / | ш | | |
| Sign ADOLTUN Prof. PO. 9731077 Print A DOLTUR Bleep 0001 | Pharmacist | 2200 | ef ve | ef VQ | R | / | / | 25 | / | ~ | | |
| Monitoring information REVIEW CULTURES AT 49 | IDURS | | | | | | | | | | | |

- 3.2.4.2 Document baseline investigations requested.
- 3.2.4.3 Obtain samples for microbiological culture before administration of antibiotics (where possible).
- 3.2.4.4 Review microbiology results and de-escalate therapy as appropriate (contact micro if advice is required).

Belfast Health and Social Care Trust Medicines Code

3.2.5 Use of Guidelines

- 3.2.5.1 Empirical guidelines are a generic indicator of good practice, which are based on Northern Ireland Regional Framework, and have been modified by Trusts to meet local conditions.
- 3.2.5.2 Treatment should be reviewed once sensitivities are known. If no bacterium is cultured the antibacterial can be continued or stopped on clinical grounds.
- 3.2.5.3. All senior clinicians are advised to note the contents of antimicrobial guidance. Whilst the guidelines are not intended to restrict the clinical judgement of senior medical staff, it is requested that they specify the reasons for making a choice outside the guidelines in patients' notes.
- 3.2.5.4 All antibiotic guidelines and policies are available on the Trust intranet and the BHSCT MicroGuide App and Internet page.

3.2.6 Restricted Antimicrobials

3.2.6.1 A small number of antimicrobials require the supervision of a microbiology/ Infectious disease consultant. This is primarily for patient safety. The Policy for Specialist Restricted Antimicrobial outlines the drugs included in this and the process to access these drugs which require the supervision of a microbiology/ Infectious disease consultant.

3.3 Prescribing of epidurals and Patient Controlled Analgesia (PCA)

3.3.1 See 'Controlled Drugs' policy.

3.4 Prescribing of unlicensed medicines

- 3.4.1 Refer to the BHSCT 'Unlicensed Medicines Policy'.
- 3.4.2 The use of an unlicensed medicinal product should only be considered when there is no equivalent licensed alternative available and if its use can be clearly justified clinically and pharmaceutically. The use of an unlicensed medicinal product should not be justified purely on the grounds of lower costs.
- 3.4.3 It is recognised that the use of an unlicensed medicine is sometimes necessary in order to provide the optimum treatment for a patient. Any liability associated with the use of Trust approved unlicensed medicines will be accepted by the employing authority provided that best practice, as outlined in the BHSCT 'Unlicensed Medicines Policy', is followed.
- 3.4.4 Where a prescriber prescribes an unlicensed medicine, they are professionally accountable for their judgement in so doing, and may be called upon to justify their actions. Prescribers should satisfy themselves that they could obtain a professional body of support for their practice in relation to the unlicensed product.
- 3.4.5 All healthcare professionals involved in the prescribing, procurement, supply and administration of medicinal products must be aware of a product's licensed status and any known relevant risks associated with its use.
- 3.4.6 Adverse drug reactions and medication incidents involving unlicensed medicines should be reported in the same manner as for licensed medicines.
- 20 Belfast Health and Social Care Trust Medicines Code

- 3.4.7 New unlicensed medicinal products should not be introduced without appropriate risk assessment and product categorisation, and approval by the Trust D&T New Drugs Subcommittee. In an emergency situation, this approval may be granted by the site designated pharmacist.
- 3.4.8 Adequate records must be kept with regard to the purchase and supply of unlicensed medicinal products in accordance with the product risk category. These records should include details of the product supplied, batch number, quantity supplied, name of prescriber and the patient's name.

3.5 Prescribing of a licensed medicine for an unlicensed indication (off-label prescribing)

- 3.5.1 Medicinal products marketed and licensed for adult patients have often not been formally evaluated for use in pregnancy, breast feeding or in children. Accepted and proven treatments in paediatric practice rely on the use of unlicensed/off-label medicinal products. Such uses are informed and guided by a respectable and responsible body of paediatric opinion.
- 3.5.2 If a prescriber uses a licensed medicine for an unlicensed indication then the manufacturer is unlikely to be found liable for any harm caused by that medicine, unless the harm is directly attributable to a defect in it, rather than the way in which it was prescribed. It is the responsibility of each prescriber to be aware of prescribing outside licensed indications.
- 3.5.3 Recommendations from bodies such as the General Medical Council and the Medical Defence Organisations place a duty on doctors to act responsibly, and to provide information to patients on the nature and associated risk of any treatment, including 'off-label' and unlicensed medicines.

3.6 Prescribing of opioid medicines

- 3.6.1 The National Patient Safety Agency (NPSA) has highlighted problems with opioid medicines whereby patients received unsafe doses of opioid medicines or where a dose or formulation was incorrect based on the patient's previous opioid dose.
- 3.6.2 To avoid problems with this high risk group of medicines, NPSA recommends that healthcare staff should:
- 3.6.2.1 Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.
- 3.6.2.2 Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not normally more than 50% higher than the previous dose).
- 3.6.2.3 Ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

3.7 **Prescribing in the outpatient setting**

3.7.1 The same principles of safe prescribing as outlined in 3.1 apply to prescribing in the outpatient setting. Additionally any unused portion of the Treatment Advice Note (TAN) should be crossed out so medicines cannot be added later by anyone other than the prescriber. See also the Trust 'Outpatient Treatment Advice Note policy'.

3.8 Prescribing for self/family/friends

- 3.8.1 Trust Prescribers should not write prescriptions for themselves, their family or other members of Trust staff unless the member of staff is also a patient of the Trust under the care of the prescriber.
- 3.8.2 Prescribers should not prescribe any medicine for themselves or for anyone with whom they have a close personal or emotional relationship other than in exceptional circumstance. Such prescribing may be necessary in circumstances where no other person with the legal right to prescribe is available to assess the patient's clinical condition and to delay prescribing would put the patient's health at risk, or cause unacceptable pain.
- 3.8.3 Each professional body provides guidance in this area for their members.

3.9 Prescribing of lithium

A lithium level should be taken on admission and a recent lithium level documented on the discharge prescription. Refer to the Trust lithium policy for further information.

3.10 Remote prescription or direction to administer

- 3.10.1 As stated by NMC, a verbal order is not acceptable on its own.
- 3.10.2 In exceptional circumstances, where medication (not including Controlled Drugs) has been previously prescribed and the prescriber is unable to attend the ward/clinical area to prescribe on the Kardex, but where changes to the dose are considered necessary, or where a medicine not previously prescribed is required, the use of information technology (such as fax or email) may be used to confirm any change to the original prescription.
- 3.10.3 The fax or email prescription or direction to administer must be stapled to the patient's existing Kardex. The prescriber should follow this up by ensuring the Kardex is completed within normally a maximum of 24 hours (72 hours maximum bank holidays and weekends).
- 3.10.4 In any event, the changes must have been authorised (via email or fax) by a registered medical prescriber before the new dosage/medicine is administered.

3.11 Verbal orders in the presence of a doctor

- 3.11.1 In an emergency situation such as resuscitation, a doctor may administer a medicine to a patient or direct a nurse/midwife they are working with to administer a medicine without first writing a prescription. The nurse/midwife who administers the medicine must confirm the instructions given to them with the doctor and have the doctor double check the medicine to be administered.
- 22 Belfast Health and Social Care Trust Medicines Code

- 3.11.2 As soon as possible after the emergency, the doctor must write up the medicine as a 'stat dose' in the 'once only' section of the Kardex and the nurse/midwife who gave the medicine should record this on the administration section of the Kardex. An appropriate entry should be made in the medical and nursing/midwifery notes.
- 3.11.3 CDs must not be administered on the basis of a verbal order in the presence of a doctor.
- 3.11.4 Any instructions to prescribe a medicine, for example, given on a ward round by a consultant to a more junior member of the medical team, should be read or repeated back to the consultant to verify the accuracy of what has been heard.
- 3.11.5 Verbal orders by a non medical prescriber are not permitted.
- 3.11.6 Any registered healthcare professional may administer adrenaline without direction or prescription in a life threatening situation. However, ideally, the Trust prefers that a Patient Group Direction should be in place to support staff in this situation.

3.12 Transfer of medicines related information

- 3.12.1 The Trust 'Policy for the Inter Hospital Transfer of Patients and their Records' must be followed.
- 3.12.2 In order to ensure that all relevant information in relation to medications is communicated from one hospital/facility to another, it is essential that the following documentation/information is transferred with the patient:
 - medical records
 - summary clinical notes; and
 - Kardex.
- 3.12.3 If for any reason the Kardex cannot be completed, for example, a patient admitted to A&E being transferred urgently, and a full medicine history cannot be obtained and documented prior to transfer, this must be clearly indicated on the Kardex and the transfer notes.
- 3.12.4 All notes must be bound together with no loose sheets sent and should be transferred with the patient.

3.13 Inpatient CD prescriptions

- 3.13.1 In-patient prescriptions for CDs must conform to the criteria set out in Section 3.
- 3.13.2 Refer also to 'Controlled Drugs Policy'.

3.14 CD prescriptions for discharge

3.14.1 Refer to 'Controlled Drugs Policy'.

3.15 Patient Group Directions (PGDs)

- 3.15.1 Patient Group Directions (PGDs) are written instructions that permit certain trained groups of named healthcare professionals to administer or supply medicines, including prescription only medicines, without a doctor's prescription.
- 3.15.2 The supply and/or 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 the appropriate professional relationship and accountability. This generally means that a PGD is best suited to acute or 'first contact' situations and it is not for the management of chronic conditions.
- 3.15.3 The Trust policy 'Developing a PGD' (including PGD template) and list of current PGDs are available on the Trust intranet.

3.16 Medical Gases

- 3.16.1 Medical gases are medicinal products under the provision of the Medicines Act 1968.
- 3.16.2 Medical gases should be managed and controlled to the same level as other medicinal products with regard to authorisation to prescribe, ordering, administration, storage and security.
- 3.16.3 Medical gases must be prescribed by a doctor, dentist or Trust non medical authorised prescriber.
- 3.16.4 For use of liquid nitrogen, follow manufacturer's data sheet. Liquid nitrogen is very safe under normal usage, however, when it evaporates e.g. due to spillage it undergoes a large volume expansion causing oxygen depletion. Liquid nitrogen oxygen depletion monitors must be used to provide early warning.
- 3.16.4.1 Staff should be aware of signs and symptoms of low oxygen levels. Asphyxiation as a result of oxygen depletion can take place on a gradual or sudden basis, depending upon the extent of the depletion.
- 3.16.5 Nitrous Oxide/Entonox[®] This medical gas may be subject to abuse and therefore any suspected abuse/diversion must be treated as per section 8.20.
- 3.16.6 Patients who require oxygen and other medical gases as a regular medicine must have it prescribed by a doctor or authorised non-medical prescriber on the Kardex. The prescription must include details such as target saturation range, initial flow rate and device type and whether it is for continuous or 'as required' use.
- 3.16.7 Refer to the Trust 'Policy for the Prescription and Administration of Emergency Oxygen in Adult Patients'.
- 3.16.8 A prescription is not required for the administration of oxygen in peri-arrest or medical emergencies but a subsequent written record must be made of the oxygen therapy prescribed and administered.
- 24 Belfast Health and Social Care Trust Medicines Code

3.16.9 A record must be made in the patient's notes giving details of the patient's clinical condition, the administration of oxygen and the delivery system, and any medical advice given.

3.17 Specialist medicines (Red/Amber) prescriptions

- 3.17.1 Prescribers should be mindful of potential difficulties which can arise in the transfer of care of patients to the community when highly specialised medicines are involved.
- 3.17.2 A system to manage the prescribing and supply of specialist medicines is in place regionally and such medicines are categorised using a red and amber 'traffic light' system.
- 3.17.3 Red List Medicines: prescribing responsibility should remain with the consultant or specialist clinician and the supply organised via the Trust Pharmacy.
- 3.17.4 Amber List Medicines: prescribing responsibility should be transferred to primary care with the agreement of the patient's GP and when shared care arrangements have been established. A copy of the relevant shared care guideline should be provided to the GP. See Trust policy 'How to Use Shared Care Guidelines (SCG) for Specialist Medicines when Requesting Shared Care with the Patients' GP' for further details. http://intranet.belfasttrust.local/Policies%20and%20Procedures/Shared%20Care%20Guidelines.pdf
- 3.17.5 A complete list of red and amber medicines and copies of shared care guidelines are available via www.ipnsm.hscni.net. Any queries about red or amber medicines, or shared care should be directed to the interface pharmacists in BCH or RVH. They can be contacted through the Pharmacy departments.

4 Administration of medicines

4.1 General principles

- 4.1.1 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.
- 4.1.2 Administration to a patient should be in accordance with professional guidance and competence and will be accomplished in one of the following ways:
- 4.1.2.1 Administration by authorised nurses/midwives in accordance with written authorisation by an authorised prescriber. A student nurse/midwife may administer medicines but only under the direct supervision of a registered nurse/midwife who must countersign beside the student's initials. Health Care Assistants and Nursing Auxiliaries must not be involved in the administration of medicines in hospital unless they have received specific training that is approved by D&T.
- 4.1.2.2 Administration by suitably qualified practitioner (doctor or dentist, or midwife within professional and statutory restrictions). A student doctor may administer medicines but only under the direct supervision of a registered medical practitioner who must countersign beside the student's signature.
- 4.1.2.3 Self-administration by an in-patient.
- 4.1.2.4 Authorised registered healthcare staff in accordance with a Trust approved Patient Group Direction (PGD).
- 4.1.2.5 Administration by a suitably trained and competent person in accordance with authorisation by a prescriber for an individual patient. The medicines can then only be given to that named patient. Those delegating the duty of medicines administration must ensure competence of the individual(s) and ensure that staff only undertake those responsibilities specified in agreed job descriptions.
- 4.1.3 All nursing/midwifery staff are deemed competent to administer medicines on their own and are professionally accountable for their actions in doing so at point of entry onto the register. Personnel who are not professionally registered must not participate in the administration of medicines unless they have undertaken a course of training endorsed by their employing authority.
- 4.1.4 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.
- 4.1.5 Lists of medicines for IV administration by nursing. Some legacy Trusts had lists stating a limited number of IV medicines that a nurse could administer. As nurses must keep their knowledge and skills up to date throughout their life and work within the limits of their competence, this negates the need for a list limiting medicines for IV administration. Such lists must not be used in the Trust and all staff who administer IV medicines will do so according to their level of competency.

4.1.6 First dose administration of an antibiotic or any medicine by any route may be carried out by a nurse, midwife or doctor. As an anaphylactic reaction may occur at the second or later doses, all staff administering medicines should be trained to recognise and manage an anaphylactic reaction.

4.2 Second check

- 4.2.1 The second check must be an independent, thorough check. The second check involves checking the prescription, preparation and administration of the medicine(s), including a second check of the patient's identity to ensure the correct patient receives the medicines. In the case of CDs, a check also involves ensuring that the patient received the medication and that any surplus CD is destroyed in the appropriate pharmaceutical waste bin. The second check also involves, for example, a check of allergy status and a check of any infusion device. The checker should also be aware of the condition being treated.
- 4.2.2 When a second practitioner is asked to check a calculation, they must undertake the full calculation by their own method. They must not be asked to confirm the first practitioner's answer until they have performed their own calculation.
- 4.2.3 A second check is required in the administration process in the following circumstances or as per Service group specific policy:
- 4.2.3.1 Administration of a schedule 2 and certain schedule 3 and schedule 5 CDs and non-controlled drugs managed within Belfast Trust as CDs (see Trust Controlled Drugs Policy).
- 4.2.3.2 Wherever possible, two qualified practitioners should check medications to be administered intravenously, including bolus injections and intravenous infusions. This check should include confirming the route of administration to the patient. Where wards/departments do not have a system of second checking the administration of IV medicines, the ward/department sister/charge nurse should undertake a risk assessment with their professional line manager to determine whether the introduction of second checking as an additional risk reduction measure is necessary. A written record of this risk assessment should be made and forwarded to the Associate Director of Nursing for the Service Group.
- 4.2.3.3 Setting up of infusion pumps including PCA and epidural pumps.
- 4.2.3.4 Changes to infusion rates or additional boluses administered via an infusion device. This includes stopping and restarting an infusion after a temporary interruption.
- 4.2.3.5 Specific medicines as per Trust/Service group guidance e.g. heparin, insulin.
- 4.2.3.6 In accordance with the Trust Intrathecal Chemotherapy Policy, registered approved nurses must be the second checker of an intrathecal injection.
- 4.2.3.7 Parenteral Chemotherapy Administration.

- 4.2.3.8 Children up to their 16th birthday if any registered nurse is unfamiliar with a medicine which has been prescribed, then he/she must double check this with an experienced RN (Child), or a seek advice from children's service or the prescriber, as appropriate.
- 4.2.3.9 Supervision of a student.
- 4.2.3.10 Where a complex calculation is required in order to determine the dose to be administered. NPSA defines a complex calculation as 'any calculation with more than one step required for preparation and/or administration, e.g. micrograms/kg/hour, dose unit conversion such as mg to mmol or % to mg.'
- 4.2.4 Second checks may be carried out by a:
 - Registered nurse
 - Registered midwife
 - Doctor
 - Pharmacist (for calculation and CD disposal)

4.3 Administration of CDs

4.3.1 See 'Controlled Drugs Policy'.

4.4 Timing of administration

- 4.4.1 Nurses and medical staff must exercise their professional judgement and knowledge each time a medicine is administered.
- 4.4.2 The nurse/midwife or other member of staff administering medicines is responsible for ensuring that prescribed medicines are administered as close to the prescribed time as possible. Medicines may be administered within two hours either side of the prescribed time and should be recorded in the normal way on the Kardex.
- 4.4.3 If two hours or more after the time the dose is due have elapsed, this delay must be discussed with medical staff and the appropriateness of the timing of the next dose reviewed, particularly if a critical medicine as outlined on next page.
- 4.4.4 An omission of a medicine (ie where a dose has not been administered before the next dose is due) must be documented on the Kardex in accordance with the guidance on the Kardex; a member of the medical team should be notified when two or more doses have been missed; every occasion when critical medicines have been omitted or delayed must be escalated, an incident form completed and the relevant manager informed. NPSA have identified particular medicines where timeliness of administration is crucial.

4.4.5 These medicines are:

Critical modicines

| Critical medicines | |
|---|---|
| Anti-infective (injectable route) Anticoagulants e.g. warfarin, enoxaparin Antiplatelets and thrombolytics (for acute indications) Anticholinesterases Anticonvulsants Antiretrovirals Bronchodilator (injectable or nebulised route) Chemotherapy (injectable route) | Clozapine Corticosteroids Opioids Oxygen Immunoglobulin Immunosuppressants Insulin Parkinson's Disease medicines Proton-pump inhibitors (injectable route) 'STAT' doses of any medicine (prescribed for immediate administration) |
| | |

Resuscitation medicines including plasma expanders and reversal agents e.g. phytomenadione, naloxone, flumazenil, prothrombin complex

Desmopressin (treatment of cranial diabetes insipidus)

- 4.4.6 The name of any medical officer contacted in relation to an omitted or delayed medicine should be recorded in the medical or nursing/midwifery notes and the action required.
- 4.4.7 A prescribed omission must only be documented on the administration record of the Kardex by a prescriber.
- 4.4.8 NPSA have also identified 'stat medicines' as a particular problem. The prescriber must verbally inform nursing staff that a 'stat medicine' has been prescribed to ensure administration in a timely manner, otherwise prescription of the 'stat medicine' may go unnoticed for several hours before they are identified at the next regular medicines administration round.

4.5 Verification of patient identity

- 4.5.1 The BHSCT Patient Identification policy states the criteria for patients who require an identification (ID) band/wrist band. This policy also states which patients are exempt from wearing a patient identification band.
- 4.5.2 Before prescribing a medicine on a Kardex or prescription, and using an addressograph, prescribers should check that the patient's name, Health and Care number and date of birth on the addressograph matches the patient name, Health and Care number and date of birth on the patient's identity wristband. On discharge prescriptions, prescribers should ensure there is an addressograph on each copy of the discharge prescription form.
- 4.5.3 Staff administering medicines should use the method of identification appropriate to the facility in which they are working.

Belfast Health and Social Care Trust Medicines Code

- 4.5.4 Before administering a medicine:
- 4.5.4.1 Verify the identity of the patient, for example, by checking the patient's name and Health and Care number on the Kardex with the patient name and Health and Care number on the patient's identity wristband.
- 4.5.4.2 Always check the date of birth.
- 4.5.4.3 If possible, ask the patient to tell you their name, rather than, for example, asking 'Are you Mrs X?'
- 4.5.4.4 If the patient is not wearing an identification bracelet e.g. in outpatients, the patient's identity must be confirmed by asking the patient, if appropriate, to independently state their full name, address and date of birth, ensuring that these details correspond to the prescription.
- 4.5.5 This standard applies to medical, nursing/midwifery staff and other registered healthcare professionals administering medicines.
- 4.5.6 When prescribing or administering a medicine, special care should be exercised where there are patients with the same or similar names on the ward.

4.6 **Process for administration of medicines**

- 4.6.1 The administration of medicines is not simply a mechanistic task performed in strict compliance with the written prescription, but requires thought and professional judgement.
- 4.6.2 It is the responsibility of the practitioner who selects and prepares a medicine dose to administer it to the correct patient. The following should be considered each time a medicine is administered:

4.6.2.1 The six rights:

- Right patient
- Right medicine and dose
- Right time
- Right route
- Right for the patient at that time e.g. an anti-hypertensive when the patient's blood pressure is low.
- Right allergy status, i.e. is the allergy status documented and is the patient allergic to the medicine or one of its constituents (if a combination product).
- 4.6.3 Practitioners (nurses/midwives and other registered healthcare professionals) must administer medicines in accordance with their professional bodies' guidance on administering medicines, Trust policies and current legislation.
- 4.6.4 Practitioners must:
- 4.6.4.1 Act only within their area of competency and training.

30 Belfast Health and Social Care Trust Medicines Code

- 4.6.4.2 Check the prescription is valid.
- 4.6.4.3 Confirm the identity of the patient. Read the prescription carefully, ensuring that it is signed by the prescriber, dated and has all the correct information with regard to dose, route, allergy etc. and that the medicine has been prescribed by its approved name.
- 4.6.4.4 Check the medicine allergy box, which should never be left blank, to ensure the patient is not allergic to the medication. Refer to a doctor if necessary. Do not administer a medicine, except in an emergency, if the allergy box is blank. Consider the ingredients of the medicines that you are about to administer e.g. is the patient allergic to one component of it e.g. a penicillin allergic patient prescribed co-amoxiclav.
- 4.6.4.5 Ensure that you have examined all sections of the Kardex and all relevant charts e.g. second Kardex or supplementary sheet.
- 4.6.4.6 Check that the medicine has not already been administered or that the total daily dose (where stated) will not be exceeded. If a patient has vomited within two hours of their medicine being administered, the nurse must contact a prescriber to ascertain if it is appropriate to re-administer. If it is, the prescriber must prescribe on the once only section of the Kardex.
- 4.6.4.7 Check the dose prescribed and the route of administration. Where a syringe is required for preparation and/or administration of an oral liquid medicine, an oral/enteral syringe must be used.
- 4.6.4.8 All regular and single insulin (bolus) doses must be measured and administered using an insulin syringe or a commercial pen device. IV syringes must never be used for insulin administration. Doses must always be administered from higher strength insulin (greater then 100units/ml) prefilled injection pens. Doses must not be withdrawn from these devices by any other means.
- 4.6.4.9 Check if the medication requires further dilution before administration e.g. IV vancomycin, IV clarithromycin, IM lorazepam, IV clindamycin. If an infusion is made up, ensure an IV additive label is attached to either the infusion bag or syringe as appropriate.
- 4.6.4.10 Check the rate of administration, if appropriate.
- 4.6.4.11 Check that the prescribed dose is appropriate.
- 4.6.4.12 Select the medicine to be administered and check its strength. Do not remove eg ampoules from their box before use. Incidents have occurred when vials/ampoules have been taken out of their boxes 'just in case', not used and returned to the wrong box.
- 4.6.4.13 Check that the medicine name on the container label matches that on the prescription sheet. For blister strips, check the name on the reverse of the blister strip matches the label in the box.
- 4.6.4.14 Check the expiry date on the medicine.

- 4.6.4.15 Give the medicine and observe the patient to ensure it has been taken.
- 4.6.4.16 Record the administration by initialling clearly on the Kardex against the time and date.
- 4.6.4.17 Under no circumstances should medicines be left unattended at the patient's bedside except as part of an approved scheme for self administration.
- 4.6.4.18 An appropriate record must be made on the Kardex if a medicine is omitted or refused using the code printed on the Kardex. If a patient repeatedly refuses a medicine, the nurse/midwife must use their professional judgement in deciding to contact a doctor for advice.
- 4.6.4.19 Patients not receiving their medicines due to a shortage of medicines or a non-stock medicine must be highlighted to the prescriber as soon as possible particularly if a critical medicine (as listed in 4.4.5).

If a medicine is omitted or delayed for a code '7' ie 'other', then the reason must be documented in the table on the Kardex.

- 4.6.4.20 Due to the hospital contract, the Pharmacy department may supply generic medicines or equivalent medicines with a different brand name. The person administering the medicine should use the BNF or eBNF to confirm the equivalence of products. If this cannot be confirmed, the nurse/midwife must contact a doctor or pharmacist for advice. All medicines should be prescribed in accordance with the Trust 'Policy for appropriate use of the generic names of medicines'.
- 4.6.4.21 Lithium products are not interchangeable and the patient must be maintained on the same branded product. Care should be taken with long acting and slowrelease products which are not always equivalent e.g. diltiazem, nifedipine and theophylline. The nurse/midwife should confirm with a pharmacist whether it is appropriate to substitute products. Refer to the Trust 'Policy for appropriate use of generic names of medicines' policy.

4.7 Administration of 'as required' medicines (PRNs)

- 4.7.1 The process for administration of medicines as outlined earlier should be followed when administering 'as required' medicines.
- 4.7.2 An additional check must be made to ensure sufficient time has elapsed since the previous dose of the medicine, and that any maximum dose in 24 hours stated for that medicine has not been exceeded in the preceding 24 hours. If a variable dose is permitted the dose given must be recorded. If optional routes are permitted, the route used must be recorded. An appropriate entry must be made in the nursing/midwifery notes stating the reasons for, and the outcome of, the 'as required' administration.

4.8 Nil by Mouth

- 4.8.1 Patients classified 'nil by mouth' (NBM) prior to a diagnostic procedure or receiving an anaesthetic must have all their prescribed medicines administered to them in accordance with the prescriber's instructions. Any oral medicines should be taken with a small quantity of water.
- 32 Belfast Health and Social Care Trust Medicines Code

- 4.8.2 It is the responsibility of the prescriber to provide clear instructions to nursing/midwifery staff concerning omission of prescribed medicines.
- 4.8.3 Patients may also be 'nil by mouth' for other reasons e.g. vomiting, unable to swallow, ileus.
- 4.8.4 The indication for each medicine should be reviewed, alternative routes and formulations explored and further information sought as necessary. It is important to clarify the instructions regarding medicine administration of 'nil by mouth' patients with medical staff.
- 4.8.5 All patients with a suspected stroke should remain 'nil by mouth' until a Speech and Language Therapist or other appropriately trained member of staff has assessed their swallow function (to reduce the risk of aspiration pneumonia).

4.9 Crushing tablets or opening capsules/administering medicines through feeding tubes

- 4.9.1 Manipulation of tablets or capsules may change the effect of the drug, may not always be suitable or effective and may render the medicine hazardous to handle. A review of the medication must be undertaken if the tablets or capsules are to be manipulated. Depending on the clinical setting, this may need to be reviewed daily.
- 4.9.2 Staff should ascertain:
- 4.9.2.1 If the medication is absolutely necessary? Non-essential medication, for example ascorbic acid should be stopped.
- 4.9.2.2 If it could be switched to another agent, formulation or route? A flexible approach may need to be taken.
- 4.9.3 Where possible the drug regimen should be reviewed by the pharmacist (or team) to determine which formulations are best to use. They can also advise on any drugs which can be discontinued, held or have the dose adjusted to accommodate enteral tube administration for example adjusting the dose of phenytoin for the liquid formulation.
- 4.9.4 Any change in medication to facilitate swallowing difficulties or feeding tubes must be clearly documented in the medical notes. If this change is a permanent change, it must be clearly documented on the discharge letter with review arrangements, if applicable. The patient (and carer if applicable) must be counselled.
- 4.9.5 It may be necessary in some circumstances to crush tablets or open capsules to ensure the continuation or commencement of essential medication. In this case, ensure that this is done in a safe and correct manner, using available references and available sources of advice. Clear documented directions must be written on the Kardex, as far as possible.
- 4.9.6 All available sources of advice must be used, including the BNF and SPC.
- 4.9.7 See also 'Advice for Health Professionals: Choosing medicines for patients unable to take solid oral dosage forms:

http://niformulary.hscni.net/Formulary/Adult/PDF/Specials/HSC%20 Guideline%20Health%20professionals%20Swallowing%20Difficulties.pdf

4.9.8 Contact the clinical pharmacist, Pharmacy or Regional Medicines and Poisons Information Service for further advice. If out of hours, contact the on-call pharmacist.

4.10 Covert administration of medicines

- 4.10.1 Patients have the right to refuse medication and this should be respected (see 4.10.4 for patients treated under mental health legislation). However, a distinction must be made between those patients who have the capacity to refuse medication and whose refusal should be respected and those patients who lack this capacity. For patients who lack capacity a further distinction should be made between those who will accept any medication offered because they are not aware they are being given medication and those who would not take the medication if it were not disguised in some way.
- 4.10.2 Administration of medicines to a patient who lacks capacity should only take place after a multi-professional assessment has concluded that such administration is in the patient's best interests. The prescriber should make an appropriate entry in the patient's care plan explaining the rationale for this decision. If the assessment concludes the patient is unlikely to take the medication, and therefore benefit from it, unless it is disguised in some way then this must also be documented. Advice should be sought from a pharmacist, preferably from the medicines information service, 028 950 40558 or by email at nirdic.nirdic@belfasttrust.hscni.net Monday-Friday 9.00am-5.00pm on the options available for disguising the medication, including mixing with food.
- 4.10.3 The need for covert administration of medicines should be kept under regular review.
- 4.10.4 Different rules apply regarding consent to take medication for patients who are detained under mental health legislation. In these cases follow the relevant guidance on the Mental Health Order.

4.11 Self or carer administration of medicines

- 4.11.1 Self administration may be defined as a system which allows patients to have possession of some or all of their prescribed medication and to take responsibility for administering them correctly.
- 4.11.2 There is no Trust self administration policy, although local self-administration policies may be in place; salbutamol inhaler, terbutaline inhaler or glyceryl trinitrate spray (non cardiology wards only) may be left with patients for immediate relief of symptoms. These patients must be instructed to inform nursing/midwifery staff when they have self administered these medicines. Administration of these medicines must be documented on the Kardex as 'self'. Local policy on cardiology wards should be followed with respect to self administration of glyceryl trinitrate spray.
- 4.11.3 Under no circumstances should other medicines be left unattended with the patient or at their bedside.
- 34 Belfast Health and Social Care Trust Medicines Code

4.11.4 Carers must not administer medicines unless in an area/specialty where involvement of a carer in administration of a medicine has been risk assessed and deemed appropriate. This administration by a carer is under the direct supervision of an approved practitioner, who retains full responsibility for the administration process. This assessment should be documented in the patient notes.

4.12 Patient's Own Drugs (PODs)

4.12.1 An assessment should be made of the suitability of the medicines to be administered (as per legacy Trust Patient's Own Drugs procedure) and the medicines must be stored in a secure area in order to prevent unauthorised access (e.g. POD locker).

4.13 Multi dose vials

- 4.13.1 Injections licensed for multiple use should be used in accordance with their Marketing Authorisation.
- 4.13.2 Each container of an injection licensed for multiple use should be reserved for a single patient and adequate systems put in place to ensure this occurs.
- 4.13.3 A new needle and syringe should be used for each withdrawal, even if a single dose requires more than one withdrawal.
- 4.13.4 Injections licensed for single use should not be used on more than one occasion, either for one or several patients, whatever the nature of the device used to access the container.
- 4.13.5 Injections should be manipulated observing normal no-touch techniques.

4.14 Extravasation

- 4.14.1 Refer to Trust policy on the management of chemotherapy extravasation.
- 4.14.2 For non cytotoxic medicines some information is available through NHS Medusa Injectable Medicines Guide online via the Trust intranet or in the NI Injectable Medicines Guide booklet 2016.
- 4.14.3 Regional Medicines and Poisons Information Service can also provide further advice and resources on extravasation. They can be contacted Monday to Friday 9.00 am 5.00 pm at 028 950 40558 or via email at nirdic.nirdic@ belfasttrust.hscni.net.

5 Ordering, supply and receipt of pharmaceuticals

5.1 Pharmacy Opening Hours

5.1.1 Pharmacies are located in Belfast City Hospital, Knockbracken, Mater Hospital, Musgrave Park Hospital and the Royal Victoria Hospital. Opening times vary across the sites and on weekdays, weekends and public holidays. Outside these times an emergency on-call service is provided.

| | Normal opening hours | Extended hours service | BHSCT on-call Pharmacist |
|--------------------|---|--|---|
| Mon | 8.30am* to 5pm | 5pm to 9pm | 9pm to 8am |
| Tues | Routine supply of all medicines, | Based at RVH site with services provided | One Pharmacist on-call from home |
| Wed | dressings,discharge prescriptions, controlled | across BHSCT | Emergency supply |
| Thurs | drugs, cylinders | Newly prescribed and urgent | ONLY |
| Fri | | | |
| Sat | NB Saturday morning services are not described as 'normal opening' as the full complement of staff are not on duty | RVH:9am to 5pm BCH:9am to 1pm MPH & MIH:10am to 1.45pm Newly prescribed and urgent | From 5pm One Pharmacist on-call from home Emergency supply ONLY |
| Sun | | RVH:9am to 5pm BCH:10am to 2pm Newly prescribed and urgent | From 5pm One Pharmacist on-call from home Emergency supply ONLY |
| Public Holidays | | RVH:9am to 5pm BCH:9am to 5pm MPH:10am to 1.45pm MIH:10am to 1.45pm Newly prescribed and urgent | From 5pm One Pharmacist on-call from home Emergency supply ONLY |

*BCH and RVH open at 8.15am

5.1.2 Site specific ward posters are accessible from the Pharmacy HUB site or via the following link http://intranet.belfasttrust.local/directorates/css/pharmacy/Pages/ Opening-Times.aspx

5.2 Normal Opening Hours

- 5.2.1 The full range of Pharmacy Services are available Monday to Friday, 8.30am to 5pm from BHSCT pharmacy departments. BCH and RVH dispensaries open at 8.15am.
- 5.2.2 All routine replenishment of stock and new requests for medicines (including CDs), dressings, IV fluids, medical gas cylinders must arrive in each pharmacy department 30 minutes before closing time.

5.2.3 All dispensed items must be collected from pharmacy departments before closing time.

5.3 Pharmacy Out of Hours Services

5.3.1 Extended Hours Services (EHS)

- 5.3.1.1 This service is accessible by all wards/depts in BHSCT and is provided primarily from RVH pharmacy.
- 5.3.1.2 Extended Hours Services are for the supply of newly prescribed medicines, medicines for new admissions, discharge prescriptions and urgent Medicines Information. Staff should consider this when altering Kardexes or ordering medicines after 5pm. Medical staff should advise if prescription changes can wait until the following day and the Kardex dated accordingly.
- 5.3.1.3 EHS Activity is monitored daily and inappropriate use followed up with the ward/dept.
- 5.3.1.4 BEFORE contacting Pharmacy EHS:
 - Consider what time the next dose is required.
 - · Check availability on ward;
 - Is medicine a ward stock item? (check under generic and trade names)
 - Check ALL possible storage locations including ALL medicine trolleys
 - Check back in the requisition book item may have been ordered earlier in the day
 - Prescriptions check prescription tracking system. Prescription may already be completed and on the ward.
 - Use patients own drugs (PODs) brought in on admission (NOT CONTROLLED DRUGS)
 - CHECK name and strength of medicine
 - Check expiry date
 - Ensure the item is ordered the following day
 - If patient is transferred from another ward/site, ensure PODs and medicines labelled for the patient are transferred with the patient. Contact the transferring ward if medicines have not been transferred.
- 5.3.1.5 Access pharmacy EHS as soon as possible to order the required medicine(s) or discharge prescription allowing time to resolve queries or arrange transport.

5.3.2 On-call 'Emergency service'

- 5.3.2.1 The Pharmacy On-call Service operates when all Pharmacy Departments are closed.
- 5.3.2.2 The On-call Pharmacy Service is one pharmacist on-call from home. The BHSCT on-call pharmacist is also first on-call for South Eastern Trust. Activity on this service is monitored daily and inappropriate use of the service is followed up with the ward/dept.

- 5.3.2.3 The Pharmacy On-Call service is for supply of Emergency items or Medicines Information only. The service does not dispense discharge prescriptions. For discharge prescriptions, follow the policy for the supply of discharge medicines from wards when Pharmacy is closed.
- 5.3.2.4 The On-Call Pharmacist should be contacted via Hospital at Night or Patient Flow, the lead nurse on site or via switchboard.
- 5.3.2.5 BEFORE contacting the Pharmacy On-Call Service:
 - · Follow the above steps to verify that the medicine is not on the ward
 - Contact the patient flow team or lead nurse for the site to access medicines held in Emergency cupboard (BCH, Musgrave only)
 - Transfer of stock medicine from another ward on the same site. A list of ward stock items for all wards is available on the Pharmacy HUB site.
- 5.3.2.6 Complete a requisition and Medicine Transfer Form. Copies must be sent to pharmacy.
- 5.3.2.7 Schedule 2, 3, 4 and 5 controlled drugs must not be transferred between wards. Contact the on-call pharmacist (Emergency supplies only). For further information on schedules of CDs, see Trust Controlled Drug policy.
- 5.3.2.8 Medicines must not be transferred between hospitals on the RVH site i.e. between RJMH, RBHSC and main RVH
 - If appropriate, request medical staff to change the prescription to an item that is available on the ward.

5.4 Using the requisition book

- 5.4.1 The nurse/midwife in charge of a ward/department or senior professional may delegate writing of a pharmacy order in the requisition book, following the instructions at the front of the book, to another nurse/midwife or appropriate person, but the finished order should be signed by the nurse/midwife in charge, ward pharmacist/pharmacy technician, senior professional or facility manager.
- 5.4.2 All remaining lines on the requisition must be cancelled by a single diagonal line. This prevents the addition of items to the requisition after it has been signed by the nurse/midwife in charge, ward pharmacist/pharmacy technician, senior professional or facility manager.
- 5.4.3 Only one requisition book will be issued to a ward at any one time. Each book is uniquely numbered for traceability. Pharmacy will issue a new book only when they receive the last order in the old book which should include an order for a replacement book. A ward/department/facility should ensure that any remaining pages in the book are cancelled. Delivery copies of requisitions must also be retained for at least one week.
- 5.4.4 The nurse/midwife in charge must report the loss or theft of the requisition book immediately to the Pharmacy department and complete an incident form. Wards will not be issued with a new book unless Pharmacy receives a copy of the incident form. In the event of a missing requisition book,
- 38 Belfast Health and Social Care Trust Medicines Code

wards/departments will still have access to medicines using a requisition book in Pharmacy.

5.4.5 Before ordering:

- 5.4.5.1 Check the ward stock holding list first i.e. list of items held in stock by the ward/department. Ward stock items will not be supplied unless the request is clearly communicated to Pharmacy by endorsing the requisition with 'no stock on ward'.
- 5.4.5.2 Pharmacy may query any request for stock medicines, especially if they are medicines liable to diversion/abuse.
- 5.4.5.3 When ordering an unlicensed medicine include the patient's name, Health and Care number and name of the prescriber.
- 5.4.5.4 Previous orders should be checked as the item may have already been ordered.
- 5.4.5.5 Print legibly and complete all sections to ensure a suitable quantity of the correct medicine is dispensed.
- 5.4.5.6 Do not write in the 'Pharmacy use only' section.

5.5 Non-stock medicines

- 5.5.1 Medicines not on the agreed stock list may be requisitioned, as demand requires, within normal working hours. Non-stock items are issued to in-patient wards on a named patient basis and full packs will be issued.
- 5.5.2 Non-stock orders must include the following details:
 - Date
 - · Name of ward or department
 - Ward/department telephone number
 - Printed name, signature and designation of nurse-in-charge or ward pharmacy staff.
 - Name of medicine required, printed and in accordance with Trust 'Policy for appropriate use of the generic names of medicines' including pharmaceutical form e.g. tablets, liquid etc.
 - Strength of medicine.
 - Quantity of medicine required.
- 5.5.3 Cancel any unused lines on the requisition book after the requisition has been signed off to ensure other items are not added by unauthorised staff.
- 5.5.4 Do not write in the 'Pharmacy use only' section.
- 5.5.5 Ensure that the ward/department is accurately recorded on the requisition. Requisitions may also be sent in the pneumatic tube, where available, using a pharmacy carrier. Certain in-patient areas which hold a specific agreement to do so may fax an urgent order to the supplying Pharmacy department.

- 5.5.6 The top two copies of the requisition should be sent to Pharmacy.
- 5.5.7 The ward/department messenger/member of staff from facility may collect orders from Pharmacy on presentation of photographic Trust ID.
- 5.5.8 BCH and RGH pharmacies label patient details on non stock medicines (for in-patient areas), therefore on these sites, the requisition must also include patient name, Health and Care number and date of birth.
- 5.5.9 At discharge, it is the responsibility of nursing staff to send non stock medicines to Pharmacy for relabelling with take home instructions.
- 5.5.10 The signed original order must be retained for a period of two years by Pharmacy.
- 5.5.11 When the medicine has been supplied:
- 5.5.11.1 A nurse/midwife must receive the order on the ward and must check each item against the order copy and sign the delivery copy of the requisition.
- 5.5.11.2 Any discrepancies must be notified to the Pharmacy department immediately.
- 5.5.11.3 It is the nurse's responsibility to ensure that the medicines received are stored appropriately.
- 5.5.12 Pharmacy will communicate shortages or queries on the comments section of the requisition. Nurses checking the returned order against the delivery copy of the requisition must read the comments section and take the appropriate action e.g. highlight shortage with the prescriber. This delivery copy of the requisition should be filed so that it is accessible to all and retained at ward level for at least one week.

5.6 Top-up

- 5.6.1 Wards or department managers will agree, where appropriate, a suitable list of stock medicines with the Pharmacy department to cover the majority of medicines required by that ward or facility. The top-up stock must be reviewed annually by a nominated pharmacist or pharmacy technician and the nurse/midwife in charge of the ward/department.
- 5.6.2 The Pharmacy department will prepare a 'stock holding list/top-up list' which is the ward's agreed stock holding. This stock holding list is available on the ward.
- 5.6.3 This list is used to order replacement stock on a weekly or twice weekly basis, depending on site. The order can be prepared by a nurse/midwife or by an approved member of pharmacy staff. The order should be signed, dated and countersigned by the nurse/midwife in charge. In departments without nurses, e.g. physiotherapy and podiatry, the senior professional in charge of the unit or facility must sign pharmacy orders. If a stock item has to be ordered in the pharmacy requisition book due to unusually large usage, then the requisition should be endorsed 'no stock on ward'.
- 40 Belfast Health and Social Care Trust Medicines Code

- 5.6.4 Pharmacy will produce a picking list of the medicines required for that top-up; a copy of the picking list acts as a delivery docket for wards and nurse/midwife in charge/senior professional must sign this picking list/delivery docket once the top-up is returned to the ward. The picking list also details stock items not currently available. A nurse/midwife must receive the top-up order on the ward and sign the delivery copy of the top-up.
- 5.6.5 A registered nurse or Pharmacy staff must put away top-up stock . This must be done as soon as possible, and if practicable within the same day as the top-up stock has been delivered. No other staff should have access to top-up medicines.
- 5.6.6 Wards should confirm that stock delivered on their top-up stock agrees with the picking list/delivery docket on the day of the top-up. Any discrepancies must be notified to the Pharmacy department immediately.
- 5.6.7 Picking lists must be stored in a designated location at ward level and must be retained for at least one week.
- 5.6.8 When a member of pharmacy staff returns the medicine cupboard keys to a nurse/midwife, the name of the nurse/midwife to whom the keys were returned should be recorded on the ward top-up sheet.

5.7 Resuscitation Trolley

- 5.7.1 This should be located where it is readily accessible in an emergency and where surveillance will prevent unauthorised access.
- 5.7.2 It should be checked daily e.g. for sufficient stock and expiry dates. This check must be recorded. Emergency packs should be routinely checked by nursing/midwifery staff.
- 5.7.3 If an emergency box is used, seal is broken or has expired, it must be sent to Pharmacy along with a requisition for a replacement.

5.8 Control Of Substances Hazardous to Health (COSHH)

- 5.8.1 COSHH is the law that requires employers to control substances that are hazardous to health (COSHH).
- 5.8.2 Hazardous substances must be transported to and from Pharmacy using designated COSHH containers.
- 5.8.3 Many pharmaceutical products used within clinical areas in the Trust come under COSHH regulations.
- 5.8.4 COSHH covers chemicals, products containing chemicals, fumes, dusts, vapours, mists and gases, and biological agents (germs). COSHH also covers asphyxiating gases. It covers germs that cause diseases such as leptospirosis or Legionnaires' disease and germs used in laboratories. COSHH does not cover lead, asbestos or radioactive substances because these have their own specific regulations. If the packaging has a hazard symbol then it is classed as a hazardous substance.

- 5.8.5 Pharmaceutical information is provided in:
 - The COSHH Pharmaceutical Guidance booklet January 2010.
 - Pharmacy COSHH Frequently Asked Questions and Answers July 2010.
 Information is also available at http://www.hse.gov.uk/coshh/
 http://www.hse.gov.uk/pubns/indg136.pdf
- 5.8.6 COSHH assessor workshops are within the Corporate Health & Safety Training Portfolio.
- 5.8.7 For further information refer to the Trust policy 'The Control of Substances Hazardous to Health (COSHH) Trust Policy & Procedural Arrangements'.

5.9 Individual patient supply/Patient's Own Drug scheme

5.9.1 Medicines may be supplied that are intended for use by an individual patient only. This may be the main method of supply for an entire ward e.g. Patient's Own Drug scheme (see section 6). Where a medicine has been dispensed for an individual patient, it must only be administered to that patient.

5.10 Expiry dates of medicines

- 5.10.1 Pharmacy staff check the expiry dates of ward stock items in the medicine cupboards/storage areas designated for top-up stock on wards with a full pharmacy top-up service. Other wards/departments that do not have a full top-up service or that order their own pharmacy top-up items are responsible for checking the expiry dates of these medicines.
- 5.10.2 Checking of expiry dates of stock medicines and non-stock medicines which are relocated to other storage areas within a ward or department is the responsibility of nursing/midwifery staff.
- 5.10.3 Liquid medicines should be endorsed with the date of opening and discarded after one month or as directed by the manufacturer.
- 5.10.4 It is good practice to check the expiry date of medicines when the medicine is removed from or returned to the medicine cupboard.

5.11 Ordering and storage of medical gas cylinders

- 5.11.1 Staff wishing to order medical gas cylinders should write their order for a medical gas cylinder on the Medical gas cylinder order form. The order must state:
 - Type of medical gas
 - Size of cylinder
 - Quantity of cylinders required
- 5.11.2 A ward/department may only requisition the number of medical gas cylinders up to the agreed stock level and must have the corresponding number of used/empty cylinders to return to Pharmacy.
- 5.11.3 The ward should send the medical gas cylinder order form to Pharmacy via the pneumatic tube, where available, or via a ward messenger. The medical
- 42 Belfast Health and Social Care Trust Medicines Code

gas cylinder is then delivered to the ward/unit by the pharmacy support staff, pharmacy courier, porter or driver.

5.11.4 The pharmacy support staff/pharmacy courier will also bring the empty cylinder back to Pharmacy.

5.11.5 Site specific arrangements:

- 5.11.5.1 Muckamore Abbey wards: contact transport who will call to the clinical area to collect the empty cylinder. Transport will obtain a replacement cylinder from the medical gas store and deliver to the ward. The nurse will forward the medical gas order form to Knockbracken Pharmacy department.
- 5.11.5.2 Community facilities: a medical gas order form should be faxed to Knockbracken Pharmacy.
- 5.11.6 Wards/Units hold an agreed stock of cylinders in a designated area on the ward/unit. This storage area will have approved signage relating to medical gases and should have Health and Safety and training information pertaining to the safe use of medical gases. There should also be statutory warning notices posted prohibiting smoking and naked lights within the vicinity of the cylinders
- 5.11.7 Cylinders should be stored in a clean, dry, and well ventilated location and free from inflammable material. Rubbish must not be allowed to accumulate.
- 5.11.8 Cylinder trolleys or restraints must be used to avoid falling or rolling of cylinders. Cylinders must not be stored or used freestanding.
- 5.11.9 Cylinders should be sited away from any source of heat or ignition and away from highly flammable liquids and other combustible materials and from sources of heat or ignition.
- 5.11.10 Medical gas cylinders must not be stored in lift lobbies but must be located near an exit so they can be removed quickly in an emergency such as a fire, however, they must not block the exit or present any other type of hazard.
- 5.11.11 The name of the medical gas, cylinder size and expiry date must be checked on the collar of the medical gas cylinder before use.
- 5.11.12 Pharmacy holds a record of the cylinders each area keeps. If a cylinder is lost, then the Trust must pay for the value of the lost cylinder as the actual cylinder is rented. An incident form must be completed if the ward loses a cylinder and Pharmacy must be informed.
- 5.11.13 If a cylinder has been transferred with a patient, the receiving ward must ensure that the cylinder is returned.
- 5.11.14 Wards/Units must not order a new issue of a cylinder unless they have an appropriate stand and regulator for the medical gas cylinder.
- 5.11.15 As part of normal service developments and change in patient mix, it will be necessary for wards/departments to request additional medical gas cylinders onto their stock and to ask for Pharmacy to remove cylinders that are no longer required. A request for adding an additional cylinder to the ward stock should be made on the medical gas cylinder order form.

- 5.11.16 Pharmacy do not supply cylinder regulators or trolleys.
- 5.11.17 Further information can be obtained in the Trust Medical gas policy.
- 5.12 Ordering Controlled Drugs (CDs) for ward stock, collection and receipt of CDs, ordering CDs for discharge
- 5.12.1 See 'Controlled Drugs Policy'.

5.13 Transferring medicines

- 5.13.1 Medicines dispensed and labelled for an individual patient may be transferred with that named patient. These medicines may be patient's own medicines that have been kept at ward level or non-stock medicines that have been issued by Pharmacy labelled with the patient's name. These medicines should be transferred in a green Patient's Own Drug bag.
- 5.13.2 Medicines dispensed and labelled for an individual patient must not be administered to another patient.
- 5.13.3 See 'Controlled Drugs Policy' for details on transferring patient's own CDs (either patient's own supply or discharge medication) with a patient to another ward and for details on the limited circumstances where a CD will move with a patient.
- 5.13.4 Only in exceptional circumstances should medicines supplied from ward stock be transferred to another ward.
- 5.13.5 Medicines can only be transferred if the medicine is urgently required and when Pharmacy departments are closed.

5.13.6 Procedure for transfer of ward stock medicines when Pharmacy departments are closed

- 5.13.6.1 The nurse-in-charge should contact the ward to determine if the ward has the required medicine and if the original pack can be supplied. NB Controlled Drugs (CDs) (Schedule 1-5) must not be transferred between wards.
- 5.13.6.2 The nurse-in-charge should complete the 'Medicine Transfer Form' in full.
- 5.13.6.3 The Medicine Transfer Form should be brought to the ward supplying the medicine. Two nurses should check the name, strength, form and expiry date of the medication required on the Medicine Transfer Form against the medication. Both nurses must sign the Medicine Transfer Form.
- 5.13.6.4 The top copy of the Medicine Transfer Form must be sent to Pharmacy on the next working day.
- 5.13.6.5 The ward supplying the medicine should retain the second copy of the Medicine Transfer Form. The ward supplying the medication must re-order the medicine, as required, when Pharmacy re-opens.
- 5.13.6.6 Note that the Medicine Transfer Form must be sent to Pharmacy to ensure that any product recall/hazard can be communicated to all relevant wards and
- 44 Belfast Health and Social Care Trust Medicines Code

to ensure that the ward supplying the medicine is credited for the medicine supplied.

5.13.6.7 When a patient with a CD containing epidural or PCA infusion is to be transferred between wards/departments, the dose/volume infused must be checked by two nurses, one from the transferring department and one from the receiving department. The amount administered (volume/dose) must be recorded on the epidural/PCA chart, as well as the signatures of those involved, the date and time of transfer and the change in location (e.g. from recovery to ward).

5.14 Transfer of medicines between containers

5.14.1 The transfer of any medicine from one container to another, other than by pharmacy staff, is strictly forbidden.

5.15 Returns to Pharmacy and reuse

5.15.1 If a medicine is no longer needed, full packs should be returned to the Pharmacy department in the pharmacy box and marked as 'Pharmacy return'. Alternatively, Pharmacy personnel providing a ward top-up service will return unwanted stock. CDs must be returned as outlined in the 'Controlled Drugs Policy'.

5.16 Pharmaceutical samples

- 5.16.1 A sample is defined as a small quantity of a medicinal product provided to a healthcare professional so that he/she may acquire experience in using it. A sample of a medicinal product may only be provided to a healthcare professional permitted to prescribe that particular medicine/dressing/enteral feed.
- 5.16.2 To ensure compliance with Product Liability Legislation, Medicines Act Regulations, Department of Health (NI) Guidelines and the ABPI code, samples of medicinal product must not be left in clinical and administration areas. All samples of medicinal products must be receipted and issued only from the relevant site Pharmacy Department.
- 5.16.3 All samples of medicinal product must be licensed and have a UK marketing authorisation.
- 5.16.4 The relevant section of the Trust policy 'Interfacing with the Pharmaceutical Industry' must be followed including the arrangements for recording, issuing and tracking of samples of medicinal products (Appendix 2).

5.17 Medicine for staff personal use

5.17.1 Medicines supplied by the Pharmacy department are for treating patients. Under no circumstances are any medicines supplied by the Trust, including medicine to be returned to Pharmacy or expired medicines, to be used for the personal use of staff as this is theft of Trust property. Expired medicines or medicines to be returned or returned to Pharmacy must not be donated to charity.

5.18 Prescribing for self/family/friends

Trust Prescribers should not write prescriptions for themselves or their family or other members of Trust staff unless the member of staff is also a patient of the Trust under the care of the prescriber. See section 3.8 for further details.

5.19 Emergency cupboards

- 5.19.1 BCH and Musgrave Park sites have an approved list of medicines held in emergency cupboards for urgent access.
- 5.19.2 The Ward/Department Sister or Charge Nurse/senior nurse on duty must contact the senior/lead nurse on the site/unit, patient flow (before 9pm Saturday and Sunday) or hospital at night (BCH after 9pm) with responsibility for the emergency cupboard and provide details of the item required, strength, formulation and quantity.
- 5.19.3 The senior/lead nurse on the site/unit, patient flow or hospital at night with responsibility for the emergency cupboard will confirm if stock is available.
- 5.19.4 The Ward/Department Sister or Charge Nurse/senior nurse on duty on the requesting ward must complete a requisition for the item(s) required.
- 5.19.5 The senior nurse from the requesting ward and senior/lead nurse on the site/unit, patient flow or hospital at night with responsibility for the emergency cupboard must both sign the requisition and complete the supply log (Appendix 2).
- 5.19.6 The senior/lead nurse from the site/unit, patient flow or hospital at night with responsibility for the emergency cupboard must forward the original requisition to the appropriate Pharmacy department.
- 5.19.7 The supply log must be completed to confirm that the supplied item has been replaced by Pharmacy staff.

6 Patient's own medicines on admission

- 6.1.1 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/midwife and/or pharmacist to determine whether the patient is taking any prescribed medicines or other medicinal preparations and if they have brought these medicines in with them.
- 6.1.2 These medicines are the property of the patient, and should not, be destroyed or otherwise disposed of without the agreement of the patient or their carer.
- 6.1.3 Medicines brought in by the patient, patient's carer or Northern Ireland Ambulance Service 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.
- 6.1.4 One of the following procedures should be followed and all actions should be recorded:
- 6.1.4.1 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.
- 6.1.4.2 The medicines may be retained on the ward, for the sole use of the patient in accordance with a POD scheme.
- 6.1.4.3 The medicines must be securely stored. PODs should be stored in a POD locker if available or in medicine trolley/cupboard separated from ward stock, securely closed and labelled with patient details at ward level. The patient's own medicines must be stored in a separate area away from ward stock. This is to avoid the inadvertent administration of one patient's property to another patient.
- 6.1.4.4 If a medicine has been changed/discontinued and the patient or patient's carer agrees, medicines may be destroyed according to local pharmacy site procedure (other than CDs). Patient's own CDs (all schedules) must be sent to Pharmacy for destruction.
- 6.1.5 Patient's own CDs should not be used for administration during the in-patient stay. They should be returned home via an identified adult; if this is not possible/appropriate, refer to CD policy for recording, storage and return to pharmacy. Return to Pharmacy of Patient's own CDs (all schedules) for destruction must be arranged with the nominated pharmacist.

6.2 Patient's own CDs

6.2.1 See 'Controlled Drugs Policy'.

6.3 Using patient's own medicines during an inpatient stay

6.3.1 The Pharmacy department will supply the majority of medicines administered during an inpatient stay. Occasionally Pharmacy may not stock a medicine a patient is taking. In exceptional circumstances where Pharmacy is unable to obtain the medicine in a timely manner, the patient's own medicine may be used, following assessment.

6.3.2 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.

6.4 Patient's Own Drugs (POD) scheme

- 6.4.1 Several wards in the Trust operate a POD scheme and such schemes have strict operating criteria; both nursing/midwifery and pharmacy staff must be trained and deemed competent to operate the POD scheme.
- 6.4.2 The POD scheme involves patients bringing their own medicines into hospital where they are assessed and, if suitable, used during the hospital stay and on discharge. If newly prescribed medication and/or an additional supply of existing medication is required, then 'one stop' dispensing is undertaken.
- 6.4.3 Medication is locked in bedside lockers for access by nurses or pharmacy staff.
- 6.4.4 PODs should be transferred with the patient when the patient is transferred to another ward.
- 6.4.5 Where POD lockers are used for the secure storage of medicines, out with an established POD scheme, this should be in accordance with a written local protocol. This written protocol should include key/fob management arrangements. This protocol should also include explicit actions to be taken to ensure POD lockers/drawers are cleared at each discharge.
- 6.4.6 Introduction of POD lockers/drawers or POD scheme should be with the approval of the Head of Pharmacy and Associate Director of Nursing for the area or their designated deputies. Staff operating a POD scheme should have their training updated every 2 years.

6.5 Destruction of patient's own medicines

6.5.1 These medicines are the property of the patient, and should not, therefore, be destroyed without the agreement of the patient or the patient's agent.

6.6 Unidentified medicines

- 6.6.1 Medicines that cannot be clearly identified must be placed in a sealed bag until they can be inspected by a pharmacist who will decide if they should be retained or destroyed.
- 6.6.2 If the nurse/midwife suspects that the medicines are illicit then they should follow the legacy Trust Policy for the management of patients and visitors in possession of illicit or suspected illicit substances.

6.7 Illicit substances

- 6.7.1 Under the Misuse of Drugs Act 1971, those in charge of premises have a responsibility to inform the police if they believe that anyone is committing an offence (in particular dealing of drugs on the premises).
- 6.7.2 Managers are liable to criminal prosecution if they allow such activity to take place on their premises.
- 48 Belfast Health and Social Care Trust Medicines Code

- 6.7.3 Patients and visitors must be informed that the Trust will not tolerate any use of illicit substances in Trust premises.
- 6.7.4 If visitors are seen to be in possession of a suspected illicit substance they must be asked to leave the Trust premises and may return only when they no longer have any illicit substances with them. The police must be informed.
- 6.7.5 If visitors are suspected of passing illicit substances to a patient or other visitors the Appointed Practitioner in Charge of the team must discuss the matter with the clinical service manager, consider banning the visitor from the Trust premises and informing the police.
- 6.7.6 If a member of staff considers that a patient may have, or be using, an illicit substance they should seek advice from a senior member of staff before approaching the patient.
- 6.7.7 Where a patient is suspected of being in possession of an illicit substance staff must discuss the situation with the patient. The patient must be asked to voluntarily give up the substance in question for the purposes of destruction. When confiscating an illicit (or suspected illicit) substance, staff must always have their actions witnessed by a colleague, must record their actions in the patient's notes and complete a BHSCT incident reporting form in line with Trust policy. If the patient refuses to hand over the suspected illicit substance, the person in charge should consider involving the police. An incident report form must be completed for any actions taken in relation to illicit/suspected illicit substances.
- 6.7.8 A search of a patient or their belongings may only be conducted if the unit has a written search policy. Where the unit does not have a search policy, a search of the patient should not take place and consideration should be given to involving the police.
- 6.7.9 Confiscated illicit substances must be handled and stored in a similar manner to Controlled Drugs and a clear audit trail must be in place.
- 6.7.10 Under no circumstances should suspected illicit substances be returned to the patient.
- 6.7.11 A decision to involve the police should only be made after consultation with senior managers of the unit and with the clinical team responsible for the patient's care. This decision should take into account the patient's current mental state including risk factors, the nature of the offence/allegation and patient/public protection issues. The discussion and outcome must be documented in the patient's record.
- 6.7.12 The PSNI may be asked to collect the illicit substances or they may be returned to Pharmacy. Staff should co-operate with any police investigation. When the police attend to remove the substance, then the officer collecting the substance should complete the appropriate part of the form for removal of unauthorised drugs or other suspicious substances. The officer should countersign the unit register of illicit substances to verify the removal. A copy of the completed form should be filed in the patient's notes.

- 6.7.13 The steps below should be followed when illicit substances are found or confiscated:
- 6.7.13.1 The unit/ward manager must be informed.
- 6.7.13.2 The unit/ward manager should contact the patient's Registered Medical Officer (or duty Consultant) and inform them of the incident. The doctor may decide to attend in person or may make arrangements for another doctor to attend.
- 6.7.13.3 The person finding the substance must complete the 'Form for Removal or Destruction of Illicit Substances' (Appendix 2). The ward name and assigned reference number from the ward register should be used as the only identifier on the form. The patient's name, Health and Care number, date of birth etc must not be used on the form.
- 6.7.13.4 Each ward should maintain a register of illicit substances found or removed from patients (Appendix 2). A sequential reference number will be assigned to each item. This will maintain confidentiality for the patient but still allow identification of the patient if necessary at a later stage.
- 6.7.13.5 The illicit substance should be placed in a suitable container e.g. sample bottle or sealable plastic bag and a label placed over the seal. The label must be signed and dated by the staff member who found the substance and the person in charge. The ward name and reference number from the ward illicit substances register should be written clearly on the label. The patient's name, Health and Care number, date of birth etc must not be used on the label.
- 6.7.13.6 A senior manager and the doctor in charge of the patient must complete Part B of the form. They must decide if the substances are to be taken for destruction by a Trust Pharmacy department and indicate this on the form.
- 6.7.13.7 Confiscated illicit substances must be returned to the nearest pharmacy department as soon as possible, i.e. within normal working hours it is not necessary to call on-call pharmacist to remove illicit substances. The ward should liaise with the pharmacy department to organise removal of the illicit substance.
- 6.7.13.8 If the Pharmacy department is taking the substance for destruction, then Part C of the form should be completed by the pharmacist. The pharmacist should countersign the ward register of illicit substances to verify the removal. A copy of the form should be filed in the patient's notes.

6.8 Overdose medicines

6.8.1 A record must be kept in the medical notes of any medicines brought into hospital with an overdose patient. The record should include patient identity details, name of the medicine(s), number of eg tablets brought in and any dose or other relevant information from the dispensing label. Once this record has been made, the medicine(s) may be destroyed. This destruction should be witnessed and the names of both members of staff involved in the destruction of the overdose medicine included in the medical notes.

7 Supplies of medication at discharge

- 7.1 At admission, patient's own medicines are either returned home with the patient representative or stored at ward level until discharge. Patient consent is required for the destruction of medications that have been discontinued during hospital stay.
- 7.2 At discharge, patients will receive a supply of medications which the patient is short of at home or medication which has been newly prescribed during hospital stay. This is to avoid duplication of medication in the patient's home.
- 7.3 Prescribers may specify an alternative quantity of medication i.e. less than 28-day supply at discharge, for either clinical or practical reasons, e.g.
- 7.3.1 Overdose/self-harm patient, (who will normally be discharged with a maximum of 7-days' supply of medicine), mental health, learning disability, Child and Adolescent Mental Health Service (CAMHS), or drug dependent patient or in unusual or specific circumstances. While these patients will normally be discharged with a maximum of 7-days' supply of medicines, more may be requested if the 7 day period is not enough time for the person to arrange a prescription from their GP.
- 7.3.2 Where it is more appropriate or practical to dispense less than 28 days for a given item in relation to available stock of unusual items or pack size.
- 7.4 It is recognised that dispensing a 28-day supply of medicines may incur waste for some patients. This may be the case, for example, if an interim arrangement is made to administer medicines until a new blister pack can be arranged. For nursing home patients particularly, a check should be made with the nursing home as to which items are needed.
- 7.5 BHSCT Pharmacy departments do not routinely supply discharge medication in a compliance aid e.g. Medidos or MDS system unless the patient is visually impaired.
- 7.6 Individual hospitals operate a variety of medication management schemes including one-stop dispensing for discharge and schemes which involve the use of patient's own medicines from admission. Patients within these schemes will be discharged with at least a 14 day supply of medication.
- 7.7 Pharmacy will provide an appropriate dosing device or oral syringe with oral liquid medicines on discharge.
- 7.8 The average time for dispensing a discharge prescription is two hours. Discharge prescriptions should arrive in Pharmacy with a minimum of four hours' notice. Priority will be given to prescriptions that have been planned and arrive in Pharmacy with greater than four hours' notice.
- 7.9 The following information is intended as a guide for prescribers and Pharmacy departments. Prescribers will not need to know the pack size of the original pack, however they will need to consider if an item is not intended to be continued for 28 days:

| Category | Examples | Guidance |
|--|---|---|
| Warfarin | The original pack for both 1mg and 3mg is 28 tablets. Pharmacy will label with either a maintenance dose (as specified by the prescriber) or e.g. 'To be taken as per INR. Take at the same time each day'. | |
| Medicines not intended for long term treatment | Night sedation (if initiated for hospital stay only) e.g. temazepam, zolpidem, zopiclone, zaleplon Anti-emetics e.g. cyclizine Laxatives <i>Helicobacter pylori</i> eradication therapy Benzodiazepines Oral potassium supplements Oral magnesium supplementation Antibiotics | Prescribers should review requirements at discharge. One original pack should be supplied at discharge. More or less than a 28-day supply of a medication may be prescribed and dispensed. The prescription should state the number of days to complete the course or original pack can be given e.g. if antibiotic prescribed for prophylaxis. In the case of night sedation or benzodiazepines, prescribers should ensure that patients are prescribed a supply to take home only in exceptional circumstances. |
| Analgesia | Paracetamol, co-codamol, tramadol, NSAIDs | Prescribers must review analgesia before discharge. One or two original packs should be prescribed depending on individual circumstances and time of discharge; for example, two original packs may be required over a bank holiday weekend. Prescribers should state if treatment with NSAID is short term (state number of days) otherwise an original pack will be issued. |

| Category | Examples | Guidance | |
|---------------------------|---|---|--|
| Dose titrations | Carbamazepine, gabapentin, lamotrigine, amiodarone | Caution if upward/downward titration of dose is required within 4 weeks of discharge. Include specific information on script. | |
| Reducing doses | Chlordiazepoxide | State the number of days required and reducing dose instructions. | |
| | Oral steroids | State full instructions for reducing dose or state maintenance therapy. | |
| Controlled drugs (CDs) | A 7-day supply should be prescribed in accordance with CD prescription writing requirements. Prescribers may specify an alternative quantity on discharge either on clinical grounds or to facilitate weekend leave. | | |
| Insulins | One original pack (one vial/one box of cartridges/one pen) to include patient information leaflet | | |
| Miscellaneous | Original packs of topical preparations, eye preparations, inhalers etc will be supplied. | | |

7.10 Prescriptions for discharge or home leave medicines

- 7.10.1 Prescriptions for discharge or home leave medicines are ordered by a doctor using the Trust discharge prescription.
- 7.10.2 BCH, Mater and RGH sites only: Where medicines have been dispensed for an inpatient, these medicines must be returned to Pharmacy for relabelling and checking at discharge with the discharge prescription.
- 7.10.3 For planned/complex discharges, best practice is that prescriptions should be sent to the Pharmacy department at least 24 hours in advance or should be prioritised and sent to Pharmacy early in the day; for some sites they must be sent on specified days in accordance with local agreement (e.g. Muckamore scripts to be in Knockbracken by Tuesday of each week).
- 7.10.4 Prescriptions for simple/non-complex discharges should be sent to Pharmacy at least four hours' in advance of discharge time.
- 7.10.5 The following information must be provided on discharge prescriptions. (There are additional requirements for CD prescriptions outlined in the 'Controlled Drugs Policy'):

- 7.10.5.1 Indicate if home leave or discharge prescription.
- 7.10.5.2 Expected date of discharge/home leave and date of writing prescription.
- 7.10.5.3 Number of days required for discharge medication (28 days will be given automatically for in-patient discharge prescriptions unless doctor indicates a shorter period of time or is a shorter length of supply eg for Mental Health units).
- 7.10.5.4 Patient's full name, address, date of birth and Health and Care number. The use of addressographs is encouraged (except for CD prescriptions).
- 7.10.5.5 Check that the patient's identification information on the prescription matches the patient's Kardex.
- 7.10.5.6 A full list of medicines should be provided on the discharge prescription, including those medicines where a supply at discharge is not required.
- 7.10.5.7 The approved name in capital letters as per Trust 'Policy for appropriate use of generic names of medicines'. When differences between brands affect the bioavailability of a medicine, the brand name should also be used, e.g. theophylline, ciclosporin, insulin and lithium.
- 7.10.5.8 The use of abbreviations for medicine names is not permitted.
- 7.10.5.9 Dosage form must be specified (solid dose, tablets or capsules, is understood unless otherwise stated).
- 7.10.5.10 For antibiotics the number of days to finish the course must be specified.
- 7.10.5.11 For reducing doses e.g. steroids, the full course should be documented.
- 7.10.5.12 For pain relief, review current medications and specify on the prescription the number of days you wish the patient to receive.
- 7.10.5.13 Roman numerals cause confusion that might lead to medication errors and should not be used.
- 7.10.5.14 The frequency of administration must be stated.
- 7.10.5.15 For medicines prescribed as 'PRN' the prescriber must indicate the quantity to be supplied or no supply will be made.
- 7.10.5.16 The signature and professional registration number (and bleep number/contact number if applicable) of the doctor must be on the prescription.
- 7.10.5.17 The original prescription and all copies must be sent to the Pharmacy department to ensure that any alterations or clarifications made by a pharmacist will appear on the GP and ward copy.
- 7.10.5.18 Patient identification information must be on all copies of the prescription.
- 7.10.5.19 Prescribers should inform the GP of any changes to therapy, such as dose changes, discontinuation or initiation of medicines, the duration of any new therapy and any monitoring the GP is required to undertake.
- 54 Belfast Health and Social Care Trust Medicines Code

7.11 Handling patient's own medicines on discharge

- 7.11.1 Prescribers must ensure that when making changes to a patient's medicines near to the point of discharge, confirmation is sought as to whether a discharge prescription has already been written. Where a discharge prescription has already been written, this must be updated and nursing/midwifery staff alerted to the change.
- 7.11.2 Prior to discharge, any medicines stored on the ward for the patient should be reviewed by a nurse/midwife or pharmacist to ensure they are safe for the patient to continue to take after discharge. If it is deemed inappropriate to return a patient's medicines to them, this should be recorded in the patient's medical notes and the medicines (other than CDs) may be destroyed according to local pharmacy site procedure. Patient's own CDs (all schedules) must be sent to Pharmacy for destruction.
- 7.11.3 As outlined in the Trust 'Policy for self discharge contrary to medical advice (CTMA)': 'Patients must be informed that they are entitled to receive sufficient medicines in accordance with policy unless their clinical team deem it an inappropriate risk. This decision must be documented in the medical notes.'

7.12 Discharge prescription for anticoagulants

- 7.12.1 It is essential to confirm who will provide monitoring of anticoagulant therapy after discharge as not all GPs provide this service.
- 7.12.2 Discharge prescriptions for oral anti-coagulants must be sent to Pharmacy with an 'Oral Anticoagulant Therapy Prescription Chart/Discharge Form'.
- 7.12.3 For patients initiated on warfarin the 'Oral anticoagulant therapy record book' (yellow book) from the anticoagulant pack is sent to Pharmacy for completion with dose instructions.
- 7.12.4 If the patient has brought their 'Oral anticoagulant therapy record book' (yellow book) into hospital this should be sent to Pharmacy with the 'Oral Anticoagulant Therapy Prescription Chart/Discharge Form'; anticoagulant doses to the next INR check should be completed in the 'Oral anticoagulant therapy record book'; if an existing warfarin patient either does not have an 'Oral anticoagulant therapy record book' or does not use one, Pharmacy should complete the dosing instructions in a 'Temporary warfarin discharge patient information' card.
- 7.12.5 Following dispensing, once the anticoagulant prescription chart has been returned to the ward, the top white copy of the anticoagulant prescription chart should be sent to the GP. If the patient is attending a hospital anticoagulant clinic, the top white copy of the prescription should be photocopied and sent to the clinic.

7.13 Oral Substitute Therapy (OST) on discharge from secondary care

7.13.1 In general there should be no requirement for supply from hospital of OST medications (methadone or buprenorphine). These medicines should not be supplied to patients on discharge, apart from under exceptional circumstances when this is necessary to maintain treatment continuity.

- 7.13.2 The supply arrangements with the patient's normal community pharmacy should be put back in place as soon as possible ie same day or next day, depending on when the final inpatient dose was given.
- 7.13.3 In the exceptional circumstances where a supply is made from hospital then:
- 7.13.3.1 It should be with the full agreement of their normal OST prescriber, where practical.
- 7.13.3.2 It must be the minimum necessary to cover days where supply will not be possible in the community, e.g. a Sunday or a Bank Holiday when the community pharmacy is closed.
- 7.13.3.3 Information about what amount will be given on discharge should be communicated to the community pharmacy preferably in advance of the discharge. If this is not possible, the community pharmacy must be contacted as soon as they reopen.
- 7.13.4 In all circumstances, it should be confirmed that clinical staff have taken the necessary steps to reinitiate treatment in the community prior to discharge, whether a supply is made or not. This includes contact with the community pharmacy and the patient's usual OST prescriber. Particular care should be taken to ensure patients do not get a duplicate supply when they leave the hospital. If doses have been omitted in hospital, this should also be communicated, as a dose reduction may be required.
- 7.13.4.1 In very rare cases, OST may be commenced in hospital by an addiction team, for example someone with an osteomyelitis not known to services prior to admission. On-going supply for these patients will be managed on a case-by case basis by the addiction team.

7.14 Specialist medicine therapy for administration in community

7.14.1 Wherever possible patients should be trained to self-administer. In certain circumstances, community nurses are asked to administer medicines to patients which have been prescribed by Hospital Consultants/Medical Staff and given to the patient on discharge (e.g. enoxaparin, filgrastim). Community nurses can only administer this medication on receipt of an 'Authorisation to Administer' form. These forms are available through the Trust Intranet and must be completed by the hospital prescriber. Staff arranging discharge must ensure the form accompanies the patient home as it is the written instruction for the Community Nurse to administer the prescribed medicine.

7.15 Collection and delivery of discharge or home leave medicines

- 7.15.1 Prescriptions will be returned to the ward by a member of pharmacy staff, via the pneumatic tube, or collected by a member of ward staff, hospital portering or transport (on display of Trust photographic ID).
- 7.15.2 Ward staff should check prescription tracking system (script tracker) if available before telephoning Pharmacy about a prescription or sending staff to collect.

56 Belfast Health and Social Care Trust Medicines Code

7.16 Discharge of a patient with a syringe pump

See Trust policy 'Subcutaneous use of the McKinley T34 Ambulatory Syringe Pump'

7.17 Dispensing of discharge prescriptions when Pharmacy is closed.

In exceptional circumstances and only when other options have been exhausted, nursing staff may supply medication for a patient to facilitate discharge. See Trust policy 'Supply of discharge medication from wards when Pharmacy is closed'.

7.18 Checking of dispensed discharge medicines at ward level

- 7.18.1 Written Standard Operating Procedures regulate the dispensing of all medicines in the Pharmacy department. This includes a check by a pharmacist for clinical appropriateness and a final check for accuracy of dispensing. An audit trail identifies all members of pharmacy staff involved in dispensing each prescription. Subsequently, checks to discharge medicines at ward level must be limited to checking the label only. Additionally, amendments or additions to Pharmacy prepared labels are not permitted.
- 7.18.2 A nurse/midwife must check the take home medicines against the Kardex to ensure no changes have been made since the discharge prescription was written. Attention should be paid to the patient's name, date of birth, the name of the medicines and the prescription dose and frequency. A check should be made to ensure that no items have been missed off the take home prescription particularly if a medicine is newly prescribed and that medicines aren't stored separately from main take home medicines such as fridge items, CDs or PODs.
- 7.18.3 In particular, the patient's attention should be drawn to changes in the dose of prescribed medicines, discontinuation of medicines or the commencement of new medicines. The patient must give their permission for the destruction of medicines that are no longer prescribed.
- 7.18.4 Nursing/midwifery staff discharging a patient should also ensure the correct bag of take home medicines is handed over to the correct patient at discharge. Patient identity should be confirmed by checking patient name, date of birth and Health and Care number on the bag of discharge medicines against the patient name, date of birth and Health and Care number on the bag of discharge medicines against the patient name, date of birth and Health and Care number on the patient and Care number on the patient's identity bracelet, as appropriate. If there are any discrepancies these must be referred to the Pharmacy Department or, outside normal opening hours, the Emergency Duty Pharmacist.
- 7.18.5 Where a family member is collecting discharge medication on behalf of a patient, then they should be asked to confirm the patient's full name and address. The identity of the person collecting should also be checked.
- 7.18.6 Where a Trust member of staff is collecting the discharge medication on behalf of a patient, they must confirm the patient's full name and address; they should have a valid Trust photo ID badge.
- 7.18.7 Where NI Ambulance Service (NIAS) (or other non BHSCT healthcare professional) are collecting medication on behalf of a patient, they should be

asked to confirm the patient's full name and address. They must also have a valid NIAS or other valid photo ID badge and this must be checked.

- 7.18.8 In exceptional circumstances, where a discharge prescription is being delivered to a patient by e.g. taxi, the person collecting the medicines from the ward should have a valid photo ID badge and this must be checked. See also section 8.23.7. The delivery address (including postcode) should be confirmed with them. The taxi driver must sign the discharge prescription and print their name. The taxi driver must confirm with the ward when the medicines have been delivered. If any problems delivering a discharge prescription, the taxi driver must return with the discharge medications to the ward.
- 7.18.9 If the Kardex has been altered since the discharge prescription was written, then the item that has been changed along with the rest of the prescription must be returned to the Pharmacy department along with a new prescription for that item.
- 7.18.10 Certain areas such as Day Case units, some outpatients and inpatient areas, and Emergency Departments, in agreement with Pharmacy, have over-labelled packs for certain classes of medicines, usually antibiotics and analgesics. These medicines must be prescribed by an authorised prescriber and are over-labelled with the dose and directions for use. The labels have sections for nursing/midwifery staff to complete patient details, date of issue and the ward/department supplying these medicines.
- 7.18.11 These departments must have a local agreed policy with Pharmacy and a protocol (including an accountability log) for supplying these medicines. The accountability log should include date and time of supply, patient name, Health and Care number, name, strength and quantity of pre-pack supplied and the signature and designation of staff who made the supply. These records should be regularly checked by Pharmacy with prescription reconciliation, where necessary.
- 7.18.12 Outpatient prescriptions are restricted to patients who require treatment which is not available in primary care e.g. red-listed medicines or unlicensed medicines. If the patient requires a change in their current medication, then the prescriber should complete the Trust outpatient treatment advice note or Emergency Department flimsy informing the GP of the required change in medication. See the Trust TAN policy.
- 7.18.13 The prescriber should inform the GP of the reason why the medication has been recommended, initiated or discontinued. The prescriber should also specify the duration of therapy and any monitoring by the GP that is required on the outpatient treatment advice note or Emergency Department flimsy.

7.19 Prescription Tracking System (script tracker)

7.19.1 An electronic prescription tracking system (script tracker) is available on BCH, Mater, Musgrave and RVH sites and can be accessed on the hospital intranet site. The username and password can be obtained from the Ward/Department Sister or Charge Nurse.

- 7.19.2 Wards and departments can access 'script tracker' to check:
 - that a prescription for a specific patient has been received in Pharmacy
 - the current status of a prescription
 - when a prescription is ready to be collected i.e. when the status reads 'checked'.
- 7.19.3 Correct use of 'script tracker' will reduce the number of phone calls made to the Pharmacy dispensary. Phone calls interrupt the dispensing process and slow down staff processing prescriptions.

7.20 Temporary home leave/pass medication

- 7.20.1 The maximum duration for a leave prescription is recommended at 28 days. For periods of leave beyond this a new prescription should be issued and a new supply made.
- 7.20.2 All patients should be advised to bring back the containers of medicines when returning from pass to allow a nurse/midwife to check the patient has taken the medicine appropriately.
- 7.20.3 On occasion, patients may leave for pass later than expected and subsequently may not require all of the doses prepared in their take home medication. Extra doses must not be removed from containers.
- 7.20.4 Provided not more than one extra day's medicine is supplied, the patient should be instructed to bring back any unused medicine to the ward. If more than one extra day's medicine has been prepared, the nurse/midwife should consult a doctor who will advise if it is appropriate to permit the patient to receive the medicines. If it is not appropriate, the doctor should write a new prescription which should then be dispensed in the normal manner.
- 7.20.5 On occasion, a patient's pass from the ward may be extended and additional take home medication might be required. Under no circumstances should extra medicines be added to take home medicines already prepared by the Pharmacy department or from ward stock.
- 7.20.6 This situation may be resolved as follows:
- 7.20.6.1 A new supply of take home medicines is obtained using a new prescription for the complete duration of pass. Any unneeded take home medicines already dispensed by the Pharmacy or from ward stock must be returned to the Pharmacy department. This is the preferred method if the patient has not yet left the ward.
- 7.20.6.2 Alternatively an additional supply of take home medicines is obtained using a new prescription for the additional period only. The two sets of medicines should be given to the patient in separate bags with instructions to finish one set before starting the other. This is the preferred method if the patient has already left the ward or intends to leave and return for additional supplies later.

8 Storage and security of medicines – general principles

- 8.1 The appointed nurse/midwife in charge of a ward or department is responsible at all times for the storage and security of all medicines on the ward or department. Medicines must be locked away at all times.
- 8.2 The Pharmacy department must approve the design and location of all new medicine storage cupboards and medicine trolleys before the order is processed by Supplies Department. The maximum temperature in the room in which medicines are stored must not exceed 25°C.
- 8.3 The appointed nurse/midwife in charge of a ward or department should review security access to medicines storage, where this is controlled electronically, annually and when staff transfer to another area or cease employment. Where electronic access control systems are used to restrict access to medicine storage areas they must be auditable.
- 8.4 The Head of Pharmacy and Medicines Management and appointed Deputy Heads of Pharmacy must approve security access to Pharmacy Departments where this is not controlled by Pharmacy.
- 8.5 Medicine cupboards, pharmaceutical burn bins and sharps bins must not be located where patients or the public can access them.
- 8.6 Doors leading to areas where medicines are stored should have controlled access.
- 8.7 There should be separate lockable cupboards or storage areas as follows:
 - CD cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973). Epidural infusions containing CDs should be stored in a separate CD cabinet solely for that use.
 - Internal Medicines Cupboard(s) including separate storage for;
 - Oral medication
 - Injections including separate storage of local anaesthetic agents
 - · External Medicines cupboard(s) including separate storage for
 - Disinfectants
 - Flammable products
 - Diagnostic agents, including urine testing
 - Dressings
 - Pharmaceutical refrigerator/freezer for medicines
 - Patient's Own Drugs
 - IV Fluids and sterile Topical Fluids including separate storage areas for high risk IV fluids such as potassium containing fluids, hypo- and hypertonic sodium chloride solution, epidural and other local anaesthetic solution for infusion and sodium bicarbonate IV fluids etc.
- 8.8 There should be a designated storage location for medical gases. Refer to the Trust Policy for the Management of medical gas pipelines and medical gas cylinders.

- 8.9 Medicine cupboards to be used for internal and external medicines should comply with the current British Standards BS 2881 (1989). The appropriate Health Building Note should be referred to in the design or refurbishment of medicine storage areas.
- 8.10 All medicine cupboards including the CD cabinet and pharmaceutical refrigerator/freezer must be kept locked at all times when not in use. Exemptions to this are only acceptable as part of an approved Trust scheme for safe custody of medicines.
- 8.11 Intravenous fluids for ward stock should be stored in the original box/container or in an appropriately labelled container.
- 8.12 The medicine trolley should be lockable and immobilised when not in use. When in use, it should not usually be left unattended when not secured, but if this is unavoidable, the trolley must be left locked.
- 8.13 On occasion, medicines may be stored at temperatures outside the manufacturer's recommendations in ward/clinical areas. While it is recognised that other considerations should be taken into account at ward/clinic level, such as timely access to medicines and their safe and secure storage, they should not be stored under conditions that may affect their quality. Further information is available at Risk Management of Medicines Stored in Clinical Areas: Temperature Control NHS Pharmaceutical Quality Assurance Committee Edition 1 June 2015.
- 8.14 For clinical emergencies, e.g. cardiac arrest, all wards should have a source of urgent medicinal products. These should be held in boxes or kits clearly marked 'for emergency use'. These boxes should be tamper-evident and should not be held in a locked cupboard, but at a strategic and accessible site. Once a box has been opened, a replacement should be provided by the Pharmacy and the opened box returned to the Pharmacy. All sharps must be removed before returning to pharmacy. Emergency boxes including hyperkalemia and other kits which are contaminated with blood must be decontaminated before returning to Pharmacy.
- 8.15 When schemes for PODs or self-administration are in operation on the ward each patient involved in the scheme should have a lockable receptacle for medicines (e.g. drawer, individual cupboard).
- 8.16 Particular care must be taken to ensure that medicines which are liable to diversion or abuse e.g. benzodiazepines, analgesics, steroids, antibiotics, are always stored correctly in order to prevent unauthorised access.
- 8.17 Visitors should be advised that if they must bring their own medicines with them when in the Trust, these personal medicines must not be left unattended.

8.18 Custody and loss of medicine cupboard keys

8.18.1 Safe and secure storage of medicines is the responsibility of the appointed nurse/midwife/AHP/registered professional in charge of the ward and they should have a system in place for the management of medicine cupboard keys. The nurse/midwife in charge is responsible for controlling access (by keys or

other means) to the medicine cupboards and trolley. The responsibility remains with the appointed nurse/midwife in charge even if he/she decides to delegate the duty to another nurse.

- 8.18.2 Medicine cupboard keys and Controlled Drug keys must be accounted for at the end of each change of shift/handover.
- 8.18.3 Loss of the medicine cupboard keys must be reported immediately for the appropriate action to the nurse/midwife in charge who will also inform their line manager and ensure an incident form completed. Pharmacy must also be notified immediately. If keys cannot be found within 24 hours, Estates should be contacted to change the medicine cupboard locks.
- 8.18.4 Medicine cupboard keys should be identifiable so that if any keys are lost they can be traced.
- 8.18.5 The nurse/midwife in charge of the ward or department and nominated Deputy must know the location of spare medicine cupboard keys.

8.19 Storage and disposal of Controlled Drugs (CDs)

8.19.1 Refer to 'Controlled Drugs Policy'.

8.20 Loss of medicines or unauthorised access

- 8.20.1 When there has been unauthorised access to medicines, discovery of evidence of tampering with medicines, unexplained high usage of medicines on a ward, theft or loss of ward medicines, this must be reported immediately to the nurse/midwife in charge and the Pharmacy Services Manager who will conduct an initial investigation and subsequently inform their line managers.
- 8.20.2 Alternatively, Pharmacy may ask the nurse/midwife in charge to explain any increase in usage of medicines especially those medicines liable to diversion. It then becomes the responsibility of the Directorate and the Pharmacy department to investigate the matter enlisting the support of other disciplines and liaising with the police as appropriate. It is the responsibility of the Pharmacy Services Manager to contact the police.

8.21 Security and storage of stationery used to order medicines

- 8.21.1 Stationery used to order medicines such as top-up lists, CD requisition books, non-stock pharmacy requisitions and discharge prescriptions must be stored securely when not in use.
- 8.21.2 Only one top-up file or requisition book is used by a ward at any one time. The requisition book is uniquely numbered and Pharmacy will only issue a new book on an order and receipt of the last page in the current requisition book.
- 8.21.3 The ward and the nurse/midwife in charge must report the loss or theft of any of these books immediately to Pharmacy and complete an incident form. Wards will not be issued with a new book unless Pharmacy receives a copy of the incident form/notification of Datixweb reference number. In the event of a missing requisition book, wards/departments will still have access to medicines using a requisition book in Pharmacy.
- 62 Belfast Health and Social Care Trust Medicines Code

8.22 Pharmaceutical refrigerators

- 8.22.1 All wards or departments that use medicines requiring refrigeration must have a Pharmacy Specification Refrigerator to include the following key features:
- 8.22.1.1 Constructed of impervious, cleanable materials both internally and externally
- 8.22.1.2 Single cooler panel without a freezer box, salad drawer or door shelves
- 8.22.1.3 Maintains the temperature between 2°C and 8°C
- 8.22.1.4 Automatic defrost
- 8.22.1.5 Grille-type shelving
- 8.22.1.6 Integral air circulating fan
- 8.22.1.7 Lockable with removable key
- 8.22.1.8 If the refrigerator will be used to store hazardous medicines e.g. cytotoxic chemotherapy, it should have a transparent glass door.
- 8.22.1.9 The refrigerator must have an external digital temperature display (to +/- 0.5°C), be able to display current, maximum and minimum temperatures.
- 8.22.2 The location or contents of a fridge should be considered and additional features such as audible or visible alarm when the temperature is out of range and audible or visible 'door open' alarm or maximum and minimum temperature memory for continuous monitoring.
- 8.22.3 Refrigerators on wards, departments or facilities holding either a high value (>£500) of stock or stock of a critical nature should be fitted with a continuous automated temperature monitoring system and/or remote alarm terminals providing mains failure alarm signal and temperature deviation alarm signal. A local written protocol should be developed to respond to refrigerator alarms including out of hours response for areas that are not staffed 24/7, 7 days per week.

8.22.4 Pharmaceutical Refrigerators - Purpose and Installation

- 8.22.4.1 Domestic refrigerators are not suitable for the purpose of storing temperature controlled pharmaceuticals. The correct storage temperature for a medicine can be found on the outer packing of its container or in the Summary of Product Characteristics (SPC) which can be accessed from http://www. medicines.org.uk/emc/ via Trust intranet.
- 8.22.4.2 The refrigerator must only be used to store medicines which require storage between 2°C and 8°C. Food, milk, drink, nutritional products or specimens must not be stored in the refrigerator.
- 8.22.4.3 The size of the fridge should reflect the normal requirements of the ward/department see also 8.22.4.6.4 regarding fridge overloading.

- 8.22.4.4 The refrigerator must be installed in an environment where the surrounding ambient temperature does not affect its temperature control. The refrigerator should be sited away from external windows, and all heat sources e.g. radiators, direct sunlight.
- 8.22.4.5 The refrigerator should be hard wired into a fused spur or as a minimum, the socket or plug must be clearly labelled with 'Do not switch off'.

8.22.4.6 Pharmaceutical Refrigerators - Operation

- 8.22.4.6.1 A written standard operating procedure (SOP) should be available for the storage of medicines in refrigerators, the process for recording and monitoring of temperatures, the staff responsible for undertaking this and the action required when temperature deviations are recorded.
- 8.22.4.6.2 The refrigerator is a medicines cupboard and therefore must remain locked. The key(s) must be kept by the nurse/midwife in charge of the ward/department.
- 8.22.4.6.3 The acceptable temperature range for pharmaceutical refrigerators is 2°C to 8°C. Any deviation must be recorded and remedial action taken.
- 8.22.4.6.4 Refrigerators must not be overloaded there should be space for the air to circulate around the internal space, medicines should not be in contact with the sides or floor of the refrigerator or come into contact with the chiller plate, coil or motor.
- 8.22.4.6.5 Refrigerators should be kept clean both inside and out, including removal of dust build-up on the rear panel. They should be inspected regularly for ice build-up which is likely to indicate a fault, and damage to door seals which will result in the fan and compressor being overworked.
- 8.22.4.6.6 The temperature (current, maximum and minimum) of pharmaceutical refrigerators in wards and departments must be recorded at least once a day, preferably at the same time each day.
- 8.22.4.6.7 Locations that hold low value of stock (< £500) and which are not open 24/7 should record fridge temperatures on each day that they are open however, it must be possible to reset the temperature recording device after temperature readings are taken and particular attention should be paid to temperature readings when the unit re-opens e.g. after a weekend. It would also be good practice to record temperature readings when the department closes e.g. on a Friday afternoon.
- 8.22.4.6.8 A record of the values must be made in the appropriate sections of the Pharmaceutical Refrigerator Temperature Log (Appendix 2) which should be located close to the fridge. The log must be retained for audit purposes for a minimum of one year.
- 8.22.4.6.9 If there is more than one refrigerator in the same room, each one should be clearly labelled and identified (e.g. Fridge 1, Fridge 2 etc) and cross referenced to the appropriate Temperature Log and operating manuals.

64 Belfast Health and Social Care Trust Medicines Code

- 8.22.4.6.10 Once the temperature has been recorded and reviewed, the temperature recording device must be reset.
- 8.22.4.6.11 Any temperature deviations must be reported to the nurse/midwife in charge of the ward or department.
- 8.22.4.6.12 Estate Services should be contacted for urgent remedial action. If a fault is detected during normal monitoring, the temperature log should be checked to ascertain when the refrigerator was last recorded as being in range.
- 8.22.4.6.13 For advice regarding the stability of the pharmaceuticals affected e.g. if a break in the cold chain, contact the Pharmacy department or the Regional Medicines Information Service (Tel: 028 950 40558) (Monday-Friday 9am-5pm).
- 8.22.4.6.14 It may be necessary to quarantine the contents of the fridge until stability information is obtained. Any medicines moved to an alternative fridge must be clearly labelled and quarantined within the fridge until the outcome of the stability enquiry is known.
- 8.22.4.6.15 If advised, all pharmaceuticals must be removed from the refrigerator and disposed of in accordance with the Trust's waste policy. A list of the items wasted (description and quantity) must be made and reported to Pharmacy. An incident form must also be completed. Replacement pharmaceuticals will only be issued when the refrigerator has been repaired and is functioning according to its specification. If a refrigerator remains out of use for any time, then temperatures must be monitored for at least 24 hours to ensure the correct temperature has been achieved before being used to store medicines.

8.22.4.7 Pharmaceutical Refrigerators – fault reporting and maintenance

- 8.22.4.7.1 Faults should be reported immediately to Estates helpdesk and any remedial action taken to prevent loss of stock.
- 8.22.4.7.2 All Pharmaceutical refrigerators must have at least an annual service. Service contracts are managed by Estate Services. Estate Services must be notified of new or disposed of refrigerators so that the contract can be updated. The nurse/midwife in charge of the ward/department or service head is responsible for ensuring that the service takes place.
- 8.22.4.7.3 Batteries for digital thermometers should be replaced 6-12 monthly. If using a stand-alone thermometer, return it to the refrigerator and ensure that the refrigerator door is securely closed.

8.23 Transport of Medicines

- 8.23.1 Systems should be in place to ensure there is an audit trail for any medicines issued, received, transferred or delivered including receipt by a patient. There should be a signature at each point of transfer.
- 8.23.2 All containers and packages are clearly labelled with the final destination.
- 8.23.3 Equipment used in the transport of medicines should be designed to ensure the security, integrity and quality of the medicine is not compromised and where appropriate the cold chain is maintained.

- 8.23.4 Designated members of hospital transport, portering staff or pharmacy support services will undertake deliveries of 'top-up' stock medicines to wards or facilities in locked or tamper evident pharmacy boxes. The box(es) will be delivered to the designated storage room for medicines.
- 8.23.5 The driver/support services must inform a nurse/midwife that an order has been delivered. The nurse/midwife should, at the earliest opportunity, open the box and place any items requiring fridge storage into the ward fridge. The order must be checked as outlined in section 5. Pharmacy requisitions, discharge prescriptions or medicines may also be transported back to the ward by ward staff (who will sign for collection) or by the pneumatic tube transfer system. Ward staff must present Trust photographic ID when collecting pharmaceuticals from Pharmacy.
- 8.23.6 The pharmacy box must be left in a designated area for pharmacy support services staff to collect and return to Pharmacy. Where locked boxes have been allocated to a ward or department, the key should be retained with the ward medicines keys.
- 8.23.7 Transfer of medicines outside the healthcare organisation e.g. to patient's homes, to other Trust pharmacies, should always be authorised and receipt acknowledged by the receiving body. Where intermediate carriers (e.g. recognised Trust taxi firm, couriers, homecare companies) are used, recording of collections should be in place.
- 8.23.7.1 Transport by taxi must meet the following criteria:
- 8.23.7.1.1 Must be a Trust recognised taxi firm.
- 8.23.7.1.2 Must be ordered as per Trust procedures.
- 8.23.7.1.3 ID should be provided by the taxi driver.
- 8.23.7.1.4 Taxis must not carry non-Trust passengers while transporting medicines.
- 8.23.7.1.5 Taxi drivers must sign to confirm receipt of the medicines for delivery. If any problems with completing the delivery the taxi driver must return with the medicines to the Trust department/ward from which they collected the delivery.
- 8.23.8 Trust staff engaged in the transportation of medicines should carry Trust identification.

8.24 Medicines transport via pneumatic tube transfer system

8.24.1 Medicine/paperwork relating to Pharmacy may be transported to and from Pharmacy, with some exceptions, in designated pharmacy (green) canisters in accordance with the pneumatic tube transfer system procedure (Appendix 1).

9 Investigational Medicinal Products (IMPs)

- 9.1 An Investigational Medicinal Product (IMP) is the pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial.
- 9.2 Products other than the test product, placebo or comparator may be supplied to subjects participating in a trial. Such products may be used as support or escape medication for preventative, diagnostic or therapeutic reasons and/or to ensure that adequate medical care is provided for the subject or to induce a physiological response.
- 9.3 Commercial and non-commercial interventional trials of medicinal products in human subjects are regulated by the provisions of The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended).
- 9.4 All research in the HPSS, including clinical and non-clinical research, research undertaken by HPSS staff using HPSS resources, and research undertaken within the HPSS by industry, charities, research councils and universities, must be undertaken in accordance with the requirements of the DHSSPS Research Governance Framework for Health and Social Care.
- 9.5 Guidance on the management of clinical trials of medicines in NHS hospitals is supplementary to the overarching guidelines for the safe and secure handling of medicines in hospitals given by the Duthie Report/Use and Control of Medicines and the NHS Controls Assurance Standards on Medicines Management (Safe and Secure Handling).
- 9.6 Clinical trials of Investigational Medicinal Products should be carried out in compliance with Trust Research Office Standard Operating Procedures.
- 9.7 The principal investigator for a clinical trial of an investigational medicinal product must contact the Pharmacy department well in advance of the planned start date to agree trial-specific procedures for management of all medicinal products to be used in the trial.
- 9.8 The Clinical Trials Pharmacist will review and provide advice on regulatory compliance, source, quality, acceptability, packaging, labelling, cost, storage and safe handling in relation to all medicinal products to be used in a clinical trial.
- 9.9 A Protocol Impact Assessment Form (PIAF) must be completed and approved by the Clinical Trials Pharmacist for submission to the Trust Research Office to gain approval to carry out a clinical trial involving medicinal products.
- 9.10 All medicinal products used in research must be procured, managed, stored, dispensed and distributed by the Trust Pharmacy.
- 9.11 Stocks of IMPs must not be held in offices, wards or departments (unless there are specific reasons for supplies to be held at a ward, clinic or department e.g. held on a ward because the medicine has been supplied for administration to an inpatient and this arrangement has been approved by the Pharmacy department. The security, storage and temperature monitoring requirements detailed in Section 8 will apply unless there are particular trial requirements which must be detailed in a trial-specific Standard Operating Procedure.)
- 9.12 Records must be kept of receipt, dispensing, issue, administration and disposal of all IMPs using approved study documents.

- 9.13 All staff directly involved in the treatment of a patient must be made aware of that patient's involvement in a clinical trial, and of the nature of the trial.
- 9.14 The patient information sheet (part of the informed consent package) should be available when medicines are given as part of a clinical trial.
- 9.15 The patient's medical notes and Kardex must be annotated to indicate that the patient is a participant in a clinical trial and has been prescribed an IMP.
- 9.16 A list of on-going Trust clinical trials of Investigational Medicinal Products with contact details for senior medical advice is available on the Medicines Management site on the Trust Intranet.

http://intranet.belfasttrust.local/directorates/css/MedicinesManagement/Pages/ Trials.aspx

- 9.17 The principal investigator is responsible for the overall conduct of a clinical trial but can delegate specific tasks to other appropriately-qualified and trained staff. The trial tasks that an individual member of staff is authorised to perform must be detailed in advance on a delegation log signed by the individual and verified by the Principal Investigator.
- 9.18 Adverse events should be notified in accordance with the Trust Research Office SOP and Trust 'Adverse Incident Reporting and Management Policy'.
- 9.19 No member of staff should start or conduct a clinical trial of an Investigational Medicinal Product in the Trust until:
- 9.19.1 An ethics committee has given a favourable opinion
- 9.19.2 The clinical trial has been authorised by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Trust Research Office has issued a Final Permission Letter.

10 Medication incident reporting

- 10.1 Refer also to the Trust 'Adverse Incident Reporting and Management Policy' and procedures including 'Procedure for Investigating an Adverse Incident', available on the Trust intranet.
- 10.2 The Trust is committed to developing a reporting and learning culture so that risks to patients and staff from preventable medication incidents are minimised. This relies on effective reporting and analysis of medication incidents and recognises that to improve safety, risks must first be identified. To ensure identification of medication risks, a Trust incident form should be completed for all medication incidents, ideally this is done online using Datixweb. Lessons can then be learned and, where appropriate, action taken to reduce recurrence.
- 10.3 A medication incident is defined as any preventable medication related event that could have or did lead to patient harm, loss or damage. This definition encompasses 'near misses', that is, those medication related occurrences where the patient did not suffer harm, but there was the potential for harm, loss or damage.
- 10.4 Medication incidents can occur in any step of the medicines use process, including prescribing, dispensing and administration of medicines, as well as in the transfer of medicines related information.
- 10.5 The Trust operates a fair and just culture with regard to incidents. Following an incident the focus is on 'what went wrong' rather than 'who went wrong'. This does not mean staff are not accountable for their actions but it is recognised that individuals can and do make mistakes. However, disciplinary action may be required in certain circumstances, for example, where the intention was to cause harm or where there are repeated, unreported errors or violations.
- 10.6 Learning Letter and safety alerts are available on the HSCB website.

11 Adverse Drug Reaction (ADR) Reporting

- 11.1 Any medicine may produce unwanted or unexpected adverse reactions.
- 11.2 Department of Health (NI) defines an adverse reaction as a harmful or nonbeneficial symptom or syndrome occurring as a result of the correct clinical use of a product which is not defective. Department of Health (NI) have asked that clinicians and pharmacists should record in the patient's notes when an adverse drug reaction of a medicine is considered to be a contributing factor for an admission, naming the medicine or class of medicine in the patient's notes as a probable cause.
- 11.3 Detection and recording of these is of vital importance. Serious reactions include those that are fatal, life threatening, disabling, incapacitating or which result in/or prolong hospitalisation and/or are medically significant.
- 11.4 Limited safety information is obtained from clinical trials on new medicines and vaccines and further understanding about the safety of medicines depends on the availability of information from routine practice.
- 11.5 The Yellow Card Scheme is a voluntary scheme, through which healthcare professionals and patients can notify the Medicines and Healthcare products Regulatory Agency (MHRA)/Commission on Human Medicines (CHM) of suspected ADRs. https://yellowcard.mhra.gov.uk/
- 11.6 Healthcare professionals are encouraged to report all suspected ADRs electronically. https://yellowcard.mhra.gov.uk/
- 11.7 The Regional Medicines and Poisons Information Service (RMPIS) also promotes pharmacovigilance locally by provision of an electronic Yellow Card reporting service direct to the MHRA on behalf of health care professionals. Contact RMPIS on 028 950 40558 Monday to Friday 9.00am to 5.00pm. Hard copies of yellow cards are also acceptable and can be found in the back of the BNF or on-line.
- 11.8 Newly licensed medicines are monitored intensively by the MHRA/CHM and are identified by a black triangle symbol in the BNF. The MHRA/CHM encourage the reporting of all suspected ADRs to newly licensed medicines as well as ADRs in all other established medicines (including unlicensed products) and vaccines. Other areas of interest include herbal medicines, delayed drug effect and congenital abnormalities. The reporting of all suspected adverse drug reactions in children is strongly encouraged for all medicines.
- 11.9 The Bulletin 'Current Problems in Pharmacovigilance' issued by the MHRA/CHM contains advice and information on drug safety issues. It is available from the MHRA website www.mhra.gov.uk.

12 Pharmacy Aseptic Services

- 12.1 The service uses state of the art clean-room facilities to prepare a range of injectable medicines including parenteral nutrition and chemotherapy which would be unsafe to be prepared at ward level. They are prepared by a team of highly trained technical staff and specialist pharmacists. The service operates under Section 10 of the Medicines Act 1968, is supported by the regional quality assurance team and receives regular external inspections from expert auditors.
- 12.2 Aseptic medicines must be completely sterile before administration to the patient therefore preparation is carried out by Pharmacy in specially constructed facilities supplied with filtered air. It is a legal requirement that the preparation and dispensing of aseptic products must be under the supervision of a pharmacist and the facility, equipment and systems must be designed to conform to all relevant current Good Manufacturing Practice and 'Quality Assurance of Aseptic Preparation Services' guidance. Staff involved in aseptic dispensing must be suitably trained to enable them to work safely and competently.
- 12.3 The prescribing and administration of aseptic medicines should only be undertaken by healthcare professionals who have undergone specific training in this skill and have demonstrated their competence to do so. Prescribing should be carried out in accordance with written protocols or clinical management plans and on pre-prepared authorised template prescription forms.
- 12.4 The pharmacy aseptic service can also provide specialist advice on all aspects of aseptic preparation of medicines conducted outside of the Pharmacy department, in conjunction with any other specialists as may be required (e.g. Regional Pharmaceutical Quality Assurance).

13 Defective medicinal products

13.1 Recall of a defective medicine

13.1.1 Official notification of a defective medicine is issued to Pharmacy from the Department of Health (NI) as a Drug Alert, or from the manufacturer or supplier. The Head of Pharmacy and Medicines Management is responsible for ensuring systems are in place to cascade Drug Alerts as appropriate within the Trust with a required timescale for action. Ward/Department Sisters or Charge Nurses are responsible for actioning Drug Alerts within the required timescale for action.

13.2 Reporting a defective medicine

- 13.2.1 If any member of staff has reason to believe that a medicine is defective, he or she must inform Pharmacy immediately.
- 13.2.2 The person who discovers the defect must ensure that the product, container and other packaging are retained. If the defect has been discovered following reconstitution or mixing with another preparation, then the mixture, remaining unmixed constituents, and all containers and other packaging must also be retained.
- 13.2.3 All retained materials must be placed in a sealed container, clearly marked 'Do not use', and returned to the Pharmacy as soon as possible.
- 13.2.4 The member of pharmacy staff receiving the product must complete a Substandard Medicinal Product Form and provide their name and contact details to enable follow up of the report.

14 Cytotoxic chemotherapy

- 14.1 Working with or near hazardous medicines in healthcare settings may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukaemia or other cancers. The health risk depends upon the degree of toxicity and the amount of exposure.
- 14.2 Cytotoxic chemotherapy is used extensively in the medical treatment of cancer and less commonly in the management of other medical conditions. For ill patients the potential therapeutic benefits outweigh the risks of side effects. Healthcare workers risk the same side effects for no therapeutic gain.
- 14.3 Healthcare workers prepare, transport, administer and dispose of hazardous drugs. They may create aerosols, generate dust, touch contaminated surfaces or clean up spills and patient excreta. Consequently they risk exposure through inhalation, skin contact, ingestion or inadvertent injection.
- 14.4 For further information on the Control of Substances Hazardous to Health (COSHH), refer to the Trust's policy and procedural arrangements and to the Pharmaceutical Guidance. Cytotoxic chemotherapy is in Pharmacy Reference Group 11.
- 14.5 Cytotoxic chemotherapy should be provided and managed during normal hours in accordance with an authorised Clinical Management Guideline and a written, referenced protocol. It should be prescribed using an electronic chemotherapy prescribing system or using pre-prepared, authorised, template prescription forms.
- 72 Belfast Health and Social Care Trust Medicines Code

14.6 The decision to treat a patient with Systemic Anti-Cancer Therapy (SACT) should be made by competent oncology or haematology Consultant medical staff, ST3 and above medical trainee staff or Non-Consultant Career Grade medical staff, with the patient's consent. The decision, intention and consent should be recorded in the patient's medical notes.

15 Intrathecal chemotherapy

15.1 Refer to 'Policy for Safe Administration of Intrathecal Cytotoxic Chemotherapy in the Belfast Trust'

16 Oral anti-cancer medicines

- 16.1 The National Patient Safety Agency (NPSA) has alerted healthcare staff (NPSA/2008/RRR001) to the potential for fatal outcomes if incorrect doses of oral anti-cancer medicines are used. The risks are increased if non-specialist practitioners prescribe, dispense or administer these medicines and bypass the normal safeguards used for injectable anti-cancer medicines.
- 16.2 The prescribing, dispensing and administering of oral anti-cancer medicines should be carried out and monitored to the same standard as injected therapy.

17 Closure of a ward/department

- 17.1 The following actions should be taken:
- 17.1.1 Controlled drug stock reconciliation (CD Check) and return of controlled drugs (designated pharmacist assigned).
- 17.1.2 Close down of Controlled drug stationery e.g. prescription pads, CD order/returns books, CD register and POD register. Arrangements confirmed with Lead nurse for archiving as appropriate.
- 17.1.3 Removal of all pharmaceuticals and a final check of all storage cupboards and areas. Re-usable items will be credited to cost centre and re-used as appropriate.
- 17.1.4 Fridge log archived with ward archived documentation.
- 17.1.5 Close down of pharmacy stationery (requisition books, script pads etc). Arrangements confirmed with Lead nurse for archiving as appropriate.
- 17.1.6 Removal of all pharmaceutical waste pharmaceutical burn bins (sealed and appropriately labelled). Partially used alcohol foam/gels from dispensers should be removed and placed in burn bins.
- 17.1.7 Inventory of medical gas cylinders & link with BOC around collection of medical gas cylinders and removal from rental agreements.
- 17.1.8 Inventory of medical gas cylinders in manifolds as necessary.
- 17.1.9 Removal of emergency boxes, anaphylactic kits, hyperkalaemia kit and return to pharmacy.

- 17.1.10 Removal of all pharmacy posters etc from medicine cupboards and medicine storage areas.
- 17.1.11 Completion of 'Add/Amend a Cost Centre to JAC' form and action changes.
- 17.1.12 Nominated senior pharmacist or technician appointed to undertake a final inspection to ensure all pharmaceuticals and any other pharmacy associated materials/resources (including posters, references etc) are removed from the ward. Complete Appendix 3 of Trust policy: Decommissioning of Trust Owned and Leased properties.
- 17.1.13 Nominated pharmacist/technician to confirm completion of inspection for sign-off by Pharmacy Services Manager

18 Pharmaceutical waste

- 18.1 Ward managers are responsible for maintaining appropriate ward stock of medicines and dressings at a correct level and not over ordering. With appropriate stock management, it should not be necessary to routinely return stock to Pharmacy. If a 'deep clean' of a ward or department is required, management of ward medicines and dressing should be discussed with Pharmacy.
- 18.2 Pharmaceuticals that are disposed of at ward level include partially used nonparenteral, non-cytotoxic pharmaceuticals, used or partially used glass and plastic pharmaceutical containers for liquid medicines and any empty glass pharmaceutical containers for tablets and capsules.
- 18.3 CDs must be disposed of in accordance with the 'Controlled Drugs Policy'. Antibiotic drug containers which are either used, or partially used, must be placed in a yellow burn bin with a purple lid.
- 18.4 Vaccine or cytotoxic waste, either empty or partially used, must be placed in a yellow burn bin with purple lid. Vaccine and cytotoxic waste must not be mixed in the same burn bin.
- 18.5 All burn bins must have an additional label stating the type of waste e.g. pharmaceutical, cytotoxic or vaccine for incineration. The details on the burn bin label must state the date and the name of the person who assembled the burn bin, the ward/unit and the name of the person who locked the bin and date of closure. All burn bins must be tagged by the ward using their unique ward tags.
- 18.6 Larvae are disposed of as follows:
- 18.6.1 Place dressings and maggots directly into a yellow clinical waste bag.
- 18.6.2 Place yellow waste bag in yellow rigid container with yellow lid.
- 18.6.3 Close, lock and label the rigid container and attach clinical waste tag to the handle of the bin. These bins can be placed directly into the clinical waste wheelie bin in the ward disposal area to be disposed as clinical waste.
- 74 Belfast Health and Social Care Trust Medicines Code

19 Medicines Information

19.1 Health Care Professionals at ward/department level have access to the following medicines information resources:

| British National Formulary | www.bnf.org or hard copy |
|--|---|
| British National Formulary for Children | www.bnfc.org or hard copy |
| Electronic Medicines Compendium | http://emc.medicines.org.uk/ or via Trust intranet |
| Injectable medicines guide | Trust intranet or hard copy |
| NI formulary | http://niformulary.hscni.net/Pages/ default.aspx |
| Department of Health Northern Ireland | http://www.health-ni.gov.uk/ |
| COSHH | |
| NHS Evidence | https://www.evidence.nhs.uk/ |
| MHRA | https://www.gov.uk/government/ organisations/medicines-and- healthcare-products-regulatory- agency |

- 19.2 Medicines Information Resources can be located via links on the Trust intranet site:
- 19.2.1 \IT systems\all IT systems\Externally Managed and Informational Sites: EMC, IMG Medusa, NEWT (for selected users) and TOXBASE (for ED staff and other registered users)
- 19.2.2 \IT systems\all IT systems\Pharmacy and Ward Based Systems: BNF Formulary Complete; BNF and BNFC.
- 19.2.3 \Sites\Medicines Management Site\Resources Section: This contains a variety of links to additional useful resources
- 19.2.4 \IT systems: BNF Formulary Complete, EMC, IMG Medusa, NEWT (for selected users) and TOXBASE.
- 19.3 Where hard copies of medicines information such as the 'Injectables Guide' or the 'BNF' are in use, it is the responsibility of the ward/department manager to ensure the most up-to-date version is in use and any superseded versions have been removed and disposed of appropriately.
- 19.4 The Regional Medicines and Poisons Information Service (RMPIS) is hosted by Belfast Health and Social Care Trust and provides information and advice on

75

all aspects of the therapeutic use of medicines, to healthcare professionals in primary and secondary care across Northern Ireland. RMPIS also contributes to pharmacovigilance by supporting other health professionals with the provision of electronic Yellow Card (eYC) reporting direct to the MHRA on their behalf.

19.5 RMPIS are members of the UK Medicines Information (UKMi) clinical and strategic network and contribute to national projects and partnership working with others across the UK.

19.6 Medicines Information Services

- 19.6.1 The service has several broad functions:
- 19.6.2 to support medicines management in the safe, effective and efficient use of medicines by the provision of evidence-based information.
- 19.6.3 to support the pharmaceutical care of individual patients by provision of advice on their therapeutic use of medicines.
- 19.6.4 to signpost to information resources: Medicines Information pharmacists have expertise in the use of many medicines information resources and can assist other healthcare professionals through signposting to resources relevant to their practice. Information is provided both in direct response to requests for assistance, and also in the form of bulletins. A local monthly current awareness bulletin 'Medicines Information for Northern Ireland' - MINI and national publications UKMi NICE Bites' (monthly) and 'What's New from UKMi' (weekly) are distributed by email to service users who have registered their interest.
- 19.6.5 Contact Information: The Regional Medicines and Poisons Information Service is open: 9.00am-5.00pm Monday to Friday and can be contacted at 028 950 40558 or via email at nirdic.nirdic@belfasttrust.hscni.net. For enquiries outside office hours refer to Pharmacy Extended Hours services and the on-call pharmacist.

19.7 Poisons Information Services:

- 19.7.1 The Regional Medicines and Poisons Information Service provides an enquiry answering service on cases of poisoning including non-medicine poisoning e.g. household products, petrol or oil products, agricultural, industrial or garden chemicals and plants. It is part of the UK National Poisons Information Service (NPIS) that provides expert advice on all aspects of acute and chronic poisoning.
- 19.7.2 All enquiries of accidental or deliberate medicines and non-medicines poisoning should be referred to this service to ensure appropriate management and documentation of all poisons cases.

20 Glossary of terms

| Administer | To administer to a human being 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). | | |
|-----------------------------------|---|--|--|
| Amber Drugs (Amber list drugs) | A classification system which categorises therapies as those which should be started by a specialist prescriber, but may be transferred to primary care after the patient has been stabilised on treatment. | | |
| Clinical Trial | A carefully designed and controlled research study designed to test the safety and/or effectiveness of drugs, devices, treatments, or preventive measures in humans. | | |
| Consultant | A fully trained specialist in a branch of medicine who accepts total responsibility for patient care. | | |
| Controlled Drugs (CDs) | Opioid or other medicines liable to misuse which are subject to special controls under the Misuse of Drugs Act 1971. | | |
| COSHH | Regulations covering Control of Substances Hazardous to Health. | | |
| Dispense | To make up or give out a clinically appropriate medicine to a patient for self administration or administration by another, usually a professional. In the case of prescription only medicines, dispensing must be in response to a legally valid prescription. The act of dispensing is combined with advice about safe and effective use. | | |
| | Or | | |
| | To prepare a clinically appropriate medicine for a patient for self-administration or administration by another. Dispensing is performed under the supervision of a pharmacist, and will include such activities as checking the validity of the prescription, the appropriateness of the medicines for an individual patient, assembly of the product, labelling in accordance with legal requirements and providing information leaflets for the patient. | | |
| Doctor | A medical practitioner fully registered with the General Medical Council (GMC). In BHSCT Medicines Code 'doctor' is also used to refer to medical practitioners with limited or provisional registration for whom certain restrictions apply. | | |
| Kardex | The term used to describe the Trust in-patient Medicines Prescription and Administration record. The term also encompasses supplementary charts and anaesthetic chart Kardexes. | | |

| Licensed medicine | A medicine which falls within the definition of a medicinal product and which is granted a marketing authorisation by the Licensing Authority when the safety, quality and efficacy of the product have been satisfactorily demonstrated by the license holder in accordance with EC directives 65/65. |
|---------------------------|--|
| Illicit Substances | A substance obtained illegally, that causes addiction, habituation, or a marked change in consciousness. |
| Medication Incident | Any preventable medication related event that could have or did lead to patient harm, loss or damage. This definition encompasses 'near misses', that is, those medication related occurrences where the patient did not suffer harm, but there was the potential for harm, loss or damage |
| 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 with a view to making a diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product'. |
| Medicine | A medicine is defined as a substance introduced into the body, or externally applied to the body, for the purpose of treating disease, preventing disease, diagnosing disease, ascertaining the existence, degree or extent of a physiological condition, contraception, inducing general or regional anaesthesia, or otherwise preventing or interfering with the normal operation of a physiological function. |
| Midwife | A person who has completed a formal program of midwifery education and is registered with the Nursing and Midwifery Council. |
| Non Medical Prescriber | A person who has successfully completed a recognised prescribing course, has registered with the appropriate professional body as a prescriber of medicines and has been approved and registered as a non-medical prescriber on the BHSCT register for non-medical prescribers. They can prescribe as either independent or supplementary prescribers. |
| Nurse | A person who has completed a formal program of nursing education and is registered with the Nursing and Midwifery Council. |
| Patient | Any service user or patient who receives medical attention, care, or treatment. |

| Patient Group Direction (PGD) | A document signed by a doctor and lead nurse/professional and agreed by a pharmacist that acts as a direction to a nurse or other healthcare professional to supply and/or administer a prescription only medicine to a patient using their own assessment of patient need, without necessarily referring back to the doctor for an individual prescription. |
|----------------------------------|---|
| Pharmacist | A person registered with the Pharmaceutical Society of Northern Ireland who is responsible for the safe, effective and efficient use of medicines. |
| Practitioner | A physician or other individual licensed in law to practise their profession. |
| Prescriber | A person authorised under the Medicines Act 1968 to order in writing the supply of a prescription only medicine for a named patient. |
| Sister/Charge Nurse | A nurse in charge of a ward, theatre or other department in a hospital. |
| Supply | To provide a medicine to a patient/carer for administration |
| Red Drugs (Red Drug List) | A classification system which categorises therapies which should be prescribed by specialist practitioners only, due to restrictions on the drug, e.g. long-term specialist monitoring required for efficacy or toxicity, designated as 'specialist-only' in the marketing authorisation, some clinical trial material. |
| Unlicensed Medicine | Is the term used to refer to a medicine that has no product license. If an unlicensed medicine is administered to a patient, the manufacturer does not have liability for any harm that ensues. The person who prescribes the medicine carries the liability. |

Appendix 1

1 Use of pneumatic tube transfer system

- 1.1 To ensure the health and safety of operators, Pharmacy will only accept requests in designated pharmacy carriers. All other carriers will be returned unopened.
- 1.2 Always check that the correct ward/department is stated on the prescription/requisition before sending to Pharmacy.
- 1.3 The system may be used to send prescriptions for discharge medicines, supplementary requisitions for stock medicines and requests for aseptic preparations to Pharmacy.
- 1.4 Pharmacy will use the system to deliver medicines to wards where appropriate, e.g. no COSHH risks.

1.5 Loss of medicines or documents in pneumatic tube transfer system

1.5.1 If medicines have been dispatched from any pharmacy station but have not arrived at the requested destination the support helpdesk should be informed immediately via RVH Dispatch on extension 34848. An incident report form should also be completed. This incident report form should clearly state the station number that it was sent from, the time it was sent, what sort of medicines the carrier contained and where it was sent. Any incidents of missing medicines should be treated as a serious and high risk and should therefore be investigated immediately by the local systems management or estates.

1.6 Requisitions

1.6.1 The first two copies from the requisition can be sent to Pharmacy via the pneumatic tube. The third copy should remain in the requisition book as a record of the items ordered. Where possible, items will be returned by the pneumatic tube with the second copy acting as a delivery docket.

1.7 Controlled Drugs (CDs)

1.7.1 Refer to 'Controlled Drugs Policy'.

1.8 Medicines via pneumatic tube transfer system

- 1.8.1 The following items will not be transported via the pneumatic tube system:
- 1.8.1.1 Cytotoxic and radioactive medicines
- 1.8.1.2 Living therapeutic modalities e.g. larvae
- 1.8.1.3 Extremely costly or difficult to procure items
- 1.8.1.4 Medicines which require refrigeration.
- 1.8.1.5 COSHH Pharmacy Reference Groups (PRGs) 5 (glutaraldehyde), 8 (formaldehyde), 9 (corrosive substances), 11 (cytotoxics), 15 (flammable substances), 16 (mercury and mercuric substances), 17 (irritant substances), 18 (toxic substances), 19 (phenol), 22 (vaccines), 24 (monoclonal antibodies). Further work and risk assessments are required in this area.
- 80 Belfast Health and Social Care Trust Medicines Code

1.8.1.6 Other specific medicines that may be adversely altered in some way e.g. ciclosporin oral solution, darbepoetin, erythropoietin, filgrastim/pegfilgrastim, insulin, interferon/peginterferon.

1.9 Pharmacy Returns

1.9.1 The tube system is not to be used to send returns to Pharmacy.

2 Security

- 2.1 Pharmacy carriers must arrive into a secure locked receptacle at ward or department level or into a room where the door must be locked. It is essential that the complete contents of each carrier are removed upon receipt and immediately stored in the appropriate ward cupboard. Keys for the secure cabinet must be held with the ward medicine cupboard keys and in the possession of the ward sister or nurse-in-charge.
- 2.2 Due care and attention must be taken when opening carriers to avoid the risk of injury.

Appendix 2

The following medicines management forms are accessible via the Hub:

Medical Gas Cylinder order form

Form for Removal or Destruction of Unauthorised Drugs or other Suspicious Substances

Ward Register for Illicit/Suspected Illicit Substances

Trust Pharmaceutical Samples Register

Log of Medication Supplied from Emergency Cupboard

Pharmaceutical Refrigerator Temperature Log





Standards and Guidelines Committee

| Medicines Code policy | | | | | | |
|----------------------------|---|--|--|--|--|--|
| Summary | The Medicines Code defines the policies and procedures to be followed within BHSCT for prescribing, administering dispensing, monitoring, ordering and storage of medicines and staff roles and responsibilities in relation to them. It also describes minimum acceptable standards for all aspects o medicines management for hospital sites in BHSCT. | | | | | |
| Operational date | March 2011 | | | | | |
| Review date | March 2014 | | | | | |
| Version Number | V1 | | | | | |
| Director Responsible | Dr Tony Stevens | | | | | |
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| | | | | | | |
| | Rick Plumb, Consultant Physician,, | | | | | |

| Reference Number | SG 09/11 |
|------------------|--|
| Supersedes | Legacy Trust Medicines Codes and 'Interim administration of medications guidance for registrants whilst medicines code is being harmonised.' |

Drug and Therapeutics Committee – Medicines Code policy – V1 – 21/03/11

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| 07/02/2011 | 0.1 | S O'Donnell | Initial Draft |
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Policy Record

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| Drug and Therapeutics committee | Approval | 04/03/11 | 0.1 |
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Local Approval Process

| Approval | |
|----------|--|
| | |

Dissemination

| Areas : | |
|---------|--|
| | |
| | |

Full Description

Medicines Code policy

1. Introduction:

The complexity and variety of medicines, their potency and potential toxicity places an exacting responsibility on doctors, nurses, pharmacists and other staff who handle medicines. To assist these staff, a Trust Medicines Code has been developed drawing on legacy Medicines Codes, legacy Medicines manuals and legacy and interim medicines management policies.

2. Purpose:

The Medicines Code defines the policies and procedures to be followed within BHSCT for prescribing, administering, dispensing, monitoring, ordering and storage of medicines and staff roles and responsibilities in relation to them. It also describes acceptable standards for all aspects of medicines management for hospital sites in BHSCT.

3. Scope

The Medicines Code applies to medical, nursing and pharmacy staff in hospital settings in BHSCT and to any other staff who handle medicines, irrespective of grade or seniority.

4. Objectives:

To describe the requirements for the safe and secure handling of medicines in BHSCT.

5. Roles and Responsibilities:

- 5.1 The Trust Chief Executive has overall responsibility for the safe and secure handling of medicines as part of the Controls Assurance medicines management framework.
- 5.2 The Head of Pharmacy and Medicines Management is responsible for maintaining the security of stocks of pharmaceuticals held in all Pharmacy departments within their authority and ensuring that systems of control operating within the area of authority are in accordance with Medicines Management Policies. The Head of Pharmacy and Medicines Management reports on these matters to the Chief Executive via the Drug and Therapeutics Committee and the Director of Cancer and Specialist Services.
- 5.3 The Drugs and Therapeutics (D&T) Committee has a responsibility to ensure that medicine availability and prescribing conforms to the highest standards and is compliant with all legal and good practice requirements.
- 5.4 All staff who are responsible for prescribing, administration, dispensing, monitoring, ordering and storage of medicines, including locum, agency and bank staff are responsible for discharging their duties in relation to medicines in accordance with the Medicines Code.
- 5.5 Senior staff, including managers, consultants, ward or departmental sisters/charge nurses are responsible for ensuring that duties are delegated to staff with appropriate knowledge and assessed as competent. Those in charge of wards and departments are responsible for ensuring that staff, especially new employees, locum staff and agency staff adhere to procedures in this Medicines Code, which may differ from procedures elsewhere.
- 5.6 As part of induction, all newly appointed medical, nursing and pharmacy staff, regardless of grade, and any other person who will have dealings with medicines, should read the Medicines Code and acquaint themselves with its contents. This requirement is the responsibility of the newly appointed member of staff's line manager as well as the

individual member of staff.

5.7 The Medicines Code also applies to medical staff, nursing/midwifery staff and other healthcare professionals from other Trusts or from private practice, who are contracted to work in BHSCT on a sessional basis. Managers who contract for these services must make it explicit within written contracts that these sessional staff must follow the procedures described in this Medicines Code.

6. The definition and background of the policy:

The Department of Health, Social Services and Public Safety (DHSSPS) requires that Trusts establish, document and maintain an effective system of safe and secure medicines management. This Medicines Code defines the policies and procedures to be followed within BHSCT for prescribing, administering, dispensing, monitoring, ordering and storage of medicines thus providing assurance of safe and secure medicines management.

7. Policy description:

The Medicines Code describes the policies and procedures to be followed in BHSCT for prescribing, administration, dispensing, monitoring, ordering and storage of medicines.

8. Policy statements:

- 8.1 The Medicines Code applies to all hospital settings in BHSCT.
- 8.2 The Medicines Code applies to all medical, nursing, pharmacy and other staff who prescribe, administer, dispense, monitor, order or store medicines.

9. Implementation / Resource requirements:

Hard copies of the Medicines Code will be printed and a copy sent to each ward/department in BHSCT. The Medicines Code will also be available on the intranet. Summary documents for medical and pharmacy technical and support staff will also be available in hard copy and on the intranet.

Awareness of the Medicines Code will be raised through nurse training on the Medicines Code, though staff meetings and at audit/governance meetings. It will be disseminated through Service Groups.

10. Source(s) / Evidence Base:

The Medicines Code is based on policies, procedures, legislative and professional guidance in relation to all aspects of the use of medicines in BHSCT

11. References, including relevant external guidelines:

- 1. A guide to pharmaceutical clinical waste (2002), DHSSPS
- 2. Circular HSS 9/2000 Patient group directions
- 3. Circular <u>HSS(MD)45/2003</u> Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy
- 4. Circular HSS (MD) 39-02 Safe administration of Intrathecal Chemotherapy.
- 5. Circular HSSE (OCE) 1/97 Aseptic Dispensing in HPSS Hospitals
- 6. EC 92/27 Labelling and Leaflet Directive
- 7. Ethics and Practice. A Guide for Pharmacists in Northern Ireland 2009 Edition Pharmaceutical Society of Northern Ireland.
- 8. Good Clinical Practice for Trials on Medical Products in the European Community, 111/3976/88 EN Final. Office for Publications for the European Community
- 9. Guidance for reporting accidents with, and defects in, medicinal products (2001), DHSSPS
- 10. Guidance on Good Clinical Practice and Clinical Trials (1999), Department of Health, London
- 11. Guidance to Trusts on reporting defective medicinal products (2001), DHSSPS

- NIAIC Safety Notice <u>MDEA (NI) 2004/01</u> Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre (NIAIC)
- 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
- 14. Health Act 2006
- 15. HPSS Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2003 (as amended) SR No 153 The Stationary Office, London
- 16. HPSS Management Executive (OP1) 2/92 Supply of Medicines and Other Pharmaceutical Products – Responsibility for Prescribing Between Hospitals and Family Practitioner Services
- 17. Environmental Protection (Prescribed Processes and Substances) Regulations 1991 SI No 472. The Stationery Office, London
- 18. HC (76) 9 Report of the working party on the additions of drugs to intravenous fluids
- 19. Medicines Act 1968 (as amended) The Stationery Office, London
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- 28. Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)
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- 30. The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2000. SR No 120
- 31. The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted)
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- 33. The Medicines (Administration of Radioactive Substances) Regulations 1978 SI No 1006 The Stationery Office, London
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- 35. The Misuse of Drugs (Northern Ireland) Regulations 2002 SR No 1 The Stationery Office, London
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- 42. Circular HSS (PPM) 8/2004 Governance in the HPSS: Controls assurance standards update
- 43. <u>http://www.dhsspsni.gov.uk/hss/governance/guidance.asp</u>

12. Consultation Process:

Pharmacy Executive Team Drug and Therapeutics committee BHSCT Central nursing and midwifery group Medical Director and Assistant Medical Directors for dissemination to lead clinicians BHSCT pharmacy staff

13. Equality and Human Rights screening carried out:

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, the Belfast Trust has carried out an initial screening exercise to ascertain if this policy should be subject to a full impact assessment.

Screening completed No action required.

Full impact assessment to be carried out.

14. Procedures:

Appendix 1 Medicines Code Appendix 2 What doctors need to know about the Medicines Code Appendix 3 What pharmacy technical and support staff need to know about the Medicines Code

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Director A B Stevens Date: March 2011 Author Sharon O'Donnell Date: March 2011

Appendix 1.

Medicines Code

http://intranet.belfasttrust.local/policies/Documents/Medicines%20Code.pdf

<u>Appendix 2</u> What doctors need to know about the Medicines Code

http://intranet.belfasttrust.local/policies/Documents/Medicines%20Code%20-%20What%20doctors%20need%20to%20know.pdf

Appendix 3

What pharmacy technical and support staff need to know about the Medicines Code

http://intranet.belfasttrust.local/policies/Documents/Medicines%20Code%20-%20Pharmacy%20technician%20and%20support%20staff.pdf



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Reference No: SG 09/11

| Title: | Medicines Code policy | | | | |
|-------------------------|---|---------------------------------|---|--|--|
| Author(s) | Sharon O'Donnell, Medicines Governance pharmacist, Royal Victoria Hospital | | | | |
| | Susan Atkinson, Consultant anaesthetist, | | | | |
| | Rhona Fair, Pharmacy services manager, Royal hospitals and Mater hospital services , services manager , Royal hospitals and Mater Eimear McCusker, Head of Pharmacy and Medicines management, | | | | |
| | Olga O'Neill, Senior Acute Pain Control nurse, Marcona , Rick Plumb, Consultant Physician, Marcona , Marcon | | | | |
| Ownership: | Dr Cathy | Jack, Medical D | irecto | r | |
| Approval by: | Drugs and Therapeutics Standards and Guidelines Policy Committee Executive Team Meeting | | Approval date: | 04/03/15 11/03/15 01/04/15 03/04/15 | |
| Operational Date: | Septembe | er 2015 | 2015 Next September 2018 Review: | | |
| Version No. | V2 | Supercedes | V1 – March 2011-2014 Legacy Trust Medicines Codes and 'Interim administration of medications guidance for registrants whilst medicines code is being harmonised. | | |
| Key words: | | S Code, Code, N S Management | de, Code, Medicines, Prescribing, Administering, anagement | | |
| Links to other policies | | | | | |

| Version control for drafts: | | | | |
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| Date | Version | Author | Comments | |
| 07/02/2011 | 0.1 | S O'Donnell | Initial Draft | |
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| 24/09/2015 | 1.1 | S O'Donnell | Put into Trust template | |

1.0 INTRODUCTION

1.1 Background

The complexity and variety of medicines, their potency and potential toxicity places an exacting responsibility on doctors, nurses, pharmacists and other staff who handle medicines. To assist these staff, a Trust Medicines Code has been developed drawing on legacy Medicines Codes, legacy Medicines manuals and legacy and interim medicines management policies

1.2 Purpose

The Medicines Code defines the policies and procedures to be followed within BHSCT for prescribing, administering, dispensing, monitoring, ordering and storage of medicines and staff roles and responsibilities in relation to them. It also describes acceptable standards for all aspects of medicines management for hospital sites in BHSCT

1.3 Objective

To describe the requirements for the safe and secure handling of medicines in BHSCT.

2.0 SCOPE OF THE POLICY

The Medicines Code applies to medical, nursing and pharmacy staff in hospital settings in BHSCT and to any other staff who handle medicines, irrespective of grade or seniority.

3.0 ROLES/RESPONSIBILITIES

The Trust Chief Executive has overall responsibility for the safe and secure handling of medicines as part of the Controls Assurance medicines management framework.

The Head of Pharmacy and Medicines Management is responsible for maintaining the security of stocks of pharmaceuticals held in all Pharmacy departments within their authority and ensuring that systems of control operating within the area of authority are in accordance with Medicines Management Policies. The Head of Pharmacy and Medicines Management reports on these matters to the Chief Executive via the Drug and Therapeutics Committee and the Director of Surgery and Specialist Services.

The Drugs and Therapeutics (D&T) Committee has a responsibility to ensure that medicine availability and prescribing conforms to the highest standards and is compliant with all legal and good practice requirements.

All staff who are responsible for prescribing, administration, dispensing, monitoring, ordering and storage of medicines, including locum, agency and bank staff are responsible for discharging their duties in relation to medicines in accordance with the Medicines Code.

Senior staff, including managers, consultants, ward or departmental sisters/charge nurses are responsible for ensuring that duties are delegated to staff with appropriate knowledge and assessed as competent. Those in charge of wards and departments are responsible for ensuring that staff, especially new employees, locum staff and agency staff adhere to procedures in this Medicines Code, which may differ from procedures elsewhere.

As part of induction, all newly appointed medical, nursing and pharmacy staff, regardless of grade, and any other person who will have dealings with medicines, should read the Medicines Code and acquaint themselves with its contents. This requirement is the

responsibility of the newly appointed member of staff's line manager as well as the individual member of staff.

The Medicines Code also applies to medical staff, nursing/midwifery staff and other healthcare professionals from other Trusts or from private practice, who are contracted to work in BHSCT on a sessional basis. Managers who contract for these services must make it explicit within written contracts that these sessional staff must follow the procedures described in this Medicines Code.

4.0 KEY POLICY PRINCIPLES

4.1 The Department of Health, Social Services and Public Safety (DHSSPS) requires that Trusts establish, document and maintain an effective system of safe and secure medicines management. This Medicines Code defines the policies and procedures to be followed within BHSCT for prescribing, administering, dispensing, monitoring, ordering and storage of medicines thus providing assurance of safe and secure medicines management.

4.2 Policy description

Definition

The Medicines Code describes the policies and procedures to be followed in BHSCT for prescribing, administration, dispensing, monitoring, ordering and storage of medicines.

4.2 Policy statements

- 4.2.1 The Medicines Code applies to all hospital settings in BHSCT.
- 4.2.2 The Medicines Code applies to all medical, nursing, pharmacy and other staff who prescribe, administer, dispense, monitor, order or store medicines.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

Hard copies of the Medicines Code will be printed and a copy sent to each ward/department in BHSCT. The Medicines Code will also be available on the intranet. Summary documents for medical and pharmacy technical and support staff will also be available in hard copy and on the intranet.

5.2 Resources

Awareness of the Medicines Code will be raised through nurse training on the Medicines Code, though staff meetings and at audit/governance meetings. It will be disseminated through Service Groups.

5.3 Exceptions

None

6.0 MONITORING

Unannounced medicines management inspections Incident reporting

7.0 EVIDENCE BASE / REFERENCES

- 1. A guide to pharmaceutical clinical waste (2002), DHSSPS
- 2. Circular HSS 9/2000 Patient group directions
- 3. Circular <u>HSS(MD)45/2003</u> Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy
- 4. Circular HSS (MD) 39-02 Safe administration of Intrathecal Chemotherapy.
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- 16. HPSS Management Executive (OP1) 2/92 Supply of Medicines and Other Pharmaceutical Products – Responsibility for Prescribing Between Hospitals and Family Practitioner Services
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- 30. The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2000. SR No 120
- 31. The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted)
- 32. The Health and Safety at Work (Northern Ireland) Order 1978. SI No 1039 (NI 9).
- 33. The Medicines (Administration of Radioactive Substances) Regulations 1978 SI No 1006 The Stationery Office, London
- 34. The Medicines for Human Use (Clinical Trials) Regulations 2004 SI No 1031

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08)

- 35. The Misuse of Drugs (Northern Ireland) Regulations 2002 SR No 1 The Stationery Office, London
- 36. The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 The Stationery Officer, London

(pp8370-10305 of 20966) (this part 1936 pages)

- 37. The Prescription Only Medicines (Human Use) Order 1997 as amended. The Stationery Office,
- 38. Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts" [MDEA (NI) 2004/01
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- 42. Circular HSS (PPM) 8/2004 Governance in the HPSS: Controls assurance standards update
- 43. http://www.dhsspsni.gov.uk/hss/governance/guidance.asp

8.0 CONSULTATION PROCESS

Pharmacy Executive Team Drug and Therapeutics committee BHSCT Central nursing and midwifery group Medical Director and Assistant Medical Directors for dissemination to lead clinicians BHSCT pharmacy staff

9.0 APPENDICES / ATTACHMENTS

Appendix 1 - Medicines Code Appendix 2 - What doctors need to know about the Medicines Code Appendix 3 - What pharmacy technical and support staff need to know about the Medicines Code

10.0 EQUALITY AND HUMAN RIGHTS SCREENING CARRIED OUT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.

The outcome of the Equality screening for this policy is:

Major impact

Minor impact

No impact. X

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

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Author

Director

Date: ____December 2015____

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Date: ____December 2015_____

Appendix 1. Medicines Code



<u>Appendix 2</u> What doctors need to know about the Medicines Code



<u>Appendix 3</u> What pharmacy technical and support staff need to know about the Medicines Code



Drug and Therapeutics Committee_Medicines Code policy_V2_2015

Page 6 of 6



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| Title: | | ľ | Medic | ines Code p | olicy |
|-------------------------|--|---|-------|-------------------|--|
| Author(s) | Sharon O'Donnell, Medicines Governance pharmacist, Royal Victoria Hospital | | | | |
| | Susan Atkinson, Consultant anaesthetist, | | | | |
| | Rhona Fair, Pharmacy services manager, Royal hospitals and Mater hospital | | | | |
| | Eimear McCusker, Head of Pharmacy and Medicines management, | | | | |
| | Olga O'Neill, Senior Acute Pain Control nurse, 90635206, | | | | |
| | Rick Plumb, Consultant Physician, | | | | |
| Ownership: | Dr Cathy Jack, Medical Director | | | | |
| Approval by: | Drugs and Therapeutics Standards and Guidelines Policy Committee Executive Team Meeting | | | Approval date: | 04/11/2016 09/11/2016 07/12/2016 14/12/2016 |
| Operational Date: | March 2017 Next March 2022 Review: | | | | |
| Version No. | V3 Supercedes V2 – September 2015-2018 | | | | 2015-2018 |
| Key words: | Medicines Code, Code, Medicines, Prescribing, Administering, Medicines Management | | | | |
| Links to other policies | | | | | |

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| 07/02/2011 | 0.1 | S O'Donnell | Initial Draft |
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| 28/10/2016 | 2.1 | S O'Donnell | Updating of policy to reflect changes in Code and appending revised Medicines Code document |

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Awareness of the Medicines Code will be raised through nurse training on the Medicines Code, though staff meetings and at audit/governance meetings. It will be disseminated through directorates.

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Unannounced medicines management inspections Incident reporting

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- 40. The Management of Clinical waste in the Delivery of Health and Social Care In the Community. Health Estates.
- 41. <u>https://www.health-ni.gov.uk/publications/controls-assurance-standards</u> [Accessed October 28th 2016]

8.0 CONSULTATION PROCESS

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The outcome of the Equality screening for this policy is:

Major impact

Minor impact

No impact. X

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

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Author

Director

Date: ____March 2017____

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Date: ____March 2017_____

Appendix 1. Medicines Code

Appendix 2 What doctors need to know about the Medicines Code

Appendix 3 What pharmacy technical and support staff need to know about the Medicines Code

Drug and Therapeutics Committee Medicines Code policy_V3_2017

Page 6 of 6



Reference No: SG 09/11

| Title: | Medicines Code policy | | | | |
|-------------------------|---|--|--|-------------------|--|
| Author(s) | Sharon O'Donnell, Medicines Governance Pharmacist, Royal Hospitals Tel: Rhona Fair, Pharmacy Services Manager, Royal Hospitals and Mater Hospital Tel: Eimear McCusker, Head of Pharmacy and Medicines Management Tel: Olga O'Neill, Senior Acute Pain Control Nurse Tel: Dr Rick Plumb, Consultant Physician Tel: | | | | |
| Ownership: | Caroline Leonard, Surgery and Specialist Services Director | | | | |
| Approval by: | Standarde and (-Illidelinge Lommittee | | | Approval date: | 06/09/2019 08/10/2019 06/02/2020 12/02/2020 |
| Operational Date: | February 2020Next Review:February 2025 | | | February 2025 | |
| Version No. | 4 Supercedes V3 – March 2017 | | | | |
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| 28/10/2016 | 3.1 | S O'Donnell | Updating of policy to reflect changes in Code and appending revised Medicines Code document |
| 27/08/2019 | 3.2 | P Armstrong | Amendment to accountability arrangements to include that all pharmacy personnel employed in BHSCT are within Pharmacy organisational accountability arrangements chart and managed within pharmacy teams |

Drug and Therapeutics Committee_Medicines Code policy_V4_February 2020

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The complexity and variety of medicines, their potency and potential toxicity places an exacting responsibility on doctors, nurses, pharmacists and other staff who handle medicines. To assist these staff, a Trust Medicines Code has been developed drawing on legacy Medicines Codes, legacy Medicines manuals and legacy and interim medicines management policies

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3.0 ROLES/RESPONSIBILITIES

The Trust Chief Executive has overall responsibility for the safe and secure handling of medicines as part of the Controls Assurance medicines management framework.

The Head of Pharmacy and Medicines Management is responsible for maintaining the security of stocks of pharmaceuticals held in all Pharmacy departments within their authority and ensuring that systems of control operating within the area of authority are in accordance with Medicines Management Policies. The Head of Pharmacy and Medicines Management reports on these matters to the Chief Executive via the Drug and Therapeutics Committee and the Director of Surgery and Specialist Services.

The Head of Pharmacy and Medicines Management is the superintendent pharmacist for Belfast HSC Trust and responsible for the safe and effective running of the pharmacy service including BHSCT pharmacy personnel, pharmacy departments and relevant pharmacy services (clinics, care homes, ward based dispensing services, community services and teams where BHSCT pharmacy staff deliver pharmacy services). All pharmacy personnel employed by Belfast HSC Trust will be included within the pharmacy organisational accountability arrangements chart(s) and managed within pharmacy teams to avail of defences for inadvertent preparation and dispensing errors by pharmacy professionals acting in the course of their profession and/or agreed roles and responsibilities

The Drugs and Therapeutics (D&T) Committee has a responsibility to ensure that medicine availability and prescribing conforms to the highest standards and is compliant with all legal and good practice requirements.

All staff who are responsible for prescribing, administration, dispensing, monitoring, ordering, storage and transport of medicines, including locum, agency and bank staff are responsible for discharging their duties in relation to medicines in accordance with the Medicines Code.

Senior staff, including managers, consultants, ward or departmental sisters/charge nurses are responsible for ensuring that duties are delegated to staff with appropriate knowledge and assessed as competent. Those in charge of wards and departments are responsible for ensuring that staff, especially new employees, locum staff and agency staff adhere to procedures in this Medicines Code, which may differ from procedures elsewhere.

As part of induction, all newly appointed medical, nursing and pharmacy staff, regardless of grade, and any other person who will have dealings with medicines, should read the Medicines Code and acquaint themselves with its contents. This requirement is the responsibility of the newly appointed member of staff's line manager as well as the individual member of staff.

The Medicines Code also applies to medical staff, nursing/midwifery staff and other healthcare professionals from other Trusts or from the independent sector, who are contracted to work in BHSCT on a sessional basis. Managers who contract for these services must make it explicit within written contracts that these sessional staff must follow the procedures described in the Medicines Code.

4.0 KEY POLICY PRINCIPLES

4.1 The Department of Health requires that Trusts establish, document and maintain an effective system of safe and secure medicines management. This Medicines Code defines the policies and procedures to be followed within BHSCT for prescribing, administering, dispensing, monitoring, ordering, storage and transport of medicines thus providing assurance of safe and secure medicines management.

4.2 Policy description

Definition

The Medicines Code describes the policies and procedures to be followed in BHSCT for prescribing, administration, dispensing, monitoring, ordering, storage and transport of medicines.

4.2 **Policy statements**

- 4.2.1 The Medicines Code applies to all hospital settings in BHSCT.
- 4.2.2 The Medicines Code applies to all medical, nursing, pharmacy and other staff who prescribe, administer, dispense, monitor, order, store or transport medicines.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

Hard copies of the Medicines Code will be printed and a copy sent to each ward/department in BHSCT. The Medicines Code will also be available on the intranet. Summary documents for medical and pharmacy technical and support staff will also be available in hard copy and on the intranet.

5.2 Resources

Awareness of the Medicines Code will be raised through nurse training on the Medicines Code, though staff meetings and at audit/governance meetings. It will be disseminated through directorates.

5.3 Exceptions

None

6.0 MONITORING

Unannounced medicines management inspections Incident reporting

7.0 EVIDENCE BASE / REFERENCES

- 1. A guide to pharmaceutical clinical waste (2002), DHSSPS
- 2. Circular HSS 9/2000 Patient group directions
- 3. Circular <u>HSS(MD)45/2003</u> Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy
- 4. Circular HSS (MD) 39-02 Safe administration of Intrathecal Chemotherapy.
- 5. Circular HSSE (OCE) 1/97 Aseptic Dispensing in HPSS Hospitals
- 6. EC 92/27 Labelling and Leaflet Directive
- 7. Ethics and Practice. A Guide for Pharmacists in Northern Ireland 2009 Edition Pharmaceutical Society of Northern Ireland.
- 8. Good Clinical Practice for Trials on Medical Products in the European Community, 111/3976/88 EN Final. Office for Publications for the European Community
- 9. Guidance for reporting accidents with, and defects in, medicinal products (2001), DHSSPS

- 10. Guidance on Good Clinical Practice and Clinical Trials (1999), Department of Health, London
- 11. Guidance to Trusts on reporting defective medicinal products (2001), DHSSPS
- 12. NIAIC Safety Notice <u>MDEA (NI) 2004/01</u> Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre (NIAIC)
- 13. 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
- 14. Health Act 2006
- 15. HPSS Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2003 (as amended) SR No 153 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
- 17. Environmental Protection (Prescribed Processes and Substances) Regulations 1991 SI No 472. The Stationery Office, London
- 18. HC (76) 9 Report of the working party on the additions of drugs to intravenous fluids
- 19. Medicines Act 1968 (as amended) The Stationery Office, London
- 20. Medicines Control Agency MCA Guidance Note 14 The Supply of Unlicensed Relevant Medicinal Products for Individual Patients. The Stationery Office, London
- 21. Misuse of Drugs Act 1971 (c.38) The Stationery Office, London
- 22. NHS Estates (1994) HTM 2022 Medical gas pipeline systems. The Stationery Office, London
- 23. Pharmaceutical Society of Northern Ireland (1997) Ethics and Practice : A Guide for Pharmacists in Northern Ireland
- 24. Poisons Act 1972 The Stationery Office, London
- Safe Disposal of Clinical Waste. Health and Safety Commission (Health Services Advisory Committee), Second Edition 1999 ISBN 07176 2492
 7.
- 26. Safety Notice SN(NI) 2003/01: Reporting Adverse Incidents and Disseminating Warning Notices Relating to Medical Devices, Non-Medical Equipment, Buildings and Plant. Health Estates, Northern Ireland Adverse Incident Centre (NIAIC).
- 27. Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft)
- 28. Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)
- 29. Safer Management of Controlled Drugs Guidance on Standard Operating Procedures (Northern Ireland)(draft)
- 30. The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2000. SR No 120
- 31. The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted)
- 32. The Health and Safety at Work (Northern Ireland) Order 1978. SI No 1039 (NI 9).

- The Medicines (Administration of Radioactive Substances) Regulations 1978 SI No 1006 The Stationery Office, London
- 34. The Medicines for Human Use (Clinical Trials) Regulations 2004 SI No 1031
- 35. The Misuse of Drugs (Northern Ireland) Regulations 2002 SR No 1 The Stationery Office, London
- 36. The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 The Stationery Officer, London
- 37. The Prescription Only Medicines (Human Use) Order 1997 as amended. The Stationery Office,
- Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts" [MDEA (NI) 2004/01
- The Segregation Primary Packaging, Secondary Packaging and Storage of Clinical Waste. Health Estates. HSS-E. PEL (99)9 dated 15 March 1999.
- 40. The Management of Clinical waste in the Delivery of Health and Social Care In the Community. Health Estates.
- 41. <u>https://www.health-ni.gov.uk/publications/controls-assurance-standards</u> [Accessed October 28th 2016]

8.0 CONSULTATION PROCESS

Pharmacy Executive Team Drug and Therapeutics Committee BHSCT Central Nursing and Midwifery Group Medical Director and Assistant Medical Directors for dissemination to lead clinicians BHSCT pharmacy staff

9.0 APPENDICES / ATTACHMENTS

Appendix 1 Hospital Medicines Code
Appendix 2 What Doctors need to know about the Medicines Code
Appendix 3 What Pharmacy Technical and Support staff need to know about the Medicines Code

10.0 EQUALITY AND HUMAN RIGHTS SCREENING CARRIED OUT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

| Major impact |
|--------------|
| Minor impact |
| No impact. X |

11.0 DATA PROTECTION IMPACT ASSESSMENT

New activities that involve collecting and using personal data can result in privacy risks. In line with requirements of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 the Trust has to consider the impacts on the privacy of individuals and ways to mitigate against the risks. Where relevant an initial screening exercise should be carried out to ascertain if this policy should be subject to a full impact assessment (see Appendix 7). The guidance for conducting a Data Protection Impact Assessments (DPIA) can be found via this <u>link</u>. The outcome of the DPIA screening for this policy is:

Not necessary – no personal data involved

A full data protection impact assessment is required

A full data protection impact assessment is not required

If a full impact assessment is required the author (Project Manager or lead person) should go ahead and begin the process. Colleagues in the Information Governance Team will provide assistance where necessary.

12.0 RURAL IMPACT ASSESSMENTS

From June 2018 the Trust has a legal responsibility to have due regard to rural needs when developing, adopting, implementing or revising policies, strategies and plans, and when designing and delivering public services. It is your responsibility as policy or service lead to consider the impact of your proposal on people in rural areas – you will need to refer to the shortened rural needs assessment template and summary guidance on the Belfast Trust Intranet. Each Directorate/Division has a Rural Needs Champion who can provide support/assistance in this regard if necessary.

13.0 REASONABLE ADJUSTMENTS ASSESSMENT

Under the Disability Discrimination Act 1995 (as amended), the Trust has a duty to make reasonable adjustments to ensure any barriers disabled people face in gaining and remaining in employment and in accessing and using goods and services are removed or reduced. It is therefore recommended the policy explicitly references "reasonable adjustments will be considered for people who are disabled - whether as service users, visitors or employees

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

10/centle

12/02/2020

Author

Date:

Carolin A. Leonard

12/02/2020

Director

Date: ___

Appendix 1

Hospital Medicines Code

The Belfast Trust Hospital Medicines Code can be found on the Policies and Guidelines page on the Trust HUB or via this <u>link.</u>

Appendix 2

What Doctors need to know about the Medicines Code

The Belfast Trust Medicines Code 'what Doctors need to know' can be found on the Policies and Guidelines page on the Trust HUB or via this <u>link.</u>

Drug and Therapeutics Committee_Medicines Code policy_V4_February 2020

Appendix 3

What Pharmacy Technical and Support Staff need to know about the Medicines Code

The Belfast Trust Medicines Code 'What Pharmacy Technical and Support Staff need to know about the Medicines Code' can be found on the Policies and Guidelines page on the Trust HUB or via this <u>link.</u>

Drug and Therapeutics Committee_Medicines Code policy_V4_February 2020



NICE guideline Published: 4 March 2015 www.nice.org.uk/guidance/ng5

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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

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Contents

| Overview | 4 |
|--|---|
| Who is it for? | 4 |
| Introduction | 5 |
| The King's Fund definitions of polypharmacy | 6 |
| Safeguarding children | 0 |
| Medicines 1 | 1 |
| Key priorities for implementation | 2 |
| 1 Recommendations | 5 |
| Terms used in this guideline | 5 |
| 1.1 Systems for identifying, reporting and learning from medicines-related patient safety incidents | 6 |
| 1.2 Medicines-related communication systems when patients move from one care setting to another | 8 |
| 1.3 Medicines reconciliation 2 | 1 |
| 1.4 Medication review 22 | 2 |
| 1.5 Self-management plans | 4 |
| 1.6 Patient decision aids used in consultations involving medicines | 5 |
| 1.7 Clinical decision support | 7 |
| 1.8 Medicines-related models of organisational and cross-sector working 28 | 8 |
| 2 Research recommendations | 0 |
| 2.1 Medication review in children – suboptimal use of medicines and medicines-related patient safety incidents | 0 |
| 2.2 Medication review – suboptimal use of medicines and patient-reported outcomes | 2 |
| 2.3 Clinical decision support systems | 5 |
| 2.4 Cross-organisational working | 7 |
| Finding more information and committee details40 | 0 |
| Update information 4 | 1 |

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This guideline replaces PSG1.

This guideline partially replaces CG76.

This guideline is the basis of QS120 and QS149.

Overview

This guideline covers safe and effective use of medicines in health and social care for people taking 1 or more medicines. It aims to ensure that medicines provide the greatest possible benefit to people by encouraging medicines reconciliation, medication review, and the use of patient decision aids.

NICE has also produced a guideline on medicines adherence.

Who is it for?

- Healthcare professionals
- Social care practitioners
- Commissioners and providers
- People taking 1 or more medicines and their families and carers

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Introduction

Getting the most from medicines for both patients and the NHS is becoming increasingly important as more people are taking more medicines. Medicines prevent, treat or manage many illnesses or conditions and are the most common intervention in healthcare. However, it has been estimated that between 30% and 50% of medicines prescribed for long-term conditions are not taken as intended (World Health Organization's world health report 2003). This issue is worsened by the growing number of people with long-term conditions. In 2012, the Department of Health's long term conditions compendium of information: third edition suggested that about 15 million people in England now have a long-term condition and the number of long-term conditions a person may have also increases with age: 14% of people aged under 40 years and 58% of people aged 60 years and over report having at least one long-term condition. The report defines a long-term condition as 'a condition that cannot, at present, be cured but is controlled by medication and/or other treatment/therapies'. When one or more non-curable long-term conditions are diagnosed, this is termed 'multimorbidity'. The number of people with multimorbidity in 2008 was 1.9 million, but this is expected to rise to 2.9 million by 2018. Twenty-five per cent of people aged over 60 years report having 2 or more long-term conditions.

Data from the <u>Health and Social Care Information Centre</u> (HSCIC) shows that between 2003 and 2013 the average number of prescription items per year for any one person in England increased from 13 (in 2003) to 19 (in 2013). When a person is taking multiple medicines this is called <u>polypharmacy</u>, a term that has been used in health care for many years. With an increasing ageing population, polypharmacy has become more important to consider when making clinical decisions for individual people.

In 2013, <u>The King's Fund polypharmacy and medicines optimisation – making it safe and</u> <u>sound</u> paper outlined the view that polypharmacy was something to avoid, but proposed an alternative approach to the concept of polypharmacy: that it may have positive (appropriate) or negative (problematic) potential. Reducing the number of medicines a person is taking may not be the only factor to consider when reviewing polypharmacy.

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The King's Fund definitions of polypharmacy

Appropriate polypharmacy

'Prescribing for an individual for complex conditions or for multiple conditions in circumstances where medicines use has been optimised and where the medicines are prescribed according to best evidence.'

Problematic polypharmacy

'The prescribing of multiple [medicines] inappropriately, or where the intended benefit of the [medicines are] not realised.'

As the population ages and life expectancy increases, more people are living with several long-term conditions that are being managed with an increasing number of medicines. Maintaining a careful balance gets more difficult for people and health professionals, particularly when also trying to reduce health inequalities of the population.

Optimising a person's medicines is important to ensure a person is taking their medicines as intended and can support the management of long-term conditions, multimorbidities and polypharmacy. Medicines optimisation is defined as 'a person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines. Medicines optimisation applies to people who may or may not take their medicines effectively. Shared decision-making is an essential part of evidence-based medicine, seeking to use the best available evidence to guide decisions about the care of the individual patient, taking into account their needs, preferences and values' (Evidence based medicine: a movement in crisis Greenhalgh et al. 2014; Evidence based medicine: what it is and what it isn't Sackett et al. 1996).

An important part of shared decision-making is about health professionals understanding the person's desired level of involvement in decision-making about their medicines. When having these discussions it is often difficult for the person and the health professional to decide whether the medicines being taken are appropriate and the decision may be different for each individual person.

Involving people in decisions about their care and treatment is not a new concept. Over several years the UK government has supported an approach to change how the NHS

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engages with patients. The <u>Department of Health's equality and excellence: liberating the</u> <u>NHS</u> outlined the government's vision of putting the public and patients first through shared decision-making. This White paper stressed that this would only happen by 'involving patients fully in their own care, with decisions made in partnership with clinicians, rather than by clinicians alone' and would be implemented by making shared decision-making the 'norm'. Subsequent to the government's White paper, <u>The King's</u> <u>Fund's making shared decision-making a reality: no decision about me, without me</u> aimed to outline the skills and resources needed by health professionals to use shared decision-making, and suggested tools that may help patients in decision-making when implementing this principle throughout the NHS.

The <u>NICE guidelines on patient experience in adult NHS services</u> and <u>service user</u> <u>experience in adult mental health</u> provide recommendations aiming to improve the experience of care for people using adult NHS and adult mental health services to create sustainable changes that aim to move the NHS towards a truly person-centred service. In relation to medicines, the <u>NICE guideline on medicines adherence</u> recommends that all patients have the opportunity to be involved in decisions about their medicines at the level they wish, through shared decision-making. Furthermore, <u>General Medical Council's good</u> <u>practice in prescribing and managing medicines and devices</u> also emphasises the need to take account of the patient's needs, wishes and preferences.

The safety of medicines is another important consideration when optimising medicines and can be a continual challenge. The <u>Department of Health's exploring the costs of</u> <u>unsafe care in the NHS</u> report found that 5% to 8% of unplanned hospital admissions are due to medication issues. This report focused on preventable adverse events which can be attributed to a specific error or errors. Incidents involving medicines have a number of causes, for example: lack of knowledge, failure to follow systems and protocols, interruptions (for example, during prescribing, administration or dispensing), staff competency, poor instruction, and poor communication. Organisations should have a standard approach to determine when a medicines-related incident or error should be referred to local safeguarding services. Effective systems and processes can minimise the risk of preventable medicines-related problems such as side effects, adverse effects or interactions with other medicines or comorbidities. The risk of people suffering harm from their medicines increases with polypharmacy.

The <u>Francis Report</u> (2013) emphasised the need to put patients first at all times, and that they must be protected from avoidable harm. In addition, the <u>Berwick report</u> (2013) recommended 4 guiding principles for improving patient safety, including:

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- placing the quality and safety of patient care above all other aims for the NHS
- engaging, empowering, and hearing patients and carers throughout the entire system, and at all times.

Adverse events of medicines represent a considerable burden on the NHS and have a significant impact on patients (<u>Adverse drug reactions as cause of admission to hospital:</u> <u>prospective analysis of 18 820 patients Pirmohamed et al. 2004</u>). When people transfer between different care providers, such as at the time of hospital admission or discharge, there is a greater risk of poor communication and unintended changes to medicines (<u>Royal Pharmaceutical Society getting the medicines right</u>). When people move from one care setting to another, between 30% and 70% of patients have an error or unintentional change to their medicines.

Patient safety in relation to medicines is not a new issue and several national initiatives exist to help improve patient safety. In 1964, the <u>Medicines and Healthcare products</u> <u>Regulatory Agency</u> (MHRA) and Commission on Human Medicines launched the national <u>yellow card scheme</u> for reporting side effects to medicines. The scheme is still in existence today and over 600,000 UK yellow cards have been received.

The <u>National Reporting and Learning System</u> (NRLS) was introduced in 2010 by the <u>National Patient Safety Agency</u> (NPSA) as a single, national reporting system for patient safety incidents in England and Wales. The NRLS staff reviewed all alerts to help NHS organisations understand patient safety incidents and why and how they happened, learning from these experiences and taking action to prevent future harm to people. In June 2012, the key functions and expertise for patient safety developed by the NPSA transferred to NHS England.

In 2014, NHS England and the MHRA issued a joint alert <u>Patient safety alert improving</u> <u>medication error reporting and learning</u>. The alerts aim to improve the quality of data reported by providers and introduce national networks to maximise learning and provide guidance on minimising harm relating to medication error reporting. NHS England also launched at this time a new National Patient Safety Alerting System (NPSAS) to strengthen the rapid dissemination of urgent patient safety alerts to healthcare providers via the <u>Central Alerting System (CAS)</u>. The new system is a three-stage system to provide 'useful educational and implementation resources to support providers to put appropriate measures in place to prevent harm and encourage and share best practice in patient safety'.

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To further support the patient safety agenda, the <u>NHS Safety Thermometer</u> was introduced by the Department of Health as a measurement tool to support an additional programme of work aimed at supporting patient safety and improvement. The tool is accessible to organisations across all healthcare settings, such as hospitals, care homes and community nursing, and allows them to measure, monitor and analyse patient harms and harm-free care at a local level to assess improvement over time.

Medicines use can be complex and how people can take their medicines safely and effectively has been a challenge for the health service for many years. The <u>Department of Health's liberating the NHS</u> emphasised the need to improve the outcomes of healthcare for all, to deliver care that is safer, more effective and provides a better experience for patients. Furthermore, the focus of health and social care to become a more integrated service, with person-centred care, has been made a priority after the Health and Social Care Act was passed in 2012. The Act aims to modernise the NHS, putting clinicians at the centre of commissioning and empowering patients. The <u>NHS Constitution</u> outlined the values and principles of the NHS in England and gave people the right to be involved in discussions and decisions about their health and care, and to be given information to enable them to do this. Patients with capacity have the right to make an informed decision and can refuse to take their medicines.

Before medicines optimisation, the term 'medicines management' was used which has been defined as 'a system of processes and behaviours that determines how medicines are used by the NHS and patients' (National Prescribing Centre 2002). Medicines management has primarily been led by pharmacy teams. Medicines management is an important enabler of medicines optimisation. The definition of 'optimise' is to 'make the best or most effective use of (a situation or resource)'. Medicines optimisation focuses on actions taken by all health and social care practitioners and requires greater patient engagement and professional collaboration across health and social care settings.

The <u>Royal Pharmaceutical Society's medicines optimisation: helping patients make the</u> <u>most of medicines</u> guide was produced to support the medicines optimisation agenda. This guide suggests 4 guiding principles for medicines optimisation, aiming to lead to improved patient outcomes:

- 'Aim to understand the patient's experience
- Evidence based choice of medicines
- Ensure medicines use is as safe as possible

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• Make medicines optimisation part of routine practice'.

To further support the implementation of the guiding principles, the prototype <u>NHS</u> <u>England medicines optimisation dashboard</u> was launched. The dashboard aims to 'encourage Clinical Commissioning Groups (CCGs) and trusts to think more about how well their patients are supported to use medicines and less about focusing on cost and volume of drugs'. <u>NHS England's medicines optimisation supporting information</u> outlines the purpose of the dashboard.

Better use of data and technology can give people more control over their health and support the medicines optimisation agenda. The <u>National Information Board</u> (NIB) has been established by the Department of Health to bring together 'national health and core organisations from the NHS, public health, clinical science, social care and local government, together with appointed lay representatives'. The <u>National Information Board</u> personalised health and care 2020: a framework for action was published to support people using health and social care services and frontline health and social care practitioners to take better advantage the digital opportunity. Using the potential of information technology and data will help bridge the gaps between care services and enable people who use these services have access to their health care information, all of which can help optimise the use of medicines.

Striving towards a person-centred service through joint working across health and social care and cross-sector working (for example with commercial organisations) achieves the best possible outcomes for the person. This incorporates a patient's values and preferences and minimises harm, supporting effective medicines optimisation. This guideline reviews the evidence available to support health and social care practitioners, and health and social care organisations, in considering the systems and processes required to ensure safe and effective medicines optimisation.

In this guideline, the term 'medicines' covers all healthcare treatments, such as oral medicines, topical medicines, inhaled products, injections, wound care products, appliances and vaccines.

Safeguarding children

Remember that child maltreatment:

• is common

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- can present anywhere
- may co-exist with other health problems.

See <u>NICE's guideline on child maltreatment</u> for clinical features that may be associated with maltreatment.

Medicines

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

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Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in <u>section 1</u>.

Systems for identifying, reporting and learning from medicines-related patient safety incidents

 Organisations should consider using multiple methods to identify medicines-related patient safety incidents – for example, health record review, patient surveys and direct observation of medicines administration. They should agree the approach locally and review arrangements regularly to reflect local and national learning.

Medicines-related communication systems when patients move from one care setting to another

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- Health and social care practitioners should share relevant information about the person and their medicines when a person transfers from one care setting to another. This should include, but is not limited to, all of the following:
 - contact details of the person and their GP
 - details of other relevant contacts identified by the person, and their family members or carers where appropriate – for example, their nominated community pharmacy
 - known drug allergies and reactions to medicines or their ingredients, and the type of reaction experienced (see <u>NICE's guideline on drug allergy</u>)
 - details of the medicines the person is currently taking (including prescribed, over-the-counter and complementary medicines) – name, strength, form, dose, timing, frequency and duration, how the medicines are taken and what they are being taken for
 - changes to medicines, including medicines started or stopped, or dosage changes, and reason for the change
 - date and time of the last dose, such as for weekly or monthly medicines, including injections
 - what information has been given to the person, and their family members or carers where appropriate
 - any other information needed for example, when the medicines should be reviewed, ongoing monitoring needs and any support the person needs to carry on taking the medicines. Additional information may be needed for specific groups of people, such as children.
- Consider sending a person's medicines discharge information to their nominated community pharmacy, when possible and in agreement with the person.

Medicines reconciliation

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- Organisations should ensure that medicines reconciliation is carried out by a trained and competent health professional – ideally a pharmacist, pharmacy technician, nurse or doctor – with the necessary knowledge, skills and expertise including:
 - effective communication skills
 - technical knowledge of processes for managing medicines
 - therapeutic knowledge of medicines use.

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1 Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>NICE's information on making decisions about your</u> <u>care</u>.

<u>Making decisions using NICE guidelines</u> explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

The following guidance is based on the best available evidence. The <u>full guideline</u> gives details of the methods and the evidence used to develop the guidance.

Terms used in this guideline

Adverse drug reaction This is a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. See also <u>Medicines and Healthcare Products Regulatory Agency</u> for further information.

Complementary medicine Treatments that fall outside of mainstream healthcare. These medicines and treatments range from acupuncture and homeopathy to aromatherapy.

'Fair blame' culture In health and social care, this enables open and honest reporting of mistakes that are treated as an opportunity to learn to improve care.

Over-the-counter medicines Medicines that can be bought without a prescription.

Person's baseline risk Patient decision aids illustrate the absolute benefits and risks of interventions, assuming a particular baseline risk. It is important to take into account the person's likely starting or baseline risk when using a patient decision aid. Even though the relative risk is the same regardless of the person's baseline risk, people with a lower baseline risk than that illustrated in a patient decision aid will have a lower absolute chance of benefiting and a lower residual risk. People with a greater baseline risk than that

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illustrated will have a greater absolute chance of benefiting but also a greater residual risk.

PINCER (pharmacist-led information technology intervention for medication errors) Method for reducing a range of medication errors in general practices with computerised clinical records.

Polypharmacy Use of multiple medicines by a person.

Preference-sensitive decision Decisions about treatment made based on the person's preferences and personal values of each treatment option presented. Decisions should be made only after patients have enough information to make an informed choice, in partnership with the prescriber.

Robust and transparent Robust and transparent processes, including sharing of information and appropriate collaboration with relevant stakeholders, aims to improve the consistency of decision-making about medicines and ensure that patient safety is not compromised. This should reduce inappropriate variation in patient care when decisions are made due to inconsistent, inadequate or unsafe processes and policies. However, even with robust and transparent processes in place, legitimate variation will remain. Organisations will make decisions within their local governance arrangements that are based on local priorities and the needs of their local population.

1.1 Systems for identifying, reporting and learning from medicines-related patient safety incidents

Improving learning from medicines-related patient safety incidents is important to guide practice and minimise patient harm. Medicines-related patient safety incidents are unintended or unexpected incidents that are specifically related to medicines use, which could have or did lead to patient harm. These include potentially avoidable medicines-related hospital admissions and re-admissions, medication errors, near misses and potentially avoidable adverse events.

- 1.1.1 Organisations should support a person-centred, <u>'fair blame' culture</u> that encourages reporting and learning from medicines-related patient safety incidents.
- 1.1.2 Health and social care practitioners should explain to patients, and their

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family members or carers where appropriate, how to identify and report medicines-related patient safety incidents.

- 1.1.3 Organisations should ensure that <u>robust and transparent</u> processes are in place to identify, report, prioritise, investigate and learn from medicines-related patient safety incidents, in line with national patient safety reporting systems – for example, the <u>National Reporting and</u> <u>Learning System</u>.
- 1.1.4 Organisations should consider using multiple methods to identify medicines-related patient safety incidents – for example, health record review, patient surveys and direct observation of medicines administration. They should agree the approach locally and review arrangements regularly to reflect local and national learning.
- 1.1.5 Organisations should ensure that national medicines safety guidance, such as patient safety alerts, are actioned within a specified or locally agreed timeframe.
- 1.1.6 Organisations should consider assessing the training and education needs of health and social care practitioners to help patients and practitioners to identify and report medicines-related patient safety incidents.
- 1.1.7 Health and social care practitioners should report all identified medicines-related patient safety incidents consistently and in a timely manner, in line with local and national patient safety reporting systems, to ensure that patient safety is not compromised.
- 1.1.8 Organisations and health professionals should consider applying the principles of the <u>PINCER</u> intervention to reduce the number of medicines-related patient safety incidents, taking account of existing systems and resource implications. These principles include:
 - using information technology support
 - using educational outreach with regular reinforcement of educational messages

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- actively involving a multidisciplinary team, including GPs, nurses and support staff
- having dedicated pharmacist support
- agreeing an action plan with clear objectives
- providing regular feedback on progress
- providing clear, concise, evidence-based information.
- 1.1.9 Consider using a screening tool for example, the STOPP/START tool in older people to identify potential medicines-related patient safety incidents in some groups (STOPP, Screening Tool of Older Persons' potentially inappropriate Prescriptions; START, Screening Tool to Alert to Right Treatment). These groups may include:
 - adults, children and young people taking multiple medicines (polypharmacy)
 - adults, children and young people with chronic or long-term conditions
 - older people.
- 1.1.10 Organisations should consider exploring what barriers exist that may reduce reporting and learning from medicines-related patient safety incidents. Any barriers identified should be addressed – for example, using a documented action plan.
- 1.1.11 Health and social care organisations and practitioners should:
 - ensure that action is taken to reduce further risk when medicines-related patient safety incidents are identified
 - apply and share learning in the organisation and across the local health economy, including feedback on trends or significant incidents to support continuing professional development. This may be through a medicines safety officer, controlled drugs accountable officer or other medicines safety lead.

1.2 Medicines-related communication systems when patients move from one care setting to

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another

Relevant information about medicines should be shared with patients, and their family members or carers, where appropriate, and between health and social care practitioners when a person moves from one care setting to another, to support high-quality care. This includes transfers within an organisation – for example, when a person moves from intensive care to a hospital ward – or from one organisation to another – for example, when a person is admitted to hospital, or discharged from hospital to their home or other location.

Recommendations in this section update and replace recommendation 1.4.2 in <u>NICE's</u> guideline on medicines adherence.

- 1.2.1 Organisations should ensure that <u>robust and transparent</u> processes are in place, so that when a person is transferred from one care setting to another:
 - the current care provider shares complete and accurate information about the person's medicines with the new care provider **and**
 - the new care provider receives and documents this information, and acts on it.

Organisational and individual roles and responsibilities should be clearly defined. Regularly review and monitor the effectiveness of these processes. See also section 1.3 on medicines reconciliation.

Take into account the 5 rules set out in the <u>Health and Social Care Information</u> <u>Centre's guide to confidentiality in health and social care</u> when sharing information.

- 1.2.2 For all care settings, health and social care practitioners should proactively share complete and accurate information about medicines:
 - ideally within 24 hours of the person being transferred, to ensure that patient safety is not compromised **and**
 - in the most effective and secure way, such as by secure electronic communication, recognising that more than one approach may be needed.

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- 1.2.3 Health and social care practitioners should share relevant information about the person and their medicines when a person transfers from one care setting to another. This should include, but is not limited to, all of the following:
 - contact details of the person and their GP
 - details of other relevant contacts identified by the person and their family members or carers where appropriate – for example, their nominated community pharmacy
 - known drug allergies and reactions to medicines or their ingredients, and the type of reaction experienced (see <u>NICE's guideline on drug allergy</u>)
 - details of the medicines the person is currently taking (including prescribed, <u>over-the-counter</u> and <u>complementary medicines</u>) – name, strength, form, dose, timing, frequency and duration, how the medicines are taken and what they are being taken for
 - changes to medicines, including medicines started or stopped, or dosage changes, and reason for the change
 - date and time of the last dose, such as for weekly or monthly medicines, including injections
 - what information has been given to the person, and their family members or carers where appropriate
 - any other information needed for example, when the medicines should be reviewed, ongoing monitoring needs and any support the person needs to carry on taking the medicines. Additional information may be needed for specific groups of people, such as children.
- 1.2.4 Health and social care practitioners should discuss relevant information about medicines with the person, and their family members or carers where appropriate, at the time of transfer. They should give the person, and their family members or carers where appropriate, a complete and accurate list of their medicines in a format that is suitable for them. This should include all current medicines and any changes to medicines made during their stay.

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- 1.2.5 Consider sending a person's medicines discharge information to their nominated community pharmacy, when possible and in agreement with the person.
- 1.2.6 Organisations should consider arranging additional support for some groups of people when they have been discharged from hospital, such as pharmacist counselling, telephone follow-up, and GP or nurse follow-up home visits. These groups may include:
 - adults, children and young people taking multiple medicines (polypharmacy)
 - adults, children and young people with chronic or long-term conditions
 - older people.

1.3 Medicines reconciliation

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.

- 1.3.1 In an acute setting, accurately list all of the person's medicines (including prescribed, over-the-counter and complementary medicines) and carry out medicines reconciliation within 24 hours or sooner if clinically necessary, when the person moves from one care setting to another for example, if they are admitted to hospital.
- 1.3.2 Recognise that medicines reconciliation may need to be carried out on more than one occasion during a hospital stay for example, when the person is admitted, transferred between wards or discharged.
- 1.3.3 In primary care, carry out medicines reconciliation for all people who have been discharged from hospital or another care setting. This should

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happen 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.

- 1.3.4 In all care settings organisations should ensure that a designated health professional has overall organisational responsibility for the medicines reconciliation process. The process should be determined locally and include:
 - organisational responsibilities
 - responsibilities of health and social care practitioners involved in the process (including who they are accountable to)
 - individual training and competency needs.
- 1.3.5 Organisations should ensure that medicines reconciliation is carried out by a trained and competent health professional – ideally a pharmacist, pharmacy technician, nurse or doctor – with the necessary knowledge, skills and expertise including:
 - effective communication skills
 - technical knowledge of processes for managing medicines
 - therapeutic knowledge of medicines use.
- 1.3.6 Involve patients and their family members or carers, where appropriate, in the medicines reconciliation process.
- 1.3.7 When carrying out medicines reconciliation, record relevant information on an electronic or paper-based form. See <u>section 1.2</u> on medicines-related communication systems.

1.4 Medication review

Medication review can have several different interpretations and there are also different types which vary in their quality and effectiveness. Medication reviews are carried out in people of all ages. In this guideline medication review is defined as 'a structured, critical examination of a person's medicines with the objective of reaching an agreement with the

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person about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'. See also <u>recommendation 1.6.3</u>.

- 1.4.1 Consider carrying out a structured medication review for some groups of people when a clear purpose for the review has been identified. These groups may include:
 - adults, children and young people taking multiple medicines (polypharmacy)
 - adults, children and young people with chronic or long-term conditions
 - older people.
- 1.4.2 Organisations should determine locally the most appropriate health professional to carry out a structured medication review, based on their knowledge and skills, including all of the following:
 - technical knowledge of processes for managing medicines
 - therapeutic knowledge on medicines use
 - effective communication skills.

The medication review may be led, for example, by a pharmacist or by an appropriate health professional who is part of a multidisciplinary team.

- 1.4.3 During a structured medication review, take into account:
 - the person's, and their family members or carers where appropriate, views and understanding about their medicines
 - the person's, and their family members' or carers' where appropriate, concerns, questions or problems with the medicines
 - all prescribed, <u>over-the-counter</u> and <u>complementary medicines</u> that the person is taking or using, and what these are for
 - how safe the medicines are, how well they work for the person, how appropriate they are, and whether their use is in line with national guidance

- whether the person has had or has any risk factors for developing <u>adverse</u> <u>drug reactions</u> (report adverse drug reactions in line with the <u>yellow card</u> <u>scheme</u>)
- any monitoring that is needed.

1.5 Self-management plans

Self-management plans can be patient-led or professional-led and they aim to support people to be empowered and involved in managing their condition. Different types of self-management plan exist and they vary in their content depending on the needs of the individual person. Self-management plans can be used in different settings. In this guideline self-management plans are structured, documented plans that are developed to support a person's self management of their condition using medicines. People using self-management plans can be supported to use them by their family members or carers who can also be involved when appropriate during discussions – for example, a child and their parents using a self-management plan.

- 1.5.1 When discussing medicines with people who have chronic or long-term conditions, consider using an individualised, documented self-management plan to support people who want to be involved in managing their medicines. Discuss at least all of the following:
 - the person's knowledge and skills needed to use the plan, using a risk assessment if needed
 - the benefits and risks of using the plan
 - the person's values and preferences
 - how to use the plan
 - any support, signposting or monitoring the person needs.

Record the discussion in the person's medical notes or care plan as appropriate.

1.5.2 When developing an individualised, documented self-management plan, provide it in an accessible format for the person and consider including:

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- the plan's start and review dates
- the conditions being managed
- a description of medicines being taken under the plan (including the timing)
- a list of the medicines that may be self-administered under the plan and their permitted frequency of use, including any strength or dose restrictions and how long a medicine may be taken for
- known drug allergies and reactions to medicines or their ingredients, and the type of reaction experienced (see the <u>NICE guideline on drug allergy</u>)
- arrangements for the person to report suspected or known adverse reactions to medicines
- circumstances in which the person should refer to, or seek advice from, a health professional
- the individual responsibilities of the health professional and the person
- any other instructions the person needs to safely and effectively self-manage their medicines.
- 1.5.3 Review the self-management plan to ensure the person does not have problems using it.

1.6 Patient decision aids used in consultations involving medicines

Many people wish to be active participants in their own healthcare, and to be involved in making decisions about their medicines. Patient decision aids can support health professionals to adopt a shared decision-making approach in a consultation, to ensure that patients, and their family members or carers where appropriate, are able to make well-informed choices that are consistent with the person's values and preferences. More information is available in <u>NICE's guidelines on decision-making and mental capacity</u> and <u>shared decision making</u>.

1.6.1 Offer all people the opportunity to be involved in making decisions about their medicines. Find out what level of involvement in decision-making

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the person would like and avoid making assumptions about this.

- 1.6.2 Find out about a person's values and preferences by discussing what is important to them about managing their conditions and their medicines. Recognise that the person's values and preferences may be different from those of the health professional and avoid making assumptions about these.
- 1.6.3 Apply the principles of evidence-based medicine when discussing the available treatment options with a person in a consultation about medicines. Use the best available evidence when making decisions with or for individuals, together with clinical expertise and the person's values and preferences.
- 1.6.4 In a consultation about medicines, offer the person, and their family members or carers where appropriate, the opportunity to use a patient decision aid (when one is available) to help them make a <u>preference-sensitive decision</u> that involves trade-offs between benefits and harms. Ensure the patient decision aid is appropriate in the context of the consultation as a whole.
- 1.6.5 Do not use a patient decision aid to replace discussions with a person in a consultation about medicines.
- 1.6.6 Recognise that it may be appropriate to have more than one consultation to ensure that a person can make an informed decision about their medicines. Give the person the opportunity to review their decision, because this may change over time – for example, a <u>person's baseline</u> <u>risk</u> may change.
- 1.6.7 Ensure that patient decision aids used in consultations about medicines have followed a <u>robust and transparent</u> development process, in line with <u>NICE's Standards framework for shared-decision-making support tools,</u> <u>including patient decision aids</u> or the <u>International Patient Decision Aid</u> <u>Standards criteria</u>.
- 1.6.8 Before using a patient decision aid with a person in a consultation about medicines, read and understand its content, paying particular attention

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to its limitations and the need to adjust discussions according to the person's baseline risk.

- 1.6.9 Ensure that the necessary knowledge, skills and expertise have been obtained before using a patient decision aid. This includes:
 - relevant clinical knowledge
 - effective communication and consultation skills, especially when finding out patients' values and preferences
 - effective numeracy skills, especially when explaining the benefits and harms in natural frequencies, and relative and absolute risk
 - explaining the trade-offs between particular benefits and harms.
- 1.6.10 Organisations should consider training and education needs for health professionals in developing the skills and expertise to use patient decision aids effectively in consultations about medicines with patients, and their family members or carers where appropriate.
- 1.6.11 Organisations should consider identifying and prioritising which patient decision aids are needed for their patient population through, for example, a local medicines decision-making group. They should agree a consistent, targeted approach in line with local pathways and review the use of these patient decision aids regularly.
- 1.6.12 Organisations and health professionals should ensure that patient decision aids prioritised for use locally are disseminated to all relevant health professionals and stakeholder groups, such as clinical networks.

1.7 Clinical decision support

Clinical decision support software is a component of an integrated clinical IT system providing support to clinical services, such as in a GP practice or secondary care setting. These integrated clinical IT systems are used to support health professionals to manage a person's condition. In this guideline the clinical decision support software relates to computerised clinical decision support, which may be active or interactive, at the point of prescribing medicines.

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- 1.7.1 Organisations should consider computerised clinical decision support systems (taking account of existing systems and resource implications) to support clinical decision-making and prescribing, but ensure that these do not replace clinical judgement.
- 1.7.2 Organisations should ensure that <u>robust and transparent</u> processes are in place for developing, using, reviewing and updating computerised clinical decision support systems.
- 1.7.3 Organisations should ensure that health professionals using computerised clinical decision support systems at the point of prescribing have the necessary knowledge and skills to use the system, including an understanding of its limitations.
- 1.7.4 When using a computerised clinical decision support system to support clinical decision-making and prescribing, ensure that it:
 - identifies important safety issues
 - includes a system for health professionals to acknowledge mandatory alerts. This should not be customisable for alerts relating to <u>medicines-related 'never</u> <u>events'</u>
 - reflects the best available evidence and is up-to-date
 - contains useful clinical information that is relevant to the health professional to reduce 'alert fatigue' (when a prescriber's responsiveness to a particular type of alert declines as they are repeatedly exposed to that alert over time).

1.8 Medicines-related models of organisational and cross-sector working

The introduction of skill mixing of various health and social care practitioners to meet the needs of different groups of people has led to different types of models of care emerging across health and social care settings. Cross-organisational working further provides seamless care during the patient care pathway when using health and social care services. The type of model of care used will be determined locally based on the resources and health and social care needs of the population in relation to medicines.

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- 1.8.1 Organisations should consider a multidisciplinary team approach to improve outcomes for people who have long-term conditions and take multiple medicines (polypharmacy).
- 1.8.2 Organisations should involve a pharmacist with relevant clinical knowledge and skills when making strategic decisions about medicines use or when developing care pathways that involve medicines use.

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2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

2.1 Medication review in children – suboptimal use of medicines and medicines-related patient safety incidents

Is a medication review more clinically and cost effective at reducing the suboptimal use of medicines and medicines-related patient safety incidents, compared with usual care or other interventions, in children?

The research should be carried out in children that use services where medication reviews can be carried out.

Study methodology can be based on other well-conducted randomised controlled trials (RCTs) that have been carried out in adults, the difference being the age of the population. Approval from ethics or other committees would be needed given the young age of the population. 'Usual care' or other interventions would be used as a comparator. 'Usual care' would need to be defined in the study. A follow-up period of 1–2 years or more would capture longer-term outcomes. The outcomes for this research question should be patient-centred and include suboptimal use of medicines, medicines-related patient safety incidents, patient-reported outcomes, clinical outcomes, medicines-related problems, health and social care resource use and cost effectiveness.

The study would need to take into account:

- the type of medication review carried out; the study needs to outline a framework of the medication review to help guidance developers to see the process used; they would then be better able to decide if it would affect clinical effectiveness of the intervention
- the health professional carrying it out

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- child, parent and carer involvement as this may affect some outcome measures, depending on their engagement level
- the frequency of medication review (this would impact on cost effectiveness of resource use).

Rationale

The GDG recognised that the key focus of the medicines optimisation agenda is to make care person-centred. In line with this and to ensure the best use of NHS resources, the GDG agreed that research needs to be carried out in children to identify the benefit from them having medication reviews. There may be some longer-term gains with this approach, as from a young age the child would become more aware of the intervention, develop a relationship with the health professional and be encouraged to understand their medicines.

Research into this area will provide guidance to organisations who may want to, or already provide, medication reviews as part of their care and enable better use of resources (for example, health professional cost and time and health and social care resources). This information would be useful to commissioners who may consider whether or not to commission providers to carry out medication reviews.

| Criterion | Explanation |
|--------------|---|
| Population | Children (this may also involve parents or carers where appropriate) taking medicines for 1 or more clinical conditions in the UK. |
| | Medication reviews. |
| Intervention | Defined in the review protocol as: 'a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'. |
| | The framework of the medication review should be outlined in the method of the study. |
| | The medication review can be professional led or carried out by a multidisciplinary team. |

Proposed format of research recommendations

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| Criterion | Explanation | | | |
|-----------------|--|--|--|--|
| Comparators | 'Usual care' such as people who may not have a medication review or may have an 'ad hoc' review of their medicines. This may be provided in all settings. Other interventions, such as another type of medication review. | | | |
| | The following outcomes should be considered: | | | |
| | suboptimal prescribing | | | |
| | medicines-related patient safety incidents | | | |
| | patient-reported outcomes (for example, patient satisfaction and medicines adherence) | | | |
| | quality of life | | | |
| Outcome | clinical outcomes | | | |
| | medicines-related problems (for example, medication errors) | | | |
| | health and social care resource use. | | | |
| | For results to be valid and reliable, outcomes should ideally be measured using validated tools, and where this is not possible the outcome measure should be detailed in the study. | | | |
| | Quality of life should be assessed using an EQ–5D questionnaire so that a cost–utility analysis can be conducted. | | | |
| Study design | Randomised controlled trial. | | | |
| Timeframe | Follow-up outcomes of 1–2 years or more. This will enable assessment or the clinical and economic impact of medication reviews on long-term conditions and associated outcomes. | | | |

2.2 Medication review – suboptimal use of medicines and patient-reported outcomes

Is a medication review more clinically and cost effective at reducing the suboptimal use of medicines and improving patient-reported outcomes, compared with usual care or other intervention in the UK setting?

The study should consider the cost effectiveness of the health professionals carrying out

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the medication review.

The medication review should be carried out by a multidisciplinary team or be professional led by any health professional other than a community or hospital pharmacist to provide data to develop an economic model for cost effectiveness. There is already economic evidence available for community and hospital pharmacists.

Research can be carried out using an RCT. Study methodology can be based on other well-conducted RCTs that have been carried out looking at medication reviews. 'Usual care' or other interventions would be used as a comparator. 'Usual care' would need to be defined in the study. A follow-up period of 1–2 years or more would capture longer-term outcomes. Outcomes for this research question should be patient-centred and include the suboptimal use of medicines, patient-reported outcomes, clinical outcomes, medicines-related problems, health and social care resource use and cost effectiveness.

The study would need to take into account:

- the type of medication review carried out; the study would need to outline a framework of the medication review to help guidance developers to see the process used; they would then be better able to decide if it would affect clinical effectiveness of the intervention
- type of health professional carrying out the medication review
- the frequency of medication review (this would impact on cost effectiveness of resource use).

Rationale

The GDG recognised that the key focus of the medicines optimisation agenda is to make care person-centred and to have services that support people in the optimal use of their medicines. Medication reviews can be offered to people by different health professionals at different levels, working in different settings. Resources (for example, staff and time) needed to enable routine medication review may vary locally depending on the setting and health professional availability.

Research into this area will provide guidance to organisations who may want to, or already provide, medication reviews as part of their care and enable better use of resources (for example, health professional cost and time and health and social care resources) and

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facilitate service delivery. This information would be useful to commissioners who may consider whether or not to commission medication reviews by providers.

| Criterion | Explanation | | | |
|--------------|--|--|--|--|
| Population | Children and adults taking medicines for 1 or more clinical conditions in the UK. | | | |
| Intervention | Medication reviews. Defined in the review protocol as: 'a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the | | | |
| | patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'. | | | |
| | The framework of the medication review should be outlined in the method of the study. | | | |
| | Carried out by health professionals (including primary care pharmacists) other than community or hospital pharmacists. | | | |
| | Carried out by a multidisciplinary team that can involve any health professional. | | | |
| | 'Usual care' such as people who may not have a medication review, or may have an 'ad hoc' review of their medicines. This may be provided in all settings. | | | |
| Comparators | Other interventions, such as: | | | |
| Comparators | another type of medication review | | | |
| | a review carried out by health professionals other than those specified in the intervention, for example a nurse rather than a doctor. | | | |

Proposed format of research recommendations

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| Criterion | Explanation | | | | |
|-----------------|--|--|--|--|--|
| Outcome | The following outcomes should be considered: | | | | |
| | suboptimal prescribing | | | | |
| | patient-reported outcomes (for example, patient satisfaction and medicines adherence) | | | | |
| | medicines-related patient safety incidents | | | | |
| | quality of life | | | | |
| | clinical outcomes | | | | |
| | medicines-related problems (for example, medication errors) | | | | |
| | health and social care resource use. | | | | |
| | For results to be valid and reliable, outcomes should ideally be measured using validated tools; where this is not possible the outcome measure should be detailed in the study. | | | | |
| | Quality of life should be assessed using an EQ–5D questionnaire so that a cost–utility analysis can be conducted. | | | | |
| Study design | Randomised controlled trial. | | | | |
| Timeframe | Follow-up outcomes of 1–2 years or more. This would enable assessme on the clinical and economic impact of medication reviews on long-terr conditions and associated outcomes. | | | | |

2.3 Clinical decision support systems

What is the clinical and cost effectiveness of using clinical decision support systems to reduce the suboptimal use of medicines and improve patient outcomes from medicines, compared with usual care, in the UK setting?

Randomised controlled trials should consider the use of clinical decision support systems to improve outcomes and safety for medicines in the UK setting compared with usual care. A follow-up period (ideally longer than 2 years) would capture longer-term outcomes.

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Outcomes for this research question should include patient-reported outcomes, clinical outcomes, medicines-related problems and cost effectiveness. The research can be carried out in all populations that use services where clinical decision support systems can be used. The research could also look at process measures for using clinical decision support systems, for example the clinical effectiveness of such systems can depend on the end users of the system and their interpretation of the active information provided on the screen.

Rationale

Clinical decision support systems (defined as 'an active, computerised intervention that occurs at the time and location of prescribing, to support prescribers with decision-making') are widely used in some primary care settings, such as in GP practices, but they may also be used in secondary care (in specialist units, for example renal units). There are many types of clinical decision support system available and they vary, from providing clinical decision support for general medicines use to highlighting specific drug interactions. As different types of clinical decision support systems are used already in some UK healthcare settings, the GDG agreed that research needs to be carried out to identify whether using clinical decision support systems is a clinically and cost effective intervention to reduce the suboptimal use of medicines and improve patient outcomes from medicines compared with usual care, in the UK setting.

Proposed format of research recommendations

| Criterion | Explanation | | |
|--------------|--|--|--|
| Population | All people taking medicines. | | |
| Intervention | Clinical decision support systems. Defined in the review protocol as 'an active, computerised intervention that occurs at the time and location of prescribing, to support prescribers with decision-making'. | | |

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| Criterion | Explanation |
|-----------------|---|
| Comparators | Usual care. 'Usual care' in the primary care setting, for example in a GP practice, uses clinical decision support systems which may highlight for example choice of formulary medicines or drug interaction to the prescriber, however 'usual care' in secondary care settings may be different when such clinical decision support systems may or may not be available to use. |
| Outcome | The following outcomes should be considered: patient-reported outcomes (for example satisfaction, medicines adherence) quality of life clinical outcomes medicines related problems (for example adverse drug reactions). An appropriate length of follow-up would be 2 years or more for the outcomes to be externally valid. Process measures may also be considered for this research question to see what impact clinical decision support systems have on the training on use of systems, updating systems, and 'alert fatigue'. |
| Study design | Randomised controlled trial. |
| Timeframe | Follow-up outcomes of 2 years or more. |

2.4 Cross-organisational working

What models of cross-organisational working improve clinical and cost effectiveness in relation to the suboptimal prescribing of medicines – for example, between NHS and social care, or primary and secondary care, or between NHS and commercial organisations?

Randomised controlled trials should consider models of cross-collaborative working to improve outcomes and safety for medicines, in the UK setting, compared with usual care. A follow-up period (ideally longer than 2 years) would capture longer-term outcomes.

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Outcomes for this research question should include patient-reported outcomes, clinical outcomes, medicines-related problems and cost effectiveness. The research should be carried out in all populations that use services across different sectors – for example, care (relating to the use of medicines) of people may be transferred from an NHS organisation to social care, from a secondary care organisation to primary care or within secondary care – for example, from one ward to another. The research could also identify benefits and challenges of cross-organisational working for suboptimal prescribing of medicines.

Rationale

The GDG was aware of pockets of good practice that involve models of care consisting of cross-organisational working relating to medicines. However, no published evidence was found to show whether or not it improves patient-reported outcomes in relation to suboptimal prescribing. This research recommendation will help to provide evidence on whether or not cross-organisational working is a cost-effective model of care when improving patient-reported outcomes for suboptimal prescribing.

| Criterion | Explanation | | | |
|--------------|--|--|--|--|
| Population | All people taking medicines using the following care settings: | | | |
| | • NHS | | | |
| | social care | | | |
| | pharmaceutical industry | | | |
| | home care companies | | | |
| | private providers of healthcare services. | | | |
| Intervention | Model used to deliver cross organisational working, for example between NHS and social care, or primary and secondary care, or NHS and commercial organisations; working together using a model to deliver a service collaboratively for medicines. | | | |
| Comparators | Routine care or usual care. | | | |

Proposed format of research recommendations

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| Criterion | Explanation | | | | |
|-----------------|--|--|--|--|--|
| Outcome | The following outcomes should be considered: patient-reported outcomes (for example satisfaction, medicines adherence) quality of life clinical outcomes medicines-related problems (for example adverse drug reactions, medicines discrepancies on records). An appropriate length of follow-up would be 2 years or more for the outcomes to be externally valid. Process measures may also be considered for this research question to see what impact cross-collaborative working has on resources such as time and staffing. Process measure outcomes may include: time required to transfer medicines-related information from one care setting to another training of staff required to solve any medicines-related queries. | | | | |
| Study design | Randomised controlled trial. | | | | |
| Timeframe | Follow-up outcomes of 2 years or more. | | | | |

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Finding more information and committee details

You can see everything NICE says on this topic in the <u>NICE Pathway on medicines</u> optimisation.

To find NICE guidance on related topics, including guidance in development, see the <u>NICE</u> webpage on medicines management.

For full details of the evidence and the guideline committee's discussions, see the <u>full</u> <u>guideline</u>. You can also find information about <u>how the guideline was developed</u>, including <u>details of the guideline committee</u>.

NICE has produced <u>tools and resources to help you put this guideline into practice</u>. For general help and advice on putting our guidelines into practice, see <u>resources to help you put NICE guidance into practice</u>.

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Update information

Minor changes since publication

October 2021: We added a link to NICE's guideline on shared decision making in section 1.6 on patient decision aids.

June 2021: In recommendation 1.6.7 we added a link to <u>NICE's Standards framework for</u> shared-decision-making support tools, including patient decision aids.

September 2019: We updated links to guidance on confidentiality in recommendation 1.2.1, and added a link to our guideline on decision making and mental capacity in section 1.6.

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Accreditation



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National Patient Safety Agency

Patient safety alert





28 March 2007

| Immediate action | |
|---------------------|--|
| Action | |
| Update | |
| Information request | |
| Ref: NPSA/2007/20 | |

Promoting safer use of injectable medicines

The National Patient Safety Agency (NPSA) received around 800 reports a month to its National Reporting and Learning System (NRLS) relating to injectable medicines between January 2005 and June 2006. This represents approximately 24 per cent of the total number of medication incidents. The majority of these resulted in no or low harm to patients. However, there were 25 incidents of death and 28 of serious harm reported between January 2005 and June 2006.

Research evidence indicates that the incidence of errors in prescribing, preparing and administering injectable medicines is higher than for other forms of medicine.¹⁻² In one study, at least one error occurred in 49 per cent of intravenous medicine doses prepared and administered on hospital wards; one per cent were judged to be potentially severe errors; and 29 per cent potentially moderate errors¹ (more details about this study are included in the background section on page 6).

Using data from the NRLS and other evidence,³ the NPSA has identified a number of latent system risks and is making recommendations that can make the use of injectable medicines safer.

Action for the NHS and the independent sector

The NPSA is recommending that all NHS and independent sector organisations in England and Wales take the following steps:

- 1 Undertake a risk assessment of injectable medicine procedures and products in all clinical areas to identify high risks, and develop an action plan to minimise them.
- **2** Ensure there are up-to-date protocols and procedures for prescribing, preparing and administering injectable medicines in all clinical areas.
- **3** Ensure essential technical information on injectable medicines is available and accessible to healthcare staff in clinical areas at the point of use.
- 4 Implement a 'purchasing for safety' policy to promote procurement of injectable medicines with inherent safety features.
- **5** Provide training for, and supervision of, all healthcare staff involved in prescribing, administering and monitoring injectable medicines.
- 6 As part of the annual medicines management audit programme, healthcare organisations should include an audit of medication practice with injectable medicines.

For response by:

- All NHS and independent sector organisations in England and Wales
- For action by:
- The chief pharmacist/pharmaceutical adviser should lead the response to this alert, supported by the chief executive, medical director, nursing director and clinical governance lead/risk manager
- We recommend you also inform:
- Clinical governance leads and risk managers
- Medical staff
- Nursing staff Pharmacy staff
- Radiographers Operating theatre practitioners
- and assistants
- · Patient advice and liaison service staff in England
- · Procurement managers

- The NPSA has informed:
 - · Chief executives of acute trusts, primary care organisations, mental health trusts, ambulance trusts, local health boards in England and WalesChief executives/regional directors
 - and clinical governance leads of
 - strategic health authorities (England) and regional offices (Wales)
 - Healthcare Commission
 - Healthcare Inspectorate Wales • Business Services Centre (Wales)
- BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08)
- (pp8370-10305 of 20966) (this part 1936 pages)

- Independent Healthcare Advisory Services · Medicines and Healthcare products Regulatory Agency
 - NHS Purchasing and Supply Agency
- Welsh Health Supplies
- Royal colleges and societies
- NHS Direct
 - Relevant patient organisations and community health councils in Wales
 - Independent Healthcare Forum Commission for Social Care Inspection
 - 8524 of 10305

MAHI - STM - 101 - 008525

Patient safety alert 20

Promoting safer use of injectable medicines Page 2 of 12



Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 2 July 2007 Action plan to be agreed and actions started

Deadline (action complete): 31 March 2008 All actions to be completed

Further information about SABS can be found at: www.info.doh.gov.uk/sar2/cmopatie.nsf

Further information on the action points

1 Undertake a risk assessment of injectable medicine procedures and products in all clinical areas to identify high risks, and develop an action plan to minimise them.

The NPSA recommends that a pharmacist and a senior practitioner(s) from the relevant clinical area carry out a risk assessment of injectable medicine products and procedures at least once a year. This should be done again before new injectable products or procedures are introduced.

The NPSA has developed a risk assessment tool that can help identify high-risk injectable medicine products and practices. This is available from **www.npsa.nhs.uk/health/alerts**

Measures that can improve patient safety are outlined below.

For high-risk injectable practices:

- Provide written essential technical information and procedures.
- Use injections that are prepared or used in closed, not open, systems.
- Reinforce and audit policy to ensure all syringes and infusions containing injectable medicines that leave the hands of practitioners during use, are labelled.
- Prepare all cytotoxic and total parenteral nutrition (TPN) products, and make all additions to TPN, in the pharmacy department.
- Reinforce a 24-hour expiry date (or less if pharmaceutically required) for infusion products prepared in clinical areas.
- Ensure there are adequate numbers and types of infusion pumps and syringe drivers available.
- Ensure that single-use products are only used to prepare single doses.
- Have an organisation-wide therapeutic protocol that clarifies unlicensed or 'off-label' use of injectable medicines.

For high-risk injectable products:

- Simplify and rationalise the range and presentation of injectable medicines and provide the most appropriate vial or ampoule sizes.
- Provide ready-to-administer or ready-to-use injectable products of standard strength. This will minimise risks when preparing and administering injectable medicines.
- Provide dose calculation tools. For example, dosage charts for a range of body weights that eliminate the need for calculating doses.
- Provide additional guidance on how to prescribe, prepare and administer high-risk injectable medicines that clarifies how to safely prepare and administer them.



- Consider providing pre-printed prescriptions or stickers that makes the prescribing, preparing and administering of high-risk products clearer.
- Use double checking systems such as an independent check by another practitioner, and dose checking software in 'Smart' infusion pumps and syringe drivers.
- Use infusion monitoring forms and check lists for the duration of the administration.

High-risk injectable medicine products and procedures should be added to the local risk register if risk reduction methods cannot be introduced or they will not sufficiently reduce the risk. The NPSA recommends that in such a situation, the healthcare organisation investigates ways to introduce safer products and/or procedures as soon as possible.

Standards for the preparation and manufacture of injectable medicines within hospital pharmacies are set out in EL(97) 52 'Aseptic Dispensing in NHS Hospitals' and the EU Guide on Good Manufacturing Practice.

2 Ensure there are up-to-date protocols and procedures for prescribing, preparing and administering injectable medicines in all clinical areas.

Healthcare organisations should have written protocols and procedures for prescribing, preparing and administering injectable medicines in all relevant areas. It is essential that procedures are clearly documented, reflect local circumstances and describe safe practice that all practitioners can reasonably be expected to achieve. Patient safety incidents commonly result where procedures are absent, incomplete or where staff do not follow written procedures due to a lack of awareness, insufficient knowledge or because they do not agree with them and routinely violate them.

To help healthcare organisations develop local protocols and procedures, the NPSA has produced:

- a multi-disciplinary practice standard which lists the core principles of safe practice;
- an exemplar standard operating procedure for prescribing, preparing and administering injectable medicines.

These are available from www.npsa.nhs.uk/health/alerts

3 Ensure essential technical information on injectable medicines is available and accessible to healthcare staff in clinical areas at the point of use.

Some injectable medicines do not have a package insert providing essential technical information about preparation and administration, or the information is insufficient to fully meet the needs of all healthcare staff. For example, an incompatibility between the diluent, infusion, other medicines or administration devices, and associated administration equipment. This technical information is not available in commonly used medicines references such as the British National Formulary.

A detailed guide to the safe preparation and administration of common intravenous medicines is available via NHSnet. The Injectable Guide is produced by pharmacists based in approximately 100 different UK hospitals and co-ordinated by the pharmacy department at Hammersmith Hospitals NHS Trust. A new partnership between The Injectable Guide and United Kingdom Medicines Information Service (UKMi) has been formed to expand and develop the content and availability. Contact details concerning this guide are available at: **www.npsa.nhs.uk/health/alerts**

Promoting safer use of injectable medicines Page 4 of 12



Healthcare staff need to have full technical information about the following for all injectable medicines products used in clinical areas:

| Reconstitution | Manufacturer's recommended solution (diluent) for diluting and reconstituting a freeze-dried powder. | |
|---|--|--|
| Concentration of final solution | Recommended concentration and volume for administration, stating maximum concentration where applicable. | |
| Example calculations | Examples of dose, preparation and rate of administration calculations. | |
| Dilution/flush solutions | Information concerning physical and chemical compatibility with diluents and infusion fluids. | |
| Stability in solution | Recommended expiry for the prepared final injection or infusion. | |
| Administration rate | For bolus administration and infusion for all routes of administration. | |
| Compatibility information (for commonly used mixtures in specialist areas only) | Mixed in the same syringe or infusion, in administration tubing and at Y-sites and three-way taps where mixing occurs. | |
| Special handling information | If special precautions and handling methods have to be used during preparation and administration e.g. protect from light. | |
| Specialist technical information (where relevant) | pH, osmolarity, sodium content and displacement values. | |

4 Implement a 'purchasing for safety' policy to promote procurement of injectable medicines with inherent safety features.

The NPSA recommends that policies advocate the purchase of injectable medicines that include technical information about how they should be prepared and administered, and are designed in such a way as to promote safer practice.

It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied. The NPSA suggests that NHS organisations should work with the pharmaceutical industry to identify new products and formulations that could make practice safer.

Frequently, an unlicensed injectable medicine has to be prepared from a licensed product in clinical areas before the prescribed medicine can be administered to the patient. Where these products have been assessed as high or moderate-risk, they should be prepared and/or supplied by a pharmacy or alternative risk reduction methods should be used to improve patient safety.

Ready-to-use and ready-to-administer products that cannot be prepared in the hospital pharmacy department should be sourced from NHS manufacturing units or commercial 'specials' manufacturers. It is essential that the quality of these medicines is assessed and approved by an appropriate quality assurance pharmacist before being purchased.

Promoting safer use of injectable medicines Page 5 of 12



5 Provide training for, and supervision of, all healthcare staff involved in prescribing, administering and monitoring injectable medicines.

Injectable medicine therapy can be complex and the variable levels of knowledge, training and competence amongst healthcare staff can put patients at risk. For example, unsafe handling or poor aseptic (non-touch) technique can lead to contamination of the injection, and harm or infect the patient. Calculation errors made during prescribing and preparing the injectable medicine can lead to administering the wrong dose and/or at the wrong concentration or rate. Additionally, many products require special handling procedures which, if not known or followed, can present health and safety risks to the member of staff carrying out the procedure and the environment.

Local organisations must ensure that healthcare staff who prescribe, prepare and administer injectable medicines have received training and have the necessary work competences to undertake their duties safely.

During training, it should be reinforced to healthcare staff that patient safety incidents with injectable medicines must be reported and will be reviewed through the organisation's usual risk management procedures.

There must also be local systems for clinical supervision where senior staff oversee and assess work competences of less experienced staff.

Using the Skills for Health format, the NPSA has developed four proposed work competences that can help local healthcare organisations define the required knowledge and skills for working with injectable medicines. These competences are:

- prescribing injectable medicines;
- preparing injectable medicines;
- administering injectable medicines;
- monitoring administration.

All are available from www.npsa.nhs.uk/health/alerts

The NPSA will work with Skills for Health to develop these proposed competences as National Workforce Competences.

The National infusion devices training programme has been developed by the NHS Core Learning Unit and the NPSA. The programme helps healthcare staff gain competence and confidence in using infusion devices, leading to safer and more efficient use. The programme is available either face-to-face or through an e-learning package. To find out more go to **www.clpu.nhs.uk**

6 As part of the annual medicines management audit programme, healthcare organisations should include an audit of medication practice with injectable medicines.

Healthcare organisations should include an audit of medication practice with injectable medicines as part of their annual medicines management report. It should include a summary of risk assessment results, incident reports, compliance with NPSA recommendations and in-year actions and improvement. It should have an action plan for improving any poorly performing aspects of the system. The report should be communicated to Clinical Governance Committees and Drugs and Therapeutics Committees each year. This information should also be used as part of the performance management process by external organisations. Developing key performance indicators can help with monitoring.

Promoting safer use of injectable medicines Page 6 of 12



Suggested indicators are:

- percentage of clinical areas that have a copy of all necessary technical information and procedures for injectable medicines;
- percentage of staff, including junior medical staff, who have received training on safely using injectable medicines in the last three years, and have achieved the required level of competence;
- percentage of clinical areas that have a documented risk assessment of injectable products and procedures;
- the number of high-risk procedures at baseline assessment and again after the introduction of risk reduction methods;
- the number of high-risk products at baseline assessment and again after the introduction of risk reduction methods;
- details of remaining high-risk products and procedures that need to be added to the risk register.

A template audit checklist has been produced by the NPSA and is available from **www.npsa.nhs.uk/health/alerts**

The cost of implementing the NPSA's recommendations

The cost of implementing these recommendations will vary depending on current local practice.

The additional cost of preparing in pharmacy or purchasing ready-to-administer and readyto-use products should be off-set against preparation in the clinical area, which incorporates the cost of the component materials, staff time, wastage and associated risk. 'Smart' infusion pumps incorporating dose checking software can cost up to £1,000 more than other pumps. However, organisations should consider the benefit of the additional features when planning pump replacement programmes.

A toolkit and further information on improving infusion device safety can be found on a website hosted by the NHS Supply Chain at **www.supplychain.nhs.uk**

Background

The risks associated with using injectable medicines in clinical areas have been recognised for some time. In 1976, The Breckenridge Report⁴ made recommendations for additional safeguards when adding medicines to intravenous infusions. In 2001, the Audit Commission found evidence that high-risk injectable medicines were often being prepared in clinical areas in English hospitals.⁵ More recently, in a risk assessment study of injectable medicine preparation in secondary care acute trusts in the north of England, high-risk products, including cytotoxics, adult parenteral nutrition bags and intra-ocular injections, were being prepared in clinical areas. In addition, there were 53 different strengths of potassium chloride-containing products also being prepared in critical care areas.⁶

In an ethnographic study of the incidence and severity of intravenous drug errors in 10 wards of a teaching and non-teaching hospital in the UK over a six and 10 day period, 249 errors were identified.¹ At least one error occurred in 212 (49 per cent) out of 430 intravenous doses. Three doses (one per cent) had potentially severe errors, 126 (29 per cent) potentially moderate errors and 83 (19 per cent) potentially minor errors. Examples of the three different error types are presented below. Most errors occurred when giving bolus doses or making up drugs that required multiple step preparation. The researcher intervened when serious errors where identified and corrective action was taken, these incidents were still included in the results as an error.

Promoting safer use of injectable medicines Page 7 of 12



Example of a potentially severe error

The whole contents of a vial containing 125,000 units of heparin were prepared as a continuous infusion, resulting in a five times overdose and the risk of life threatening haemorrhage.

Example of a potentially moderate error

The administration of 80mg furosemide over 45 seconds through a peripheral vein. The recommended duration of administration should have been 20 minutes. Tinnitus and deafness are amongst the side effects reported after rapid administration.

Potential minor errors

Preparation of 1.2g of co-amoxiclav using 10ml instead of 20ml of water for injection. The drug may not dissolve completely when insufficient solvent is used. Concentrated solutions also increase the risk of thrombophlebitis.

Today, injectable medicines are being used to a greater extent in the NHS than ever before but there are few additional safeguards operating. The NHS in Scotland issued a *Good practice statement for the preparation of injections in near patient areas* in 2002.⁷ This guidance led to the development of policies and procedures to ensure safe practice in Scottish hospitals, where adherence to safe practice is regularly monitored.⁸ Until now, there have been no similar publications for the NHS in England and Wales.

Data extracted from the NPSA's NRLS, for the period January 2005 to June 2006, offers an insight into the level of risk associated with injectable medicine treatment.

Table 1: National Reporting and Learning System reports(January 2005 to June 2006)

| Type of incident reported to the NRLS | Number | Per cent of all incidents | Per cent of medication incidents |
|---------------------------------------|---------|------------------------------|-------------------------------------|
| All incidents | 653,674 | 100.0 | n/a |
| Medication incidents | 59,802 | 8.3 | n/a |
| Injectable medicines incidents | 14,228 | 2.2 | 23.79 |

Table 2: Injectable medicines incident reports: degree of harm(January 2005 to June 2006)

| Degree of harm (severity) | Number | Per cent of total |
|------------------------------|--------|-------------------|
| Death | 25 | 0.2 |
| Severe | 28 | 0.2 |
| Moderate | 728 | 5.1 |
| Low | 2,253 | 15.8 |
| No harm | 11,178 | 78.6 |
| Reports with inadequate data | 16 | 0.1 |
| Total | 14,228 | 100.0 |

Promoting safer use of injectable medicines Page 8 of 12



Table 3: Injectable medicines incident reports: stage of the medication process(January 2005 to June 2006)

| Stage of medication process | Number | Per cent of total |
|--|--------|-------------------|
| Administration (which may include preparation) | 10,394 | 73.1 |
| Prescribing | 1,566 | 11.0 |
| Preparation of medicines in all locations/dispensing in a pharmacy | 1,403 | 9.9 |
| Monitoring/follow-up of medicine use | 647 | 4.6 |
| Supply or use of over-the-counter (OTC) medicine | 61 | 0.4 |
| Advice | 37 | 0.3 |
| Reports with inadequate data | 13 | 0.1 |
| Other | 107 | 0.8 |
| Total | 14,228 | 100.0 |

Table 4: Injectable medicines incident reports: type of medication incident(January 2005 to June 2006)

| Type of medication incident | Number | Per cent of total |
|---|--------|-------------------|
| Wrong dose, strength or frequency | 4,107 | 28.9 |
| Omitted medicine/ingredient | 2,054 | 14.4 |
| Wrong drug/medicine | 1,445 | 10.2 |
| Wrong quantity | 1,232 | 8.7 |
| Wrong route | 724 | 5.1 |
| Wrong/transposed/omitted medicine label | 470 | 3.3 |
| Wrong formulation | 452 | 3.2 |
| Patient allergic to treatment | 433 | 3.0 |
| Wrong method of preparation/supply | 428 | 3.0 |
| Mismatching between patient and medicine | 415 | 2.9 |
| Adverse drug reaction (when used as intended) | 405 | 2.8 |
| Wrong/omitted/passed expiry date | 385 | 2.7 |
| Contraindication to the use of the medicine | 243 | 1.7 |
| Wrong storage | 190 | 1.3 |
| Wrong/omitted verbal patient directions | 24 | 0.2 |
| Wrong/omitted patient information leaflet | 10 | 0.1 |
| Other | 1,016 | 7.1 |
| Unknown | 183 | 1.3 |
| Reports with inadequate data | 12 | 0.1 |
| Total | 14,228 | 100.0 |

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)

Promoting safer use of injectable medicines Page 9 of 12



Glossary

| Administration devices | Medical devices designed to regulate or control, mechanically or electronically, the administration of injections or infusions of medicines. |
|--|---|
| Aseptic technique (non-touch technique) | Handling technique designed to minimise the risk of microbial contamination of a sterile medicine during preparation. |
| Bolus (push) | Administration from a syringe of a small volume of a single dose of a sterile solution directly into a tissue, organ or vein, over a short time of, usually, between 30 seconds and 10 minutes. |
| Clinical areas | Wards, clinical departments, operating theatres, clinics, GP surgeries. In the context of homecare, the term may also be considered to include the patient's home. |
| Closed system | Packaging and presentation of an injectable medicine, and/or procedures followed, to prepare doses for use which are designed to ensure that the injection solution never comes into direct contact with the open air. |
| Diluent | Any sterile injection solution, such as water for injection or sodium chloride 0.9%, commonly used to dissolve (reconstitute) or dilute a medicine immediately before administration. |
| Flush, flushing solution | A sterile solution of diluent such as sodium chloride injection 0.9%, used to purge (flush) access devices (e.g. cannulae) before and/or after injection of a medicine or between injections of different medicines. |
| Hazard, risk | Any factor, such as a difficult procedure or a complex calculation, with the potential to cause harm if carried out incorrectly. |
| High-risk procedures | Generic procedures involving the preparation and administration of (medicinal) products that have been identified by risk assessment as most likely to pose a significant risk to patients. |
| High-risk products | Those (medicinal) products whose preparation and/or administration have been identified by risk assessment as most likely to pose a significant risk to patients. |
| Infusion | Administration, from a syringe or other rigid or collapsible container e.g. plastic bag, of a volume of sterile solution of an injectable medicine directly into a tissue, organ, vein or artery, at a constant rate, under gravity or by means of an electronic or mechanical pump or other means of rate control, over a defined period usually of at least 10 minutes. |
| Injectable medicines | Sterile medicines intended for administration by bolus injection, perfusion or infusion by any of the following routes: intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intradermal, intraventricular, epidural, intravesicular, intravitreal, intrapleural and intraocular. |
| Latent risks | Flaws within the overall healthcare system. They can result from decisions made in almost any field that impacts on the delivery of healthcare. For example, environmental building and design, written procedures and management decisions. These strategic decisions can unknowingly create error-provoking conditions and system weaknesses in the workplace. |
| Licensed medicine | Medicines (medicinal products) placed on the market in the UK require a Marketing Authorisation formerly called a Product Licence. Marketing Authorisations are granted under European Community Council Directives and Regulations by the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Evaluation Agency (EMEA). Licensed medicines are manufactured or assembled by commercial organisations that have a Manufacturing Licence and operate Good Manufacturing Practice. |
| Low-risk products | Those (medicinal) products whose preparation and/or administration have been identified by risk assessment as least likely to pose a significant risk to patients. |
| Luer | A type of connection used to allow connection of syringes and similar medical devices to catheters, cannulae and other access devices. |

Promoting safer use of injectable medicines Page 10 of 12



| Multi-dose injectable medicines vs single- dose injectable medicines | Most injections do not contain an antimicrobial preservative and are licensed for single use only i.e. for the preparation of a single dose for administration to one patient on one occasion. Use of single-dose products to prepare more than one dose for the same patient means that a prepared injection or a part-used container must be stored before use and increases the risk of infection; use for more than one patient also adds a risk of cross-infection. Injectable medicines 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. | | |
|---|---|--|--|
| Multi-professional | Doctors, nurses, pharmacists and all other healthcare professionals involved with prescribing, preparing or administering injectable medicines. | | |
| 'Off-label' use | Use of a licensed medicine in a way not covered by its Manufacturing Authorisation (Product Licence). | | |
| Open systems | Packaging and presentation of an injectable medicine, and/or procedures followed to prepare doses for use, which do not prevent the injection solution from coming into direct contact with the open air. Excludes a single withdrawal of solution from an open ampoule into a syringe. | | |
| 'Purchasing for safety' | Procuring presentations and formulations of medicines approved for use in local medicine formularies. In this process, medicine products are reviewed by purchasing and pharmacy groups, and products that are designed in such a way as to promote safer practice are selected. This process does not involve therapeutic substitution. | | |
| Ready-to-administer injectable products | These products require no further dilution or reconstitution and are presented in the final container or device, ready for administration or connection to a needle or administration set. For example, an infusion in a bag with no additive required. | | |
| Ready-to-use injectable products | These products require no further dilution or reconstitution before transfer to an administration device. For example, a liquid with an ampule, of the required concentration, that only needs to be drawn up into a syringe. | | |
| 'Specials' | Unlicensed medicines custom-manufactured to order by hospital pharmacies or other facilities licensed by the MHRA. 'Specials' themselves are not licensed, cannot be advertised for sale and have not been formally assessed for quality, safety or efficacy, responsibility for which rests solely with the prescriber and purchaser. | | |
| Unlicensed medicine | A medicine (medicinal product) that does not have a Marketing Authorisation (Product Licence). Unlicensed medicines may be manufactured or assembled (prepared) from licensed products in clinical areas by clinical staff in order to be able to administer a medicine to a patient. Unlicensed medicines may also be manufactured or assembled in controlled environments in hospital pharmacy departments. Units with Specials Manufacturing Licences in hospital pharmacies and commercial organisations are also able to manufacture or assemble unlicensed 'Specials' in controlled environments that are inspected by the MHRA. | | |

Promoting safer use of injectable medicines Page 11 of 12



Acknowledgements

The NPSA gratefully acknowledges the contributions of the multi-disciplinary working group and the individuals, teams and organisations who contributed to the consultation process. Further information about the group can be found at **www.npsa.nhs.uk**

Further details

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For more information on the NPSA, visit www.npsa.nhs.uk

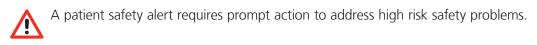
For more information about how you can improve patient safety, visit **www.saferhealthcare.org.uk** – one stop for knowledge and innovation for safer healthcare.

Promoting safer use of injectable medicines Page 12 of 12



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This patient safety alert was written in the following context:

It represents the view of the National Patient Safety Agency, which was arrived at after consideration of the evidence available. It is anticipated that healthcare staff will take it into account when designing services and delivering patient care. This does not, however, override the individual responsibility of healthcare staff to make decisions appropriate to local circumstances and the needs of patients and to take appropriate professional advice where necessary.

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28 March 2007

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)



Reference No: SG 71/16

| Title: | Injectable Medicines Code Policy | | | | | | |
|---|---|--|--|--|---------------------|------------|-------------------|
| Policy Author(s) | Julia Tolan, Professional Manager Pharmacy Services Tel: Paula Crawford, Consultant Pharmacist for Older Peoples Services Tel: | | | | | | |
| Responsible Director: | Caroline Leonard, Director of Surgery and Specialist Services | | | | | | |
| Policy Type: (tick as appropriate) | *Directorate Specific Clinical Trust Wide Non Clinical Trust Wide | | | | Clinical Trust Wide | | |
| If policy type is cor local Committee/G | | | | | list th | e nam | e and date of the |
| Name: | Date: | | | | | | |
| Approval process: | Drugs and Therapeutics Committee Standards and Guidelines Committee Executive Team MeetingApproval date:07/08/2020 13/10/2020 11/11/2020 | | | | | 13/10/2020 | |
| Operational Date: | November 2020 Review November 2025 Date: | | | | November 2025 | | |
| Version No. | 2 Supercedes V1 – February 2017 – February 2022 | | | | | | |
| Key Words: | Injectable medicines' 'NPSA Patient Safety Alert 20' | | | | | | |
| Links to other policies | See 'Evidence base/references' section 7 | | | | | | |

| Date | Version | Policy Author | Comments |
|------------|---------|---------------|---|
| 09/06/2016 | 0.1 | P Crawford | Initial draft |
| 13/06/2016 | 0.2 | P Crawford | Appendix added, version control of Injectable Medicines Code. Circulated to healthcare professionals and managers for comment 23/06/2016 |
| 15/11/2016 | 0.3 | P Crawford | Equality Impact Assessment completed after consultation with L Jamieson. Formatting as per P King. Appendix 1: version control updated to incorporate changes in code and D&T input August 2016 and October 2016. |
| 09/01/2019 | 1.1 | P King | Inclusion of BHSCT Trust Injectable Medicines Guide - paediatric patients (April 2017) and 2019 update. |
| 22/07/2020 | 1.2 | J Tolan | Update of the Injectable Medicines Code sections 1.2.2 and 2.2.4 with requirements for pharmacy units in accordance with Royal Pharmaceutical Society (RPS) Quality Assurance of Aseptic Preparation Services: Standards |

Drug and Therapeutics Committee_Injectable Medicines Code Policy_V2_November 2020

Page 1 of 17

1.0 INTRODUCTION / SUMMARY OF POLICY

- **1.1** Research evidence indicates that the incidence of errors in prescribing, preparing and administering injectable medicines is higher than for other forms of medicine as outlined in the National Patient Safety Agency (NPSA) Patient Safety Alert 20 Promoting safer use of injectable medicines.
- 1.1.1 The BHSCT Injectable Medicines Code describes standards and guidance on the safe and effective administration of intravenous, intramuscular, subcutaneous and other non-enteral medicines. The Code was initiated by the Injectable Policy Group (IPG) 2013-14 comprising multidisciplinary healthcare professionals and reporting to the Trust Drug and Therapeutics Committee and the Pharmacy Governance Group. The Code was further developed 2015-16 and finalised after consultation with a wider group of Trust healthcare professionals and staff (section 10 of Injectable Code).

1.2 Purpose

This Code has been written to comply with the National Patient Safety Agency (NPSA) Patient Safety Alert 20 <u>Promoting safer use of injectable medicines</u> and applies to all members of staff involved in the prescribing, supply, preparation and administration of injectable medicines. This Code should be read in conjunction with the <u>BHSCT Medicines Code policy (2020) SG 09/11</u> & <u>BHSCT Community Medicines Code (2020) SG 06/13</u> and relevant policies listed in section 12 of Injectable Medicines Code.

2.0 SCOPE OF THE POLICY

This document applies to all BHSCT managers, healthcare practitioners and staff involved in the prescribing, administration and supply of injectable medicines. These same staff are expected to familiarise themselves with this document, the current <u>BHSCT Medicines Code policy (2020) SG 09/11</u> & <u>BHSCT Community Medicines Code (2020) SG 06/13</u>, and other relevant local and national policies and/or guidelines depending on their area of practice. These include the most recent versions of the following:

- Nursing and Midwifery Council: <u>Standards for medicines management</u> (2010) NMC London
- Nursing and Midwifery Council: Professional standards of practice and behaviour for nurses and midwives 2015 <u>The Code for nurses and midwives</u> NMC London
- Royal College of Nursing <u>Standards for Infusion Therapy 2010</u> 3rd Edition London
- General Medical Council Good Medical Practice 2013
- General Medical Council Tomorrow's Doctors Outcomes and Standards for undergraduate medical education 2009
- Health & Care Professions Council (HCPC) Standards of Proficiency <u>www.hcpc-uk.org</u>

3.0 ROLES AND RESPONSIBILITIES

The Chief executive of the Trust has overall responsibility for the safe and secure handling of medicines as part of the Controls Assurance Medicines Management Framework.

The Head of Pharmacy and Medicines Management is responsible for ensuring that safe systems of control operating within the area of authority are in accordance with Medicines Management Policies. The Head of Pharmacy and Medicines Management reports on these matters to the Chief Executive via the Drug and Therapeutics (D&T) Committee and the Director of Surgery and Specialist Services.

The D&T Committee is accountable to the Trust Senior Management Team and the Trust Board via the Medical Director. It is responsible for promoting safe and effective prescribing within BHSCT and across the interface with primary care.

Any practitioner who administers a medicine to a patient is accountable for their actions and their omissions. Practitioners must exercise their professional judgement and apply their knowledge and skills every time they administer a medicine. Before administering any medicine, practitioners must know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions, contra-indications and drug interactions. Practitioners must always work within their own Codes of Professional Practice, BHSCT Injectable Medicines Code, <u>BHSCT Medicines Code policy</u> (2020) SG 09/11 & <u>BHSCT Community Medicines Code (2020) SG 06/13</u>

Managers should ensure:

- All staff who prescribe, prepare and administer injectable medicines have undertaken appropriate training and have the necessary work competences to undertake their duties safely(NPSA Patient safety Alert 20). This includes mandatory hyponatraemia training if appropriate, and training in injectable medicines specific to their specialist area e.g. insulin, intravenous cytotoxic medicines including systemic anti-cancer treatment (SACT) and intrathecal chemotherapy if appropriate.
- Risk assessments are carried out in all clinical areas where injectables are prepared and administered including when new injectable products or practices are introduced (NPSA risk assessment tool for preparation and administration of injectable medicines in clinical areas <u>NPSA Injectables</u> <u>risk assessment tool</u>). Risk reduction methods should be introduced to minimise risks.

4.0 <u>CONSULTATION</u>

The BHSCT Injectable Medicines Code was initiated by the Injectable Policy Group (IPG) meetings in 2013-14(led by pharmacist Louise Brown) and revisited with Trust wide comments (led by pharmacist Paula Crawford) sought from multiple healthcare professions throughout 2015-16. These included nursing, pharmacy, Regional Medicines Information, physiotherapy, radiotherapy, aseptic pharmacy, community nursing, oncology, paediatrics, mental health and medical device co-ordinator. A full list of contributors is listed in section 10 of Injectable Medicines Code. The Draft Code & Policy were presented to BHSCT D&T Committee August 2016 for comment and amendments incorporated.

5.0 POLICY STATEMENT/IMPLEMENTATION

5.1 Dissemination

Electronic version of the Injectable Medicines Code will be available on BHSCT intranet and disseminated via service directors.

5.2 Resources

Awareness of the Injectable Medicines Code will be raised through Nurse training on injectable medicines provided by HSC Clinical Education Centre, staff meetings for healthcare staff and audit/governance meetings. The Code will be publicised on BHSCT intranet hub and available to download.

5.3 Exceptions

The Injectable Medicines Code has been written to encompass, as much as possible, the range of practice within the Trust at the time of publication. It incorporates evidence based practice, recommendations of expert bodies, accepted best practice both locally and at other UK Trusts and the views of a multi-professional group of local practitioners. It is however, recognised that BHSCT healthcare practice constantly evolves due to the introduction of new and innovative techniques, the review of existing practices in the light of new evidence, and as the skill mix and the responsibilities of different staff groups change. As a result certain areas may wish to define local guidelines or protocols to facilitate the implementation of new developments. These additional guidelines must define which of the local procedures vary from this document. In all cases, the BHSCT Drug and Therapeutics Committee, or the BHSCT Standards and Guidelines Committee, must approve and register these additional documents prior to their implementation and they must be reviewed at least once every 2 years.

5.4 Definitions

This document identifies minimum standards and best practice in the administration of medicines by the following routes:

• Intravenous (IV) - through a peripheral or central line

- The term 'intravenous administration' covers all the procedures where a medicine is administered by this route. This means that the policy not only covers bolus injection and intermittent or continuous infusion, but also practices such as flushing of a cannula and the replacement of an infusion bag
- Intramuscular (IM)
- Subcutaneous (SC)
- Other routes-intrathecal, intraperitoneal, intraventricular, intraosseus, intraocular, epidural, intra-arterial, intra-articular, intradermal, intravesicular, intravitreal, intrapleural and localised nerve blocking injections.

This code has been written to encompass, as much as possible, the range of practice within the Trust in regard to injectable medicines at the time of publication. It incorporates evidence based practice, recommendations of expert bodies, accepted best practice both locally and at other UK Trusts and the views of a multi-professional group of local practitioners and managers.

5.5 Key Policy Statement(s)

This Code has been written to comply with the National Patient Safety Agency (NPSA) Patient Safety Alert 20 <u>Promoting safer use of injectable medicines</u> and applies to all members of staff & their managers, involved in the prescribing, supply, preparation and administration of injectable medicines. This Code should be read in conjunction with the <u>BHSCT Medicines Code</u> policy (2020) SG 09/11 & <u>BHSCT Community Medicines Code</u> (2020) SG 09/11 & <u>BHSCT Community Medicines Code</u> (2020) SG 06/13 and national guidance/BHSCT policies outlined in section 7.

5.6 Policy Principles

BHSCT Injectable Medicines Code supports the key actions outlined in the NPSA Patient Safety Alert 20 <u>Promoting safer use of injectable medicines</u> NPSA/2007/20:

- Risk assessment of injectable medicine procedures and products in all clinical areas and development of action plans to minimise high risks (as per <u>NPSA Injectables risk assessment tool</u> and Regional Unlicensed Medicines Policy)
- Ensure up to date protocols and procedures exist for prescribing, preparing and administering injectable medicines (see Section 12 of BHSCT Injectable Medicines Code)
- Ensure that essential technical information on injectable medicines is available and accessible at the point of use (see Section 9 of Injectable Medicines Code)
- Implementation of a 'purchasing for safety' process to promote procurement of injectable medicines with inherent safety features as per:
 - BHSCT Policy for medicines procurement and purchasing for safety (2018) SG 27/14
 - o BHSCT Medicines procurement & purchasing for safety policy
 - Regional Unlicensed Medicines Policy (N.Ireland)

- <u>BHSCT Adjudication of new medicines and treatments policy (20189)</u> <u>SG 64/11</u>
- Training and supervising staff (see Section 1.6 of Injectable Medicines Code)
- Auditing medication practice with injectable medicines as part of the medicines management audit programme including COSHH (Control Of Substances Hazardous to Health), Belfast Risk Audit and Assessment Tool and HSC Medicines Management - Controls Assurance Standards.

6.0 MONITORING AND REVIEW

Department and line managers are responsible for ensuring that staff have undertaken required training appropriate to their role with injectable medicines and that appropriate risk assessments are undertaken for preparation of injectable medicines within a department/area.

Risk assessment of injectable medicine procedures and products in all clinical areas and development of action plans to minimise high risks (as per <u>NPSA</u> <u>Injectable risk assessment tool</u> and Regional Unlicensed Medicines Policy) will inform best practice.

Trust Incident reporting will continue to capture data relating to medication incidents with injectable medicines.

7.0 EVIDENCE BASE/REFERENCES

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- 2. BHSCT Injectable Medicines Code Policy
- 3. BHSCT Community Medicines Code (2020) SG 06/13
- 4. BHSCT Controlled Drug Policy & Procedures
- 5. BHSCT Intravenous Flushing Lines Policy (2017) SG 29/12
- 6. BHSCT Medicines Code policy (2020) SG 09/11
- 7. BHSCT Guidelines for the Safe Prescribing, Handling and Administration of Hazardous Drugs (2010) SG 29/10
- 8. BHSCT The Control of Substances Hazardous to Health (COSHH) Policy & Procedural Arrangements (2018) TP 35/08
- 9. BHSCT Policy for the Safe Administration of Intrathecal Cytotoxic Chemotherapy (2019) SG 19/11
- **10.** <u>BHSCT Chemotherapy Extravasation Management of Chemotherapy</u> Extravasation (2020) SG 15/10
- 11. BHSCT Policy for postoperative analgesia with intrathecal opioids for adult non obstetric patients (2016) SG 27/16
- **12.** <u>BHSCT Administration of intravenous fluids to children aged from 4 weeks</u> until the 16th birthday: reducing the risk of hyponatraemia (2016) SG 02/08

- **13.** <u>BHSCT Potassium chloride concentrate and other strong potassium</u> solution(s) policy (2020) SG 25/12
- 14. BHSCT Policy for Treatment of Hyperkalaemia in Adults (2020) SG 10/08
- **15.** <u>BHSCT Policy for recording fluid prescription and balance charts (2015) SG</u> <u>16/08</u>
- 16. BHSCT Medical Devices Policy (2017) TP 16/08
- 17. BHSCT Medical Devices Procedures and Guidelines (2017) TP 41/07
- **18.** BHSCT Policy for Identification and Labelling of Invasive Lines and Tubes (2017) SG 10/15
- 19. BHSCT Policy for Intravenous Vancomycin use in adults (2020) SG 21/16
- 20. BHSCT Hand Hygiene Policy (2017) SG 34/09
- 21. BHSCT Aseptic Non Touch Technique Policy (2016) SG 01/14
- **22.** <u>BHSCT Preparation for the insertion of a peripherally inserted central catheter</u> (PICC) in the Regional Neonatal Unit (RNU), RJMS (2020) SG 235/14
- **23.** BHSCT Guidelines for nurses and midwives checking peripheral intravenous cannula sites in neonates and observing for complications (infiltration/ extravasation) and procedure for management (2020) SG 118/08
- 24. BHSCT Procedure for administration of intravenous immunoglobulin (IVIg) replacement therapy to a baby in the Regional Neonatal Unit (RNU), RJMS (2020) SG 150/09
- 25. BHSCT Haemodialysis: Administration of intravenous therapy (209) SG 45/10
- 26. BHSCT Epidural Analgesia for Adult Patients (2018) SG 19/08
- 27. BHSCT Clinical Guidelines for management and care of children (0-16 years) with epidural analgesia in the post-operative setting (2019) SG 55/09
- **28.** BHSCT Guideline: Management of accidental dural puncture during epidural insertion (2019) SG 133/09
- 29. BHSCT Guideline: Remifentanil (administration of Remifentanil patient controlled analgesia in labour ward) (2017) SG 166/11
- **30.** BHSCT Guideline: patient controlled analgesia (PCA) and nurse controlled analgesia (NCA) in children (0-16 years) in RBHSC (2016) SG 19/16
- **31.**<u>BHSCT Management of Patient Controlled Analgesia in Adult Patients (2017)</u> <u>SG 30/08</u>
- **32.** BHSCT Guidelines for administration of intravenous (IV) paracetamol (2017) SG 49/13
- **33.** BHSCT Management of Adult Patients receiving subcutaneous fluids within a community setting (2017) SG 07/12
- **34.** BHSCT Intramuscular and subcutaneous Diamorphine for analgesia in labour: supply and administration by midwives (2019) SG 190/12
- **35.** BHSCT Guidelines for insertion and management of Central Venous Catheters/ Central Venous Access Device Guidelines (excluding nontunnelled catheters) (2017) SG 37/08
- **36.** BHSCT Insertion and Management of peripheral intravenous cannulae (2011) SG 16/09
- **37.** BHSCT Policy to enable band 3 health care assistants working within oncology/haematology undertake peripheral venous cannula observation (2020) SG 38/15
- **38.** BHSCT Flush Solution: administration of 0.9% sodium chloride- following insertion of peripheral intravenous cannula by non-registrants (2010) SG 28/10

- **39.** <u>BHSCT Policy Subcutaneous Use of the McKinley T34 Ambulatory Syringe</u> <u>Pump (2019) SG 42/10</u>
- **40.** <u>BHSCT CME McKinley T34 ambulatory syringe pump community nurse</u> <u>guidance manual (2014) SG 45/13</u>
- **41.**BHSCT CME McKinley T34 ambulatory syringe pump operation manual
- 42. BHSCT Adverse Incident Reporting and Management Policy (2018) TP 08/08
- **43.** <u>BHSCT Policy on recognition and management of anaphylactic reactions</u> (2012) SG 18/12
- **44.** <u>BHSCT Policy for the Safe Prescribing, Preparation and Administration of</u> <u>Insulin for inpatients (2014) SG 17/14 including Appendix 5: Guidelines for</u> <u>patient involvement in the administration of insulin under supervision in</u> <u>hospital (Adult patients)</u>
- **45.** BHSCT Guidelines for the use of insulin pumps in patients aged over 16 years undergoing investigations or procedures (2019) SG 01/15
- **46.** <u>BHSCT Community Nursing 'Patient Specific Direction (PSD) to Administer</u> <u>Medication' and 'Medicine Administration Recording' charts (2017) SG 08/13</u>
- 47. BHSCT Blood Transfusion Manual, Policy, Procedures and Guidelines (2019) SG 34/18
- 48. BHSCT Community Nursing 'Patient Specific Direction to Administer Regular and PRN medication form' and 'Medicine Administration Recording form (2017) SG 08/13
- **49.** BHSCT Guidance on Administration of Long Acting Injectable Formulations (Depot Antipsychotic Injections) for Community Mental Health Nurses (2015) SG 25/15
- **50.** BHSCT Prevention and management of sharps injuries and blood and body fluid exposures (2017) TP 65/10
- 51. BHSCT Waste policy (2011) SG 73/11
- **52.** BHSCT Policy for medicines procurement and purchasing for safety (2018) SG 27/14 including Appendix A: BHSCT safer procurement and management of injectable medicines
- **53.** BHSCT Policy Developing and maintaining Patient Group Directions (2018) SG 08/09
- **54.** BHSCT Adjudication of new medicines and treatments Policy (2018) SG 64/11
- **55.** BHSCT Guidelines for empirical antibiotic prescribing in hospitalised adults (2018) SG 27/12
- **56.** <u>BHSCT guidelines for empirical antibiotic prescribing in hospitalised children</u> <u>0-14 years (2015) SG 39/14</u>
- **57.** <u>BHSCT guidelines for antimicrobial prophylaxis in specific adult surgical procedures (2016) SG 44/09</u>
- 58. BHSCT policy for intravenous vancomycin use in adults (2020) SG 21/19
- **59.** BHSCT Policy for specialist restricted antimicrobial (2019) SG 31/09
- **60.** BHSCT Community Nursing 'Patient Specific Direction to administer regular/prn and diabetes medication' and 'Medicine Administration Recording charts (2017) SG 08/13
- **61.**BHSCT Internal Alert 023: Administration of emergency drugs using glass pre-filled syringes and needle-free access devices. April 2016
- **62.** BHSCT Medicines alert no. 24: levobupivacaine and sodium chloride 0.9% ampoules. May 2016

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- **64.** Epic3: National evidence-based guidelines for preventing healthcareassociated infections in NHS hospitals in England 2014.
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- **66.**General Medical Council(GMC) Tomorrow's Doctors: Outcomes and standards for undergraduate medical education www.gmc-uk.org
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- **68.** Guidance on the safe handling of monoclonal antibody (MAB) products 4th Edition January 2008 NHS Pharmaceutical QA Committee
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- 71. HSC Controls Assurance Standards: Medicines Management
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- 74. Medicines Act 1968 www.legislation.gov.uk
- 75. Medusa Injectable Medicines Guide (available on BHSCT intranet)
- 76. Memorandum of Understanding: Investigating patient or client safety incidents (unexpected death or serious untoward harm: Promoting liaison and effective communications between Health & Social Care, Police Service NI, Coroners Service for NI, and Health & Safety Executive NI
- 77. Multiple use of Injections 3rd Edition 2004 NHS Pharmaceutical QA Committee
- **78.**National Guidance on the Safe Administration of Intrathecal Chemotherapy (DH 2008)
- 79. BHSCT NI Injectable Medicines Guide Policy (2019) SG 03/13
- **80.** NI Management of Infection Guideline for Primary Care 2015
- **81.**Northern Ireland Cancer Network (NICaN) Northern Ireland Chemotherapy Service Standards 'The administration of chemotherapy clinical competence framework' 2007
- **82.**Nursing and Midwifery Council: Standards for Medicines Management (2010) NMC London <u>Standards for medicines management</u> www.nmc.org.uk
- **83.**Nursing and Midwifery Council: The Code: Professional standards of practice and behaviour for nurses and midwives 2015 <u>The Code for nurses and</u> <u>midwives www.nmc.org.uk</u>
- 84.NPSA Patient Safety Alert 21: Epidural medicines (HSC SQSD 28/2007 addendum 1/08) <u>www.npsa.nhs.uk</u>
- 85.NPSA Rapid Response Report 'Preventing fatalities from medication loading doses' NPSA/2010/RRR018 <u>www.npsa.nhs.uk</u>
- **86.**NPSA Signal- Multiple Use of Single Use Injectable Medicines. March 2011 www.npsa.nhs.uk
- **87.**NPSA Patient Safety Alert 20 'Promoting Safer Use of Injectables' <u>www.npsa.nhs.uk</u> NPSA/2007/20 <u>www.npsa.nhs.uk</u> including:
 - -Template standard operating procedure for: prescribing, preparing and administering injectable medicines in clinical areas, March 2007
 - -Risk assessment tool for preparation and administration of injectable medicines in clinical areas

- **91**. NPSA Signal-Injectable Medicines in Theatres, February 2010 <u>www.npsa.nhs.uk</u>
- **92.** NPSA Rapid Response Report <u>Reducing harm from omitted & delayed</u> <u>medicines in hospital NPSA 2010.pdf</u> RRR009
- **93.** NHS Improvement Patient Safety Alert: <u>Patient Safety Alert: Restricted use</u> of open systems for injectable medication NHS/PSA/D/2016/008
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- **97**. Royal Marsden Manual: Chapter 12: Medicines management. www.rmmonline.co.uk
- **98**. The Medicines <u>Administration of Radioactive Substances</u> Amendment Regulations 2006. www.legislation.gov.uk
- 99. The Medicines for Human Use (Administration and Sale or Supply) <u>Miscellaneous Amendments</u> Order 2006. www.legislation.gov.uk
- **100**. <u>The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006</u> www.legislation.gov.uk
- **101**. 'Vial Sharing in Aseptic Services' NHS Pharmaceutical Quality Assurance Committee (1st Edition) 2014 <u>Vial sharing in aseptic services 2014 pdf</u>.

8.0 APPENDICES

- Appendix 1 Outlines version control of the Injectable Medicines Code. Also refer to NPSA Patient Safety Alert 20 Promoting safer use of injectables NPSA/2007/20 www.nrls.npsa.nhs.uk/resources
- Appendix 2 Injectable Medicines Code

9.0 EQUALITY IMPACT ASSESSMENT

The Trust has legal responsibilities in terms of equality (Section 75 of the Northern Ireland Act 1998), disability discrimination and human rights to undertake a screening exercise to ascertain if the policy has potential impact and if it must be subject to a full impact assessment. The process is the responsibility of the Policy Author. The template to be complete by the Policy Author and guidance are available on the Trust Intranet or via this <u>link</u>.

All policies (apart from those regionally adopted) must complete the template and submit with a copy of the policy to the Equality & Planning Team via the generic email address <u>equalityscreenings@belfasttrust.hscni.net</u>

The outcome of the equality screening for the policy is:

Major impact Minor impact No impact

| \square |
|-----------|

Wording within this section must not be removed

10.0 DATA PROTECTION IMPACT ASSESSMENT

New activities involving collecting and using personal data can result in privacy risks. In line with requirements of the General Data Protection Regulation and the Data Protection Act 2018 the Trust considers the impact on the privacy of individuals and ways to militate against any risks. A screening exercise must be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this link.

If a full impact assessment is required, the Policy Author must carry out the process. They can contact colleagues in the Information Governance Department for advice on Tel: 028 950 46576

Completed Data Protection Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

The outcome of the Data Protection Impact Assessment screening for the policy is:

Not necessary – no personal data involved A full data protection impact assessment is required A full data protection impact assessment is not required

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Wording within this section must not be removed.

11.0 RURAL NEEDS IMPACT ASSESSMENT

The Trust has a legal responsibility to have due regard to rural needs when developing, adopting, implementing or revising policies, and when designing and delivering public services. A screening exercise should be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this link

If a full assessment is required the Policy Author must complete the shortened rural needs assessment template on the Trust Intranet. Each Directorate has a Rural Needs Champion who can provide support/assistance.

Completed Rural Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

Wording within this section must not be removed.

12.0 REASONABLE ADJUSTMENT ASSESSMENT

Under the Disability Discrimination Act 1995 (as amended) (DDA), all staff/ service providers have a duty to make Reasonable Adjustments to any barrier a person with a disability faces when accessing or using goods, facilities and services, in order to remove or reduce such barriers. E.g. physical access, communicating with people who have a disability, producing information such as leaflets or letters in accessible alternative formats. E.g. easy read, braille, or audio or being flexible regarding appointments. This is a non-delegable duty.

The policy has been developed in accordance with the Trust's legal duty to consider the need to make reasonable adjustments under the DDA.

Wording within this section must not be removed.

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

Julia Tolan

____ Date: _____

Policy Author

Caroline A. Leonard

11/11/2020

13/10/2020

Date: _____

Director

| Date | Version | Author | Comments |
|--|---------|------------|---|
| September 2013 | Draft | L Brown | IPG 1 st edition draft prepared |
| March 2015 | 0.1 | P Crawford | L Brown handover to P Crawford |
| April 2015 | 0.2 | P Crawford | Formatting, Trust template, foreword & bibliography removed, BHSCT logo added |
| June 2015 | 0.3 | P Crawford | Amended format to bring in line with Trust Medicines Code & Community Code. New sections added: Index, glossary & how code was developed/ contributors. Contributors expanded to include AHP, dental, physiotherapy, podiatry, clinical education centre, medical training, cardiac perfusionist, healthcare support worker manager, bank/ locum manager. Consultation on training requirements |
| September 2015 - October 2015 | 0.4 | P Crawford | Accountability arrangements added, comments from S Maginn (clinical education centre), B Burnside, D Hamilton uplifted on IV training of nurses. U Carrabine comments (medical training). |
| November 2015 | 0.5 | P Crawford | ANNT, Hand hygiene, sharps injury sections added. Training on bank staff amended as per R McMahon. Pharmacy aseptic consultation (G Douris). |
| 03/12/2015 | 0.6 | P Crawford | Ref section 12 added & collated BHSCT/ national policies & references. Nuclear medicine technologist comments on training/ legislation added (M Todd, P Todd). V0.6 circulated to original IPG chairs L Brown/ S Austin for comments & Trustwide consultation with original IPG & additional nursing, AHP, pharmacy & managers. |
| February 2016 - March 2016 | 0.7 | P Crawford | Comments from consultation December 2015 incorporated. Training added for therapy radiographers (as per J McCarthy). New sections added: shelf-life, pharmacy role (including aseptics), vial sharing, 'General principles' section amended to include main points of NPSA 20 Alert (as per G Douris). Advice on mixing of injectables & risk assessment added. Ref to 'purchasing for safety' process added & reference to BHSCT policy 'Medicines procurement & purchasing for safety' including appendix A of policy (injectable |

Appendix 1: Injectable Medicines Code – Version control record

| | | | medicines). Updated syringe driver to syringe pump & reference to new McKinley policy as per P Armstrong, B Gray & K Bowes. ODP training updated as per F Moody. Regional MI comments added on extravasation section, MI contact details (P King). Comments from E Doherty incorporated on anti-siphon, anti-backflow & MHRA infusion system reference. Prescribing section reworded to ensure community areas not using kardex are included (F Connor). Section 6 on flushing lines updated & section 5.1.2 updated to clarify discarding of cytotoxic & CD waste as per B Gray. Infusion pump section updated to include ref to McKinley trainers in community (B Gray). Comments from F Green added referencing BHSCT guidelines for safe prescribing, handling & administration hazardous drugs. |
|--------------------------|-----|------------|---|
| April 2016 - May 2016 | 0.8 | P Crawford | New NMC code 2015 added as per D Hamilton. Updated unregistered practitioner training & newly 'qualified' nursing amended to newly 'registered' throughout & inclusion of midwife as per M Mannion. Managers responsibility added under section 1.5. IV Training of agency, bank & locum staff (section 1.6 &1.7) updated as per M Devlin. Section added on patient/carer involvement. |
| June 2016 | 0.9 | P Crawford | Risk section expanded to include extravasation/ phlebitis, cytotoxic/home cytotoxics, loading doses, critical medicines, IV fluid, loose ampoules alert, cytotoxic spillage. MI comments incorporated on vol of IM/SC injection (J Lambert). D Wallace comments added (Regional Pharmaceutical QA). Comments from S Uprichard cardio perfusionist included. Hyperlinks added. High risk medicines section added & appendix 2- high risk medicines table from S O'Donnell. Injectable Medicines Code 'Policy' developed to accompany the Code & referenced within Code. A Wilson & G Casey comments (vial sharing). A Pelan comments added on HCSW (hospital at night) & Mater- flushing lines. HCSW flushing lines policy referenced. Draft circulated to H/C professionals & managers |

| | | | for final comments 23/06/2016 (deadline 15/07/2016) |
|-------------------|------|------------|--|
| July 2016 | 0.10 | P Crawford | Final formatting & hyperlinks check. Final comments incorporated from B Gray (carer administration of CD medicines in community, McKinley syringe pump practice), D Kean (Posiflush®) & J Kayes (IV antibiotics section added & community inreach team referenced). Self administration section updated with comments from S J Hanna (IV antibiotics) & G Millar (Emergency dept). |
| August 2016 | 0.11 | P Crawford | Cross check against revised BHSCT Medicines Code July 2016. E Johnston consulted on medical undergrad training & comments added. Section 4.7 updated to emphasise Intrathecal route. D&T committee consulted 05/08/2016 & comments uplifted: Section 1.5.9 wording amended around mandatory hyponatraemia training. Sect 6.1.2 Posiflush® wording amended. R Fair comments included. Section 1.7.2: K Deveney consulted on Trust stance regarding band 3 HCSW administering IV flush sodium chloride. Section 2.6.1: amended wording on self- administration. Section 2.6.2: PCEA amended to include PCA. (S. Austin). Section 1.6.2.2 & section 4.7: include need for written protocol on intrathecal route eg baclofen. Section 5.1 & appendix 1: added copy of revised additive labels (SO'D) & theatre/critical care labelling advice (D Kean) Section 2.3.1: uplifted section on 'How to prescribe iv medicine infusions' from BHSCT medicines code. (SO'D) Final EQIA decision received. G Douris update: RPS ref. 'Quality Assurance of Aseptic Preparation Services' 5 th edtn 2016 |
| September 2016 | 0.12 | P Crawford | Added ref to September 2016 Patient safety Alert: Open systems (J Tolan) |
| October 2016 | 0.13 | P Crawford | Presented to D&T 07/10/2016. Final comments incorporated: J Tolan: Sect 2.3.3 revised Community Medicines Code; Sect 2.2.5.4 Out Of Hours/ emergency chemo. Sect 8.9: R Fair: nutrition pumps as per R Smyth. COSHH policy ref. Final wording unregistered practitioners Sect 1.7.4. Final formatting by C Miskimmin/ K Bell |

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Appendix 2

Injectable Medicines Code

Please use this <u>link</u> to access.



caring supporting improving together

Belfast Health and Social Care Trust Community Medicines Code

July 2017

Index

| 1 | Intro | duction | 5 |
|---|-------|---|----|
| | 1.1 | Introduction | 5 |
| | 1.2 | Accountability arrangements | 6 |
| | 1.3 | Trust Medicines Optimisation Committee | 7 |
| | 1.4 | General principles | 7 |
| | 1.5 | Responsibilities of staff | 8 |
| 2 | Pres | cribing of medicines | 12 |
| | 2.1 | General principles | 12 |
| | 2.2 | Writing of prescriptions | 12 |
| | 2.3 | Security and safe handling of prescription forms | 14 |
| | 2.4 | Medication history | 14 |
| | 2.5 | Prescribing of warfarin | 15 |
| | 2.6 | Prescribing of opioid medicines | 18 |
| | 2.7 | Prescribing of antibiotics | 18 |
| | 2.8 | Prescribing for syringe pumps | 18 |
| | 2.9 | Specialist medicines (red/amber) prescriptions | 19 |
| | 2.10 | Prescribing of unlicensed medicines | 20 |
| | 2.11 | Prescribing of a licensed medicine for an unlicensed indication (off-label prescribing) | 20 |
| | 2.12 | Remote prescription or direction to administer | 21 |
| | 2.13 | Verbal orders in the presence of a doctor/dentist | 22 |
| | 2.14 | Prescribing for self/family/friends | 22 |
| | 2.15 | Transfer of medicines related information | 22 |
| | 2.16 | Patient Group Directions (PGDs) | 24 |
| | 2.17 | Patient Specific Directions (PSDs) | 24 |
| 3 | Adm | inistration of medicines | 25 |
| | 3.1 | General principles | 25 |
| | 3.2 | Administration of medicines previously checked by another practitioner | 26 |
| | 3.3 | Second check | 26 |
| | 3.4 | Administration of controlled drugs | 27 |
| | 3.5 | Timing of administration | 27 |
| | 3.6 | Verification of client identity | 28 |
| | 3.7 | Process for administration of medicines | 29 |
| | 3.8 | Administration of medicines by non-registered practitioners | 31 |
| | 3.9 | Single use medication | 35 |
| | 3.10 | Administration of 'as required' medicines (PRNs) | 35 |
| | 3.11 | Nil by mouth | 35 |
| | | | |

Belfast Health and Social Care Trust Community Medicines Code 🔳 🕴 1

| | 3.12 | Crushing tablets or opening capsules | 36 |
|---|-------|---|----|
| | 3.13 | Covert administration of medicines | 36 |
| | 3.14 | Trust Medication Record/Administration Sheet | 36 |
| | 3.15 | Specialist medicine therapy for administration in community | 37 |
| | 3.16 | Administration of medicines in community facilities | 37 |
| | 3.17 | Administration of medicines in a client's home or non Trust facility | 37 |
| | 3.18 | Administration of medicines by midwives | 37 |
| | 3.19 | Self administration of medicines in a community setting (excluding client's own home) | 38 |
| 4 | Orde | ring, supply and receipt of pharmaceuticals | 40 |
| | 4.1 | General | 40 |
| | 4.2 | Ordering medicines other than controlled drugs | 41 |
| | 4.3 | Using the Trust requisition book | 41 |
| | 4.4 | Using pre printed top up sheets | 43 |
| | 4.5 | When the medicine has been supplied | 43 |
| | 4.6 | Expiry date of medicines | 44 |
| | 4.7 | Supply of medicines to community midwives for home birth | 44 |
| | 4.8 | Ordering of non-formulary dressings | 44 |
| | 4.9 | Ordering of child health vaccines | 44 |
| | 4.10 | Ordering of medical gas cylinders | 44 |
| | 4.11 | Ordering of clozapine | 45 |
| | 4.12 | Control of Substances Hazardous to Health (COSHH) | 45 |
| | 4.13 | Transfer of medicines between containers | 46 |
| | 4.14 | Returns to pharmacy and recycling | 46 |
| | 4.15 | Pharmaceutical samples | 46 |
| 5 | Clien | t's own medicines | 47 |
| | 5.1 | General | 47 |
| | 5.2 | Use of client's own medicines | 48 |
| | 5.3 | Residential facility | 48 |
| | 5.4 | Illicit substances | 49 |
| | 5.5 | Overdose medicines | 50 |
| 6 | Stora | age and security of medicines | 51 |
| | 6.1 | General principles | 51 |
| | 6.2 | Medicine storage units | 51 |
| | 6.3 | Containers | 53 |
| | 6.4 | Custody and loss of medicines keys | 53 |
| | 6.5 | Security and storage of stationery used to order medicines | 54 |
| | 6.6 | Loss of medicines and unauthorised access | 54 |
| | | | |

2 Belfast Health and Social Care Trust Community Medicines Code

| | 6.7 | Pharmaceutical refrigerators | 55 |
|----|-------|--|----|
| | 6.8 | Medical gases | 57 |
| | 6.9 | Controlled drugs | 57 |
| 7 | Trans | sport | 58 |
| | 7.1 | General principles | 58 |
| | 7.2 | Maintaining the cold chain | 59 |
| | 7.3 | Medical gas cylinders | 59 |
| | 7.4 | Action in the event of a breach of security | 59 |
| | 7.5 | Posting of medicines | 60 |
| 8 | Dispo | osal of unwanted medicines | 61 |
| | 8.1 | General principles | 61 |
| | 8.2 | Disposal of medicines by nursing homes | 62 |
| | 8.3 | Disposal of medicines by residential homes | 62 |
| | 8.4 | Disposal of client's own medicines | 62 |
| | 8.5 | Sharps bins | 63 |
| 9 | Refri | gerated medicines (including vaccines) | 64 |
| | 9.1 | General principles | 64 |
| | 9.2 | Receiving refrigerated medicines | 64 |
| | 9.3 | Storage conditions | 65 |
| | 9.4 | Vaccines | 65 |
| 10 | Medi | cal Gases | 69 |
| | 10.1 | General principles | 69 |
| | 10.2 | Areas of responsibility | 70 |
| | 10.3 | Storage of medical gas cylinders | 70 |
| | 10.4 | Safe handling and use of medical gas cylinders | 71 |
| | 10.5 | Equipment for use with medical gases | 72 |
| | 10.6 | Precautions for oxygen therapy | 72 |
| | 10.7 | Safe transport of medical gases | 72 |
| | 10.8 | Faulty cylinders | 73 |
| | 10.9 | Ordering of medical gas cylinders | 74 |
| | 10.10 | Provision of medical gases for home births | 74 |
| | 10.11 | Emergency Use | 74 |
| 11 | Medi | cation incident reporting | 75 |
| 12 | Adve | rse drug reaction (ADR) reporting | 76 |
| 13 | Defec | ctive medicinal products | 77 |

Belfast Health and Social Care Trust Community Medicines Code 🔳 🗍 3

| 14 Investigational medicinal products (IMPs) | 77 |
|--|----|
| 15 Closure of a facility | 78 |
| 16 Complementary alternative therapies and homeopathy | 79 |
| 17 Regional Medicines and Poisons Information Service | |
| Glossary of terms | 80 |
| Appendix 1 Transfer of medicines information between care settings | 86 |
| Appendix 2 Non Formulary Dressings form | 88 |
| Appendix 3 Clozapine Community Prescription form | 89 |
| Appendix 4 Pharmaceutical Refrigerator Temperature Log | 90 |
| Appendix 5 Consent for removal of unwanted medicines form | 91 |

4 Belfast Health and Social Care Trust Community Medicines Code

1 Introduction

- 1.1.1 The Department of Health, Social Services and Public Safety (DHSSPS) requires that Trusts ensure the safe and secure handling and storage of medicines. Medicines management is 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 client care. This Medicines Code defines the policies and procedures to be followed within Belfast Health Social Care Trust (BHSCT) community settings, to ensure effective medicines management throughout the Trust.
- 1.1.2 Refer to BHSCT Hospital Medicine Code March 2017 for guidance to staff employed within secondary care settings.
- 1.1.3 The community medicines code applies to;
- 1.1.3.1 All Trust employed staff who provide BHSCT services within community settings e.g. community nursing team, 24 hour nursing team, acute care at home team, dental services, addiction services, non-registered practitioners providing home care services and school health services. These services may be provided to BHSCT facilities or non-BHSCT facilities, which are regulated by the Regulation and Quality Improvement Authority (RQIA), or in the client's home.
- 1.1.3.2 BHSCT community facilities e.g. GP out-of-hours units, health and wellbeing centres, residential homes including elderly people homes and childrens homes, day care facilities and intermediate care facilities.
- 1.1.3.3 Non Trust personnel contracted to provide community services on behalf of the Trust e.g. Independent Service Providers participating in waiting list initiatives, independent domiciliary care providers. The community medicines code acts as guidance to ensure that they have in place appropriate policies and procedures for the safe and secure prescribing, administration, storage and handling of medicines. This will enable compliance with current legislation and the requirements of local risk management and clinical governance frameworks, with respect to the management of medicines.
- 1.1.4 Where the term community setting is used it includes the above facilities and services.
- 1.1.5 Throughout the document, the senior manager, healthcare professional, nurse or nurse/midwife in charge is named as the responsible person for certain elements of the system.
- 1.1.6 'Client' is the term used to refer to service users and patients in the Medicines Code.
- 1.1.7 Trust staff who prescribe, supply and administer medicines must practise within the current legislative requirements, their code of professional practice, this Community Medicines Code and any locally agreed procedures available. If necessary this Code may be supplemented by additional departmental procedures. Any such procedure must be written in accordance with the Community Medicines Code.

| 1.1.8 | Each member of staff is accountable for their own practice and also for identifying any training needs with their line manager. A practitioner who does not fulfil this requirement must work under the direction and supervision of a registered practitioner, who will be responsible for ensuring that the person is |
|-------|---|
| | competent to carry out the task. |

- 1.1.9 Medicines supplied by Trust Pharmacy departments are for treating clients. Under no circumstances are any medicines supplied by the Trust to be used for the personal use of staff as this is theft of Trust property.
- 1.1.10 A medicine is defined as a substance introduced into the body, or externally applied to the body, for the purpose of:
 - Treating disease;
 - Preventing disease;
 - Diagnosing disease;
 - Ascertaining the existence, degree or extent of a physiological condition;
 - · Contraception;
 - · Inducing general or regional anaesthesia; or,
 - Otherwise preventing or interfering with the normal operation of a physiological function.
- 1.1.11 Medicines may be categorised as follows:
 - Medicines and medicinal preparations which come under the provisions of the Medicines Act (1968). They include medicines used in clinical trials, unlicensed medicines, dressings, and medical gases;
 - Controlled drugs (CDs) i.e. substances controlled under the provisions of the Misuse of Drugs Act (1971) and Regulations made under the Act; or,
 - Alternative medicinal products e.g. herbal or homeopathic remedies, which are used for therapeutic purposes.
- 1.1.12 Disinfectants, reagents (e.g. blood glucose testing strips) and other preparations not used directly to treat clients do not have to be prescribed for an individual client. Their ordering and storage however, must comply with the relevant section of the Medicines Code.
- 1.1.13 DHSSPS Good Management Good Records Schedule M provides guidance on the retention and disposal of records relating to pharmacy and medicines management.
- 1.1.14 Acute Care at Home (ACAH) is a service established to support the care of Older people in their own home and prevent hospital admission. The ACAH is a developing service which interfaces the traditional primary and secondary care boundaries. A range of local priocedures have been developed to support the developing service.

1.2 Accountability arrangements

- 1.2.1 The Chief Executive of the Trust has overall responsibility for the safe and secure handling of medicines as part of the Controls Assurance Medicines Management Standard.
- 6 Belfast Health and Social Care Trust Community Medicines Code

1.2.2 The Head of Pharmacy and Medicines Management is responsible for ensuring that systems are in place to appropriately address all aspects of the safe, secure and cost effective handling of medicines. The Head of Pharmacy and Medicines Management is also the appointed Accountable Officer for Controlled Drugs within Belfast Trust. The Head of Pharmacy and Medicines Management reports to the Chief Executive via the Medicines Optimisation Committee and the Director of Surgery and Specialist Services and the Medical Director.

1.3 Medicines Optimisation Committee

- 1.3.1 The Medicines Optimisation Committee is responsible for the review, analysis and monitoring of medicines management processes contributing to achievement of Trust corporate objectives through effective medicines management and in accordance with the Medicines Management Strategy.
- 1.3.2 The Medicines Optimisation Committee is accountable to the Trust Executive Team and the Trust Board via the Medical Director. The Medicines Optimisation Committee is responsible for ensuring the safe effective, economic and optimal use of medicines within BHSCT inpatient and community settings. The Committee is also responsible for the introduction of new medicines into the Trust, supporting medicines safety and governance, nonmedical prescribing, therapeutic review of commissioned treatments and the development of Trust policies and procedures relating to medicines.
- 1.3.3 The Medicines Optimisation Committee achieves these objectives through the following sub-groups; Drugs and Therapeutics (D&T) Committee and its sub-committees (New Drugs Group, Antimicrobial sub-committee, paediatric D&T, psychiatry D&T), Medicines Safety and Risk Management sub-group, Non-Medical Prescribing sub-group, the Medical gases sub-group and the Immunoglobulin assessment panel.
- 1.3.4 Policies approved by the Drug and Therapeutics committee are subsequently ratified by the Standards and Guidelines committee and finally approved for the Trust by the Policy committee.

1.4 General principles

- 1.4.1 All BHSCT employed staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in this Code.
- 1.4.2 Senior staff, including consultants, departmental and facilities managers, nurse/midwife in charge are responsible for ensuring that duties are delegated to staff with appropriate knowledge and assessed practice. Those in charge of services, facilities and departments are responsible for ensuring that their staffs, especially new employees, locum staff and agency staff, adhere to procedures in this Medicines Code, which may differ from procedures elsewhere.
- 1.4.3 The Community Medicines Code also applies to medical staff, nursing/midwifery staff and other healthcare staff from other Trusts, private practice or contracted agencies, who are contracted to work in BHSCT community services. Managers who contract for these services must make

Belfast Health and Social Care Trust Community Medicines Code

7

it explicit within written contracts that these staff must follow the procedures described in this Medicines Code.

1.4.4 The complexity and variety of medicines, their potency and potential toxicity places an exacting responsibility on doctors, nurses and pharmacists. Errors can occur in any of the procedures relating to medicines including prescribing, dispensing, interpretation of the prescription, preparation, administration and storage.

1.5 Responsibilities of staff

1.5.1 Prescribing, ordering, dispensing, storing, monitoring, administration and transport of medicines is the responsibility of various staff. All staff must be aware of the tasks for which they are responsible, as detailed in this section.

1.5.2 Doctors, dentists and non-medical prescribers

- 1.5.2.1 Doctors, dentists and all non-medical prescribers employed by the Trust, must comply with legislation, Trust policies, the relevant Medicines Code(s) and professional guidance when performing such duties. Prescribers must keep up-to-date with cost effective, evidence-based prescribing and adhere, where appropriate, to local practice formularies and local and national prescribing guidelines e.g. NI Formulary, NICE, GAIN, NI Wound Care Formulary and NI Pharmaceutical Clinical Effectiveness Program (PCEP) including cost effective choices guidance and HSCB Commissioning Plans.
- 1.5.2.2 Prescribers must not prescribe or recommend to GPs new medicines that have not been approved by the BHSCT New Drugs Group. Refer to BHSCT policy 'Adjudication of new medicines and treatments' – BHSCT intranet.
- 1.5.2.3 Prescribers are professionally accountable and must ensure their practice is safe and that they maintain their competence through continuous professional development (CPD).
- 1.5.2.4 Trust prescribers have a responsibility for prescribing in accordance with the appropriate marketing authorisation (product licence) of a medicine. Where a product does not have a UK marketing authorisation, prescribing should be in accordance with an adequate body of evidence or expert opinion, and with the support of the BHSCT D&T Committee as per the Trust 'Unlicensed Medicines policy'.
- 1.5.2.5 Medical students are not permitted to prescribe.
- 1.5.2.6 Prescribers must sign all prescriptions for medicines, and it is essential that the identity of the prescriber is known. Bleep/contact telephone number and professional registration number, if applicable, should be included on Trust discharge or out-patient prescriptions. Prescribers working in Trust GP Out-of-hours centres are identified by their name, centre address and code.
- 1.5.2.7 Non-Medical Prescribers must only prescribe in accordance with the Trust 'Non-Medical Prescribing Policy'.

8 Belfast Health and Social Care Trust Community Medicines Code

1.5.3 Pharmacy staff

- 1.5.3.1 Pharmacists, employed by the Trust, are responsible for ensuring the safe, effective and economic use of medicines in the Trust. This process includes regular monitoring of prescribing to ensure appropriateness, accuracy, safety and clarity.
- 1.5.3.2 Trust Pharmacy staff are responsible for the stock of medicines held in the Pharmacy to ensure that medicines are stored under the proper legal and environmental conditions. They are responsible for manipulation and preparation into user ready presentation and for their supply to appropriate facilities and departments.
- 1.5.3.3 Trust Pharmacy staff, where appropriate, have a responsibility to advise practitioners on the safe and secure storage of medicines in clinical areas and community settings.
- 1.5.3.4 Trust Pharmacy staff will ensure that when medicines are prescribed, supplied and administered, there is a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.
- 1.5.3.5 Trust Pharmacy staff provide information to clients, carers, nursing/midwifery, medical and other healthcare professions with the aim of improving concordance, and the safety and effectiveness of therapy. Where advice from a member of Pharmacy staff has not been followed in respect of a patient's medicines, this should be addressed with the medical team looking after the patient. An incident form may also be completed in this situation.
- 1.5.3.6 Trust Pharmacies are responsible for the purchase of all pharmaceuticals to be used within the Trust's hospitals, BHSCT clinics, outpatient facilities including Trust Health and Wellbeing Centres. Trust pharmacies are not responsible for supplying pharmaceuticals for individual clients for use in their own home, residential or other care home or day centre as these are supplied against NHS prescriptions. Exceptions to this are the supply of specialist medicines (red/amber medicines), the Acute Care at Home service, alternative or exception dressings and where Trust staff require a small amount of stock to initiate a new treatment or carry out a procedure and it would be unreasonable to delay this in order to obtain the necessary goods through the GP and community pharmacy.

1.5.4 Registered nurses/midwives in a community setting

- 1.5.4.1 The nurse/midwife in charge is responsible for ensuring that the Medicine Code procedures are followed correctly and that staff having access to up to date medicines information.
- 1.5.4.2 The nurse/midwife in charge is responsible for the safe custody of pharmaceuticals held in BHSCT community settings and is responsible for ensuring that duties are delegated to staff with appropriate knowledge and assessed practice.
- 1.5.4.3 The nurse/midwife in charge is responsible for controlling access (by keys or other means) to the medicines cupboard (including client's own drugs) and trolley(s). This responsibility remains with the appointed nurse/midwife in charge even if he/she decides to delegate the duty to another nurse.

Belfast Health and Social Care Trust Community Medicines Code

9

- 1.5.4.4 The nurse/midwife in charge must ensure that a written protocol is in place identifying control of the medicine cupboard keys and that the keys are only supplied to authorised healthcare staff in accordance with the local protocol.
- 1.5.4.5 The nurse/midwife in charge of a department, clinic, facility or service is responsible for monitoring the standard of administration of medicines by staff within the department, clinic, facility or service.
- 1.5.4.6 Each registered nurse/midwife is responsible for ensuring the safe and appropriate administration of medicines and is expected to adhere to the standards as defined by the Nursing and Midwifery Council standards for Medicines Management and elsewhere in this Code.
- 1.5.4.7 Trust staff who may also be in the Trust as healthcare students or bank staff may only undertake duties appropriate for the role in which they are in the Trust for at any one time, whether that be their employed role or their student/bank role.

1.5.5 Nursing/midwifery students on pre-registration programmes

- 1.5.5.1 Nurses/midwives in training must be given every opportunity to become proficient in medicines related activities under appropriate supervision. The supervising registered nurse/midwife has responsibility for medicines related procedures at such times.
- 1.5.5.2 Prior to registration, nursing/midwifery students are not permitted to administer medicines without supervision. They may, under the direct supervision of a registered nurse/midwife, administer for the purpose of instruction and learning and sign for the administration. The supervising registered nurse/midwife must countersign the medicine chart following administration of the medicine by a nursing/midwifery student.
- 1.5.5.3 Student midwives may administer medicines on the midwife exemption list, except controlled drugs, under the direct supervision of a midwife.
- 1.5.5.4 If a particular medicine needs a second check (see section 3.3) the second signatory can be a student nurse/midwife provided the registered nurse/ midwife administers the medicine.

1.5.6 Senior non medical professionals/managers

- 1.5.6.1 For each community team base or Trust facility where medicines are stored, a suitably qualified practitioner must be designated as the Appointed Practitioner in Charge. This includes non medical professionals and managers with designated responsibility for the facility. This Appointed Practitioner in Charge is ultimately accountable for the stock of all medicines and pharmaceuticals held, including key holding, ensuring that Medicine Code procedures are followed correctly and that the security and safe handling of medicines is maintained.
- 1.5.6.2 The Appointed Practitioner in Charge is responsible for the safe custody and security of medicines in the department, clinic or facility and is responsible for ensuring that duties are delegated to staff with appropriate knowledge and assessed competence.
- 10 Belfast Health and Social Care Trust Community Medicines Code

- 1.5.6.3 The Appointed Practitioner in Charge is responsible for controlling access (by keys or other means) to the medicines cupboard (including client's own drugs) and trolley(s). This responsibility remains with the Appointed Practitioner in Charge even if he/she decides to delegate the duty to another member of healthcare staff.
- 1.5.6.4 The Appointed Practitioner in Charge must ensure that a protocol is in place identifying control of the medicine cupboard keys and they are not given over to other healthcare staff unless a designated member of staff.

1.5.7 Transport personnel

1.5.7.1 Transport personnel are responsible for the safe, secure and timely transport of pharmaceuticals from hospital pharmacy departments to Trust community facilities. An audit trail from collection to delivery of pharmaceuticals must be maintained.

2 Prescribing of medicines

2.1 General principles

- 2.1.1 Refer to section 1.5.2 for responsibilities of prescribers.
- 2.1.2 Only practitioners who are suitably qualified, either by professional group (doctors/dentists) or by qualification and annotation on the relevant register of the professional body (nurses, Allied Health Professionals (AHPs), pharmacists) may prescribe medicines. See Trust Non-Medical Prescribing Policy BHSCT intranet.
- 2.1.3 It is good practice to physically see the patient when prescribing or reviewing their medicines.
- 2.1.4 It is the prescriber's responsibility to ensure that any medicines prescribed take account of the client's allergy status and medicine intolerances.
- 2.1.5 A medicine allergen must be recorded by generic (approved) name in the appropriate documentation. The type of reaction, e.g. rash, must also be recorded, where known, for each medicine allergen.
- 2.1.6 The BNF approved name of a medicine should be used whenever possible, except where this would not be clinically appropriate or where there is no approved generic name, in accordance with the Trust 'Policy for appropriate use of generic names of medicines' – BHSCT intranet.
- 2.1.7 Medicines for administration to a client must be prescribed in writing by an authorised prescriber except:
 - In an emergency where the client has an actual or potential life threatening condition that requires immediate administration of medication;
 - Where administration is undertaken in accordance with an authorised patient group direction;
 - · Under exemption as a registered midwife;
 - Under approved guidelines for administration of non-prescribed medication e.g. in residential care homes and nursing homes/children's homes/special schools. Refer to local procedures.
- 2.1.8 In Out Patient Clinics, Day procedure units etc, medical and non medical prescribers will use the Trusts Treatment Advice Note to record details of treatment and/or recommendations to GPs. Non Medical prescribers will also clearly annotate their status as outlined (e.g. NISP/PISP/AHISP).

2.2 Writing of Prescriptions

- 2.2.1 Medicines for clients in the community are prescribed by a General Practitioner on a HS21 or HS21CS form; General Dental Practitioner on a HS21D; Community Practitioner Nurse Prescriber on a HS21(N); and Supplementary Prescriber on a HS21M prescription or by hospital prescribers on a Trust discharge or out-patient prescription e.g. for specialist medicines such as clozapine.
- 2.2.2 Prescribers must comply with the relevant legislation when writing prescriptions. The guidance to which they must adhere is given in the BNF under 'General Information and Prescription Writing'.
- 12 Belfast Health and Social Care Trust Community Medicines Code

- 2.2.3 Before writing a prescription the prescriber should have assessed the client and have knowledge of:
 - Client's full medication (this should include all prescribed and non-prescribed medication including over the counter and alternative remedies).
 - · Past medical history.
 - Allergy status.
 - Client's current health status.
 - A thorough knowledge of the item to be prescribed, i.e. dosage, therapeutic action, side effects, and interactions, frequency of use.
- 2.2.4 Dosage form must be specified e.g. tablets, liquid, injection, and inhaler. The dose should be clearly stated in metric units (e.g. 250mg) or the number of dosage units where appropriate.
- 2.2.5 'Microgram' and 'nanogram' must be spelt out in full and not abbreviated to 'mcg', 'µg' or 'ng'.
- Quantities less than 1g should be written in milligrams e.g. '500mg', not '0.5g'. Quantities less than 1mg should be written as micrograms e.g. '100 micrograms', not 0.1mg.
- 2.2.7 Avoid 'trailing zeros' in prescribing i.e. prescribe as '2mg' and not '2.0mg'. As appropriate, medicines must be prescribed using 'leading zeros' i.e. '0.5 units' instead of '.5 units'.
- 2.2.8 'Units' or 'international units' must be written out in full and not abbreviated to 'u' or iu'.
- 2.2.9 Roman numerals may cause confusion that could lead to medication errors and should not be used.
- 2.2.10 The route of administration must be clearly stated. The table below indicates acceptable abbreviations for various routes of administration. Other routes of administration must be written in full. Instructions indicating specific sites of administration e.g. 'the left ear' may be required.

| O or PO | Oral by mouth | PR | Per Rectum |
|---------|---------------|------|-----------------|
| Тор | Topical | PV | Vaginal |
| Inh | Inhalation | IV | Intravenous |
| IM | Intramuscular | SC | Subcutaneous |
| Neb | Nebulised | PEG | Per gastrostomy |
| NG | Nasogastric | BUCC | Buccal |
| SL | Sublingual | TD | Transdermal |

Belfast Health and Social Care Trust Community Medicines Code

13

2.3 Security and safe handling of prescription forms

- 2.3.1 Prescription forms should not be left unattended and when not in use should be locked away. Clients and visitors should never be left alone with prescription forms or allowed into secure areas where forms are stored. Under no circumstances should prescription forms be pre-signed before use.
- 2.3.2 Prescribers should take all reasonable precautions to prevent loss or inappropriate use of the prescription pad.
 - Use only one prescription pad at a time;
 - Keep a record of the first and last serial number of prescriptions in pads issued to them;
 - It is good practice to record the serial number of the first and last remaining prescription form of an in-use pad at the beginning and end of each working day. This would help to identify any forms lost or stolen overnight;
 - On termination of employment or a change of team all prescribers have a responsibility to return any unused prescriptions to their local supply point where they are to be shredded. This should be witnessed and signed by two people.
 - When making home visits prescribers should carry their prescriptions on their person at all times.
- 2.3.3 For non-medical prescribers employed in community and primary care settings the security of prescription forms is the responsibility of both the prescriber and their employing organisation. Refer to BHSCT 'Non-Medical Prescribing policy' for the process of obtaining prescription pads from the Business Service Organisation (BSO).
- 2.3.4 If prescriptions are stolen or missing the procedure is to notify:
 - Local Medicines Management Office, Eastern Office, Linenhall Street, Belfast 028 9055 3782

AND

- CFPS Fraud hotline (Tel: 0800 096 3396)
- Local district police station. Ring 0845 600 8000 to get local office number.

Trust prescribers must inform their manager and a Trust incident form completed.

2.4 Medication history

- 2.4.1 On admission to a BHSCT facility e.g. residential care home, nursing home, children's home or supported living, full details of the client's current medication, including the allergy status must be recorded on an admission letter. All prescribed medicines must be recorded on a medicines record/administration sheet e.g. Medicines Administration Record (MAR) chart that must be maintained for each client. Ideally, a pharmacist or other healthcare profession will complete medicines reconciliation against at least two or more information sources.
- 2.4.2 Writing of a medicines record/administration sheet or any subsequent changes must be completed by registrant or senior member of staff and checked by
- 14 Belfast Health and Social Care Trust Community Medicines Code

another registrant where possible, and where not, another competent health professional or senior member of staff.

2.4.3 Doctors are not contractually obliged to sign the client's medicines record/administration sheet. However, doctors MUST be ASKED to sign their client's medicines record/administration sheet confirming the details therein. If a doctor refuses to sign their client's medicines record/administration sheet the fact and date of that refusal MUST be recorded on the reverse of the sheet. Treatment should not be delayed by a refusal.

2.4.4 The medicines record/administration sheet should detail:

- Full name and date of birth of the client
- Allergy status of the client
- Name, form and, where appropriate, strength of each medicine
- Dose to be administered
- Time and route of administration and, where appropriate, the specific site of application (e.g. left eye, right eye, both eyes).
- Frequency and, where appropriate, the dilution and rate of administration of the prescribed medicine. 'As required' medicines must state the minimum intervals.
- The duration of therapy
- Any special requirements e.g. before meals
- The date prescribed and by whom.

2.5 Prescribing of warfarin

- 2.5.1 Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harm and admission to hospital. Managing the risk associated with anticoagulants can reduce the chance of clients being harmed in the future.
- 2.5.2 Guidance has been produced for the safer use of oral anticoagulant therapy in primary care, and is available at:

http://www.medicinesgovernance.hscni.net/primary-care/high-risk-medicines/

For secondary care guidance refer to BHSCT trust policy 'Guidelines for Safe Warfarin Management' – BHSCT intranet

2.5.3 Warfarin initiation is undertaken in secondary care where GPs are not GMS funded.

2.5.4 General

- 2.5.4.1 To use warfarin safely, clients must have their treatment explained to them by a healthcare professional at the start of the treatment, when they leave hospital, at their first warfarin clinic appointment, if applicable, and when necessary throughout the course of their treatment.
- 2.5.4.2 When warfarin is initiated, all clients should be given the NPSA booklet called 'Oral Anticoagulant Therapy: Important information for patients'. This is for them to keep and it includes general information and practical advice. On the

Belfast Health and Social Care Trust Community Medicines Code

15

front page is an alert card, the size of a credit card, which should be carried at all times. It tells healthcare staff that the person is taking warfarin. This is important if they are in a medical emergency or about to receive another treatment. Booklets are available from the Business Services Organisation (Order Line: 028 9053 5652). In addition to this method, Trust facilities may also obtain these items using the BSO/PALS order form.

- 2.5.4.3 Clients should keep the last six months' records of their INR blood test results in the record booklet and take it with them whenever they visit a healthcare professional. It is recognised that whilst the NPSA record book is the preferred written record, some practices may use an alternative written record.
- 2.5.4.4 Checks should be performed each time a client requests and receives a supply of warfarin. This should include a review of INR blood test results, warfarin dose information and checking that it is safe to supply more anticoagulants.
- 2.5.4.5 There should be clear instructions for each client on who is responsible for dosing & INR interpretation, where samples should be sent, how clients will be informed of the results and dose and how community nurses will be informed of the date of the next INR.

2.5.5 Drug interactions

- 2.5.5.1 Many medicines, including herbal and supplement products, can interact with warfarin. Refer to the individual product information or the BNF. There are also potential interactions with certain foods and drinks.
- 2.5.5.2 If possible, medicines should be selected that do not produce clinically significant interactions. If this is not possible, the prescriber who initiates or discontinues a prescription for an interacting medicine is responsible for ensuring that the client is informed that an interacting medicine has been commenced or discontinued.
- 2.5.5.3 The client should be instructed to provide details of the change in therapy when the blood sample is taken. This information can then be recorded on the test request form to inform the anticoagulant clinic or appropriate prescriber. Once notified in this way, the anticoagulant clinic or GP practice may require additional INR tests and may need to adjust the dose of the warfarin accordingly.

2.5.6 Prescribing

- 2.5.6.1 Warfarin dose must be expressed in 'mg' not in number of tablets. Warfarin tablets come in different strengths so by confusing the number of tablets with 'mg', the person could get the wrong dose.
- 2.5.6.2 Warfarin strengths in Northern Ireland have been successfully rationalised to 1mg and 3mg tablets to minimise the risk of confusion between different strengths. These will continue to be the recommended strengths of warfarin tablets used in Northern Ireland and all users are reminded of the importance of ensuring this consistent approach. A note should be made in the client record if there is deviation from the regional policy indicating reasons and that the risks have been explained and accepted by the client.
- 16 Belfast Health and Social Care Trust Community Medicines Code

2.5.7 Communication of prescribed dose

2.5.7.1 To the client/carer:

A written record of the latest INR and warfarin dose must be held by the client in the oral anticoagulant record book or a printed/written record. If results are given over the phone, GP practices should ensure that a named person is responsible for this and that the client has been instructed on how to document the dose clearly. Verbal instructions should be followed up by a written instruction posted to the client.

2.5.7.2 To community settings:

Service providers must provide clear written dosing instructions for care workers. The National Patient Safety Agency (NPSA) recommends that the written record from the clinic or practice is attached to the medicines record/administration sheet used by the care provider. Verbal changes to the dose must only be accepted in emergencies and must be read back to the prescriber to confirm accuracy, ensuring that any abbreviations are spoken in full. Refer to section 2.12 for further information on remote prescription or direction to administer.

- 2.5.7.3 At discharge from hospital;
- 2.5.7.3.1 The Belfast Trust 'Oral anticoagulant therapy prescription chart/discharge form' should be completed with doses to the next INR check and the date of the INR check post discharge. The top (white) copy will be sent to the clients GP. If the patient is attending a hospital anticoagulant clinic, the top white copy of the prescription will be photocopied and sent to the clinic.
- 2.5.7.3.2 For patients initiated on warfarin the 'Oral anticoagulant therapy record book' (yellow book) from the anticoagulant pack is sent to Pharmacy for completion with dose instructions.
- 2.5.7.3.3 If the patient has brought their 'Oral anticoagulant therapy record book' (yellow book) into hospital, this will be sent to the hospital Pharmacy with the 'Oral Anticoagulant Therapy Prescription Chart/Discharge Form'; anticoagulant doses to the next INR check should be completed in the 'Oral anticoagulant therapy record book'; if an existing warfarin patient either does not have an 'Oral anticoagulant therapy record book' or does not use one, the hospital pharmacy will complete the dosing instructions in a 'Temporary warfarin discharge patient information' card.

Caution: Communication of the daily dose in milligrams and not the weekly dose is the preferred and safer option, particularly when a written record will not be provided e.g. dose queries from hospital staff.

2.5.8 Dentists

- 2.5.8.1 Dental practitioners must manage clients on anticoagulants according to evidence-based therapeutic guidelines.
- 2.5.8.2 The British Dental Association, the NPSA and the British Society for Haematology issued joint guidelines for the management of clients requiring dental procedures whilst taking oral anticoagulants. See web link <u>http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814</u>

Belfast Health and Social Care Trust Community Medicines Code

17

- 2.5.8.3 Clients taking anti-coagulants who need dental treatment may require a blood test up to 72 hours before treatment takes place. Where required the social care provider should discuss this with the client's dentist at least three days prior to treatment.
- 2.5.8.4 Clients taking oral anticoagulants should not be prescribed NSAIDs or COX-2 inhibitors as analgesia following dental surgery.

2.6 Prescribing of opioid medicines

- 2.6.1 The National Patient Safety Agency (NPSA) has highlighted problems with opioid medicines whereby clients received unsafe doses of opioid medicines or where a dose or formulation was incorrect based on the client's previous opioid dose.
- 2.6.2 NPSA recommends that healthcare staff should:
 - Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the client. This may be done for example through discussion with the client or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.
 - Ensure where a dose increase is intended, that the calculated dose is safe for the client (e.g. for oral morphine or oxycodone in adult clients, not normally more than 50% higher than the previous dose).
 - Ensure they are familiar with the following characteristics of the prescribed opioid and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

2.7 Prescribing of antibiotics

2.7.1 Where it is considered appropriate to prescribe an antibiotic, the antibiotic, strength, dose and duration should follow the NI Antimicrobial Guidelines for Primary Care available as a Smartphone/Tablet App. Download the free MICROGUIDE app via the App Store or Google Play and select 'Northern Ireland Primary Care' when prompted for trust. Alternatively: <u>http://niformulary.hscni.net/Formulary/Adult/5.0/Pages/default.aspx</u>

These guidelines are empiric and do not override local prescribing decisions to address local circumstances, e.g. where microbiologists are aware of an emerging pattern of resistance they can issue guidance to local prescribers on the current most appropriate antibiotic for that infection.

- 2.7.2 Microbial resistance is a public health matter of major importance and great care should be taken to ensure that prescribing of antimicrobials will not jeopardise strategies to combat increasing resistance.
- 2.7.3 Where intravenous antibiotics are required to be administered a medicine kardex will be completed by the prescriber. Administration will be recorded on the medicine kardex.

2.8 Prescribing for syringe pumps

- 2.8.1 All drugs to be delivered via a syringe pump within the community should be prescribed by the client's General Practitioner, Out of Hours doctor on behalf of the GP or Designated Trust Prescriber within agreed guidelines.
- 18 Belfast Health and Social Care Trust Community Medicines Code

- 2.8.2 When clients are discharged from hospital, a patient specific direction to administer medicines (authorisation to administer) must be completed which will enable community nursing to administer medicines via syringe pump. The 'prescription and administration of medicines via subcutaneous CME/McKinley T34 syringe pump' chart, written at discharge and designated as an authorisation to administer for community nursing, will accompany the client at discharge. This will be active until the prescription is changed by the GP or for up to a maximum of 7 days from discharge. Thereafter, the patient specific direction to administer will be provided by the clients GP.
- 2.8.3 Refer to BHSCT Trust policy: Subcutaneous use of the McKinley T34 ambulatory syringe pump BHSCT intranet, for processes to be followed when administering medicines via an ambulatory syringe pump.

2.9 Specialist medicines (red/amber) prescriptions

- 2.9.1 Prescribers should be mindful of potential difficulties which can arise in the transfer of care of clients to the community when highly specialised medicines are involved.
- 2.9.2 A system to manage the prescribing and supply of specialist medicines is in place regionally and such medicines are categorised using a red and amber 'traffic light' system.
- 2.9.3 **Red list medicines:** prescribing responsibility should remain with the consultant or specialist clinician and the supply organised via the Trust Pharmacy. The prescriber MUST complete a patient specific direction to administer, which will accompany the specialist medicine, if the medication is to be administered by community nursing. This authorises community nursing to administer the specialist medicines.
- 2.9.4 Amber list medicines: prescribing responsibility should be transferred to primary care with the agreement of the client's GP and when shared care arrangements have been established. A copy of the relevant shared care guideline should be provided to the GP. See Trust policy 'How to Use Shared Care Guidelines (SCG) for Specialist Medicines when Requesting Shared Care with the Clients' GP' for further details or via the following link: <u>http://intranet.belfasttrust.local/policies/Documents/Shared%20Care%20</u> <u>Guidelines%20%20How%20to%20use%20(SCG)%20for%20specialist%20</u> <u>medicines%20when%20requesting%20shared%20care%20with%20the%20</u> <u>patients'%20GP.pdf</u>
- 2.9.5 A complete list of red and amber medicines and copies of shared care guidelines are available via <u>www.ipnsm.hscni.net</u>. Any queries about red or amber medicines, or shared care should be directed to the interface pharmacists in BCH or RVH. They can be contacted through the hospital Pharmacy Departments.
- 2.9.6 Prescribers should inform their medical colleagues (especially General Practitioners) of the medicine's licence status when advising them to use unlicensed medicines or medicines outside of their marketing authorisation (off-label use).

2.10 Prescribing of unlicensed medicines

- 2.10.1 The use of an unlicensed medicinal product should only be considered when there is no equivalent licensed alternative available and if its use can be clearly justified clinically and pharmaceutically. The use of an unlicensed medicinal product should not be justified purely on the grounds of lower costs.
- 2.10.2 Refer to the BHSCT 'Unlicensed Medicines Policy' and the BHSCT Non-Medical Prescribing Policy' – BHSCT intranet
- 2.10.3 Adverse drug reactions and medication incidents involving unlicensed medicines should be reported in the same manner as for licensed medicines.
- 2.10.4 Recommending unlicensed medicines to practitioners see section 2.9.6

2.11 Prescribing of a licensed medicine for an unlicensed indication (off-label prescribing)

- 2.11.1 Off-label use is when a drug, which has a marketing authorisation (licence), is used outside of the terms of the Marketing Authorisation. This includes prescribing for unlicensed indications, at higher than licensed doses, by routes and to age groups not included in the licence, in palliative care and pain management etc. Also included are those situations where the form of a preparation is changed before administration (e.g. tablets need to be crushed, capsules opened, etc).
- 2.11.2 Medicinal products marketed and licensed for adult clients have often not been formally evaluated for use in pregnancy, breast feeding or in children. Accepted and proven treatments in paediatric practice rely on the use of unlicensed/off-label medicinal products. Such uses are informed and guided by a respectable and responsible body of paediatric opinion.
- 2.11.3 If a prescriber uses a licensed medicine for an unlicensed indication then the manufacturer is unlikely to be found liable for any harm caused by that medicine, unless the harm is directly attributable to a defect in it, rather than the way in which it was prescribed. It is the responsibility of each prescriber to be aware of prescribing outside licensed indications.
- 2.11.4 Recommendations from bodies such as the General Medical Council and the Medical Defence Organisations place a duty on doctors to act responsibly, and to provide information to clients on the nature and associated risk of any treatment, including 'off-label' and unlicensed medicines.
- 2.11.5 Nurse and pharmacist independent prescribers may prescribe medicines off licence or off label i.e. for uses outside their licensed indications/UK marketing authorisation. The non-medical prescriber must accept professional, clinical and legal responsibility for that prescribing and should only prescribe off licence where it is acceptable clinical practice and in accordance with individual competence. Prescribing must be in accordance with Trust policy. Refer to BHSCT 'Non-Medical Prescribing Policy' BHSCT intranet.

2.12 Remote prescription or direction to administer

- 2.12.1 In exceptional circumstances, where
 - medication (not including controlled drugs) has been previously prescribed but where changes to the dose are considered necessary or
 - a previously unprescribed medicine (not controlled drugs) is required and the prescriber is unable to issue a new prescription

a verbal order may be given by an authorised prescriber (see also sections 2.12.1.2 and 2.12.1.7).

- 2.12.1.1 Where a verbal instruction is given to a registered nurse/midwife by an authorised prescriber 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 client,
 - write down the message and read it back to the prescriber checking the clients name, the medicine, the dose, the route and time of administration.
- 2.12.1.2 A verbal order is not acceptable on its own. The use of information technology (such as fax or email) may be used but must confirm any change to the original prescription **before the new dosage is administered**.
- 2.12.1.3 The fax or email prescription or direction to administer must be stapled with the clients existing medication record/administration sheet.
- 2.12.1.4 The fax or email must be followed up by a new prescription or patient specific direction to administer, signed by the prescriber who sent the fax or email confirming the changes, within normally a maximum of 24 hours (72 hours maximum bank holidays and weekends). A prescription is required when the drug is to be both supplied and administered. For administration only, a patient specific direction to administer is sufficient.
- 2.12.1.5 Where a medication has not been prescribed before, a nurse or midwife independent prescriber may not prescribe remotely if they have not assessed the client, except in life threatening situations.
- 2.12.1.6 If a verbal instruction has been given the verbal order is treated as a 'Once only' entry on the client's notes/record.
- 2.12.1.7 The nurse/midwife retains the right to refuse to take a verbal order to administer a medicine if it compromises care to the client.
- 2.12.2 In the case of a care home the senior member of staff/registrant should request the prescriber to confirm and sign changes to existing medication on the client's individual medicines record/administration sheet. Remote prescribing of new medication cannot be undertaken in a care home because they do not have access to a stock of medicines.

Where a verbal instruction is given to non-registered staff the details of the requested change (including who requested the change, date and time of request and who received the request) must be recorded, the information must be read back to the prescriber (including spelling the name of the medicine) and the prescriber should be asked to repeat the request to someone else e.g. to the client and/or family member or carer. These steps must be completed before the medicine is administered. [NICE NG67: 2017]

Belfast Health and Social Care Trust Community Medicines Code 🔳 🕴 21

2.13 Verbal orders in the presence of a doctor/dentist

- 2.13.1 In an emergency situation such as resuscitation, a doctor/dentist may administer a medicine to a client or direct a nurse/midwife they are working with to administer a medicine without first writing a prescription. The nurse/midwife who administers the medicine must confirm the instructions given to them with the doctor/dentist and have the doctor/dentist double check the medicine to be administered.
- 2.13.2 As soon as possible after the emergency, the directions and administration must be recorded in writing on the client's notes/record.
- 2.13.3 Any registered healthcare professional may administer adrenaline without direction or prescription in a life threatening situation. However, ideally, the Trust prefers that a Patient Group Direction should be in place to support staff in this situation.

2.14 Prescribing for self/family/friends

- 2.14.1 Trust Prescribers should not write prescriptions for themselves or their family or other members of Trust staff unless the member of staff is also a client of the Trust under the care of the prescriber.
- 2.14.2 Prescribers should **not** prescribe any medicine for themselves or for anyone with whom they have a close personal or emotional relationship other than in exceptional circumstance. Such prescribing may be necessary in circumstances where no other person with the legal right to prescribe is available to assess the client's clinical condition and to delay prescribing would put the client's health at risk, or cause unacceptable pain.
- 2.14.3 Each professional body provides guidance for their members.

2.15 Transfer of medicines related information

2.15.1 Transfer of clients when they move care settings

Guidance has been issued by GAIN (Guidelines and Audit Implementation Network) - Guidelines on Regional Immediate Discharge Documentation for Patients being discharged from Secondary to Primary Care (June 2011) available at www.gain-ni.org, and the Royal Pharmaceutical Society of Great Britain (RPSGB) June 2012.

- 2.15.1.1 To reduce the risk of errors and harm to clients, the minimum standards outlined in box 1 represent the information that should be transferred with clients when they move care settings.
- 2.15.1.2 The minimum standards focus on the critical information about medicines that the healthcare professional taking over responsibility for the client's care has access to when the client arrives in their care setting.
- 2.15.1.3 The minimum standards for information about medicines apply whenever a client is transferred from one care setting to another. It is likely that these minimum standards would form part of more detailed transfer records, which are tailored specifically to each transfer setting. However, in the absence of a detailed record, or where there are doubts about the timely transfer of the
- 22 Belfast Health and Social Care Trust Community Medicines Code

record, it is expected that the healthcare professional transferring the client would ensure that, as a minimum, information outlined in box 1 is supplied. If for any reason the information is not readily available, e.g. the client is being transferred out of hours, this should be clearly indicated and the information should be forwarded within the next working day.

- 2.15.1.4 Information about clients' medicines should be communicated in a way, which is timely, clear, unambiguous and legible; ideally printed or transferred electronically. An example of a Form: 'Transfer of medicines information between care settings' is given in Appendix 1.
- 2.15.1.5 The health care professional transferring a client's care to a different care setting and the healthcare professional taking over the care of the client both have a responsibility to ensure that all necessary information about the client's medicines has been accurately transferred.
- 2.15.1.6 Box 1: Minimum standards for information about medicines to be transferred with clients when they move settings.

| Client Details | Surname, forename (known as), date of birth, gender, Health & Social Care number, address & telephone number |
|--|---|
| GP Details | GP name, name of practice, practice address & telephone number |
| Conditions (if known and/or appropriate) | |
| Current Medications (including herbal, dressings, over the counter medication, devices etc) | Medicine – generic name and brand (where relevant) Dose Frequency/time Formulation e.g. tablets, liquid etc Route of administration Storage where relevant e.g. fridge |
| Medication Changes relating to latest episode of care | Medication started, stopped or dosage changed, and reason for change |
| Allergies, adverse reactions to medicines or contraindications | Causative medicineBrief description of reaction |
| Additional information given to the client and/or authorised representative | For exampleHow long a new medicine may take to workAdherence support required |
| Person completing record | Name, time, job title Contact telephone number Signature (if paper based) |

2.16 Patient group directions (PGDs)

- 2.16.1 Patient group directions (PGDs) are written instructions that permit certain trained groups of named healthcare professionals to supply and/or administer medicines, including prescription only medicines, without a doctor's prescription in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment. Health care assistants cannot supply or administer prescription only medicines under the authorisation of a PGD.
- 2.16.2 The supply and/or administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage for client care (without compromising client safety) and where it is consistent with the appropriate professional relationship and accountability. This generally means that a PGD is best suited to acute or 'first contact' situations and it is not for the management of chronic conditions. Examples of where PGDs may be appropriate are services where assessment and treatment follows a clearly predictable pattern (e.g. immunisation, family planning).
- 2.16.3 The Trust policy 'Developing a Patient Group Direction' is available on the Trust intranet.

2.17 Patient specific directions (PSDs)

- 2.17.1 A patient specific direction, also referred to as an authorisation to administer, is a written instruction from a doctor or dentist or other independent prescriber for a medicine to be supplied or administered to a named client e.g. a prescription or simple written instruction in the client's notes. PSDs to administer are commonly used to give authority to community based practitioners to administer a medicine(s).
- 2.17.2 A PSD must:
 - · State the name of the client and
 - State the name and the dose of the medicine to be administered
 - Show evidence to confirm that the client has been considered as an individual.
- 2.17.3 A PSD does not limit those who can supply or administer the medicine. For example, a suitably trained health care assistant can do so, even though they cannot work under a PGD.
- 2.17.4. If a community based nurse is required to administer a medicine e.g. enoxaparin, insulin, erythropoietin or a depot injection, which has been initiated in secondary care, a PSD must be completed and must accompany the patient at discharge.
- 2.17.5 Refer also to sections 2.8 and 3.1.11 for specific examples.

3 Administration of medicines

3.1 General principles

- 3.1.1 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.
- 3.1.2 Trust facilities must audit the management and administration of medicines on a regular basis. Audits should be available for inspection.
- 3.1.3 Medicines may only be prepared, checked and administered to clients by those working within their own competencies and following appropriate training.
- 3.1.4 The prescriber will need to use their judgement about the competence of the client or carer to administer the medicine safely and according to instructions.
- 3.1.5 For continuous administration (e.g. via intravenous infusions, subcutaneous fluids, or syringe pumps) there should be a record of those involved in settingup the medication and of those involved in monitoring the administration. There must be clear and legible appropriate documentation stating the client's name, ID number, drug/s and diluents/s to be administered, batch numbers and expiry dates of drugs, route of administration, and rate of infusion, infusion time and known allergies.
- 3.1.6 Clients must have undergone a medical assessment prior to commencement of IV antibiotics.
- 3.1.7 All staff who administer IV medicines, which can be safely administered within a community setting, will do so according to their level of competency.
- 3.1.8 First dose administration of any medicine by parenteral administration in a community setting, may be carried out by a nurse, midwife, doctor or appropriate non medical prescriber.
- 3.1.9 As an anaphylactic reaction may occur at the second or later doses, all staff administering medicines should be trained to recognise and manage an anaphylactic reaction.
- 3.1.10 Where administering medicines to children up to the age of sixteen and the registered nurse is unfamiliar with a medicine which has been prescribed, then he/she must clarify prescription/direction to administer with an experienced RN (child), or seek advice from children's service or the prescriber, as appropriate.
- 3.1.11 Trust policies, guidelines and local operational guidelines must be followed. See examples below:-
 - Community Nursing Patient Specific Direction to Administer Medication. Refer to Trust HUB
 - Guidance on administration of long action depot formulations (depot antipsychotic medication) for community mental health nurses

http://intranet.belfasttrust.local/policies/Documents/Long%20Acting%20 Injectable%20Formulations%20(Depot%20Antipsychotic%20Medication)%20 for%20Community%20Mental%20Health%20Nurses%20-%20Administration %20of.pdf

Belfast Health and Social Care Trust Community Medicines Code 🔲 25

- Operational policies for management of medicines in residential homes; day centres, special schools
- BHSCT Trust policy: Subcutaneous use of the McKinley T34 ambulatory syringe pump.

3.2 Administration of medicines previously checked by another practitioner

- 3.2.1 It is unacceptable to prepare medicines for injection in advance of their immediate use or administer medication drawn into a syringe or container prepared by another practitioner if this practitioner is not present (NMC–Standard 14 www.nmc.org.uk).
- 3.2.2 There are some exceptions to this i.e.
 - Where medication from a central additive service has been prepared under the direction of a pharmacist and clearly labelled for that client.
 - Where the specific summary of product characteristic (SPC) or patient leaflet (PIL) indicates an infusion should be prepared in advance, e.g., some chemotherapy treatments.
 - Continuous or intermittent infusion whereby an infusion device is already in place.

In these circumstances the following criteria must exist:

- · A valid prescription;
- The container must be clearly labelled, signed and dated; accurate administration records are kept including the name of the person who initiated the infusion;

Once these checks have taken place the registered nurse/midwife who has accepted responsibility for the client's care is accountable for the administration of the medicine.

3.2.3 Where a syringe pump has been disconnected from a client e.g. washing/showering client, administration MUST NOT BE restarted. The syringe contents must be discarded and a new syringe prepared.

3.3 Second check

- 3.3.1 Single person administration is acceptable for all aspects of medicines administration (apart from the exceptions, as stipulated in 3.3.4). However, should a practitioner choose to have his/her practice checked it must be realised that full accountability for the correct administration of the medicine lies wholly with the administering practitioner. Anyone checking is individually accountable for his/her part in the process.
- 3.3.2 If second checking is required, all aspects of preparation, administration and documentation must be carried out from start to finish by both practitioners.
- 3.3.3 A second checker can be another healthcare professional e.g. registered nurse/midwife, student nurse/midwife, doctor, pharmacist, dentist, or healthcare support worker, who has undertaken appropriate training. In exceptional circumstances the second checker can be a member of the client's
- 26 Belfast Health and Social Care Trust Community Medicines Code

family or carer but the nurse must be sure that they understand their role in the checking of medication and are able to understand and perform the calculations

- 3.3.4 A second check is required in the following circumstances:
 - Supervision of a student where the student is administering the medicine.
 - A schedule 2 Controlled Drug is being administered by a nurse e.g. diamorphine, morphine sulphate
 - A complex calculation* is required.
 - * The use of calculators to determine the volume or quantity of medication should not act as a substitute for arithmetical knowledge and skill (NMC Standard 8 www.nmc.org.uk).

NPSA defines a complex calculation as 'any calculation with more than one step required for preparation and/or administration, e.g. micrograms/kg/hour, dose unit conversion such as mg to mmol or % to mg.'

3.3.5 When a second practitioner is asked to check a calculation, they must undertake the full calculation by their own method. They must not be asked to confirm the first practitioner's answer until they have performed their own calculation.

3.4 Administration of controlled drugs

Refer to Trust Community CD policy http://intranet.belfasttrust.local/policies/ Documents/Community%20Controlled%20Drugs%20Policy.pdf

3.5 Timing of administration

- 3.5.1 Community services staff should be aware of the importance of prescribing, obtaining and administering medications to clients in a timely manner.
- 3.5.2 Trust facilities should include within their operational policies the procedures to be followed for omitted/delayed medicines including refused medicines.
- 3.5.3 The nurse/midwife or other member of staff administering medicines is responsible for ensuring that prescribed medicines are administered as close to the prescribed time as possible. Where there has been a change in timing of administration consideration must be given to timing of previous/future doses and discussed with the prescriber if necessary.
- 3.5.4 A **critical** medicine, (see table below), is a medicine where timeliness of administration is crucial. Missing doses of critical medication compromises client treatment and can be potentially harmful.

| | Critical medicines | |
|---------------------|---|---|
| | Anti-infective (injectable route) Anticoagulants e.g. warfarin, enoxaparin Antiplatelets and thrombolytics (for acute indications) Anticholinesterases Anticonvulsants Antiretrovirals Bronchodilator (injectable or nebulised route) Chemotherapy (injectable route) | Clozapine Corticosteroids Opioids Oxygen Immunoglobulin Immunosuppressants Insulin Parkinson's Disease medicines Proton-pump inhibitors (injectable route) 'STAT' doses of any medicine (prescribed for immediate administration) |
| | Resuscitation medicines including pla e.g. phytomenadione, naloxone, fluma Desmopressin (treatment of cranial di | azenil, prothrombin complex |
| 3.5.5 | If any client requires medications out of unit should be contacted. A prescription dispensed by a community pharmacy. I GP Out of Hours when a pharmacy is n urgently. The GP Out Of Hours service drugs. | n will be issued for the medication to be Medication will only be supplied from the not open and the medication is required |
| 3.6 3.6.1 | Verification of client identity Staff administering medicines should us appropriate to the facility in which they | |
| 3.6.2 3.6.2.1 | Before administering a medicine: Verify the identity of the client e.g. by cl of resident or identification (ID) band/w Number. | |
| 3.6.2.2 | If possible check the client's date of bir | th. |
| 3.6.2.3 | If possible, ask the client to tell you the asking 'Are you Mrs X?' | ir name, rather than, for example, |
| 3.6.2.4 | When prescribing or administering a me | edicine, special care should be |

exercised where there are clients with the same or similar names in the facility.

28 Belfast Health and Social Care Trust Community Medicines Code

3.6.2.5 Ascertain from the medicines record/administration sheet or from the medical/nursing/client-held record, that medication has not already been given and that there are no allergies to the medication being administered.

3.7 **Process for administration of medicines**

- 3.7.1 The administration of medicines is not simply a mechanistic task performed in strict compliance with the written prescription, but requires thought and professional judgement.
- 3.7.2 Staff who administer medicines should have access to and be familiar with a range of appropriate reference sources e.g. BHSCT Community Medicines Code, the most recent British National Formulary and NMC Standards for Medicines Management www.nmc.org.uk).
- 3.7.3 It is the responsibility of the practitioner who selects and prepares a medicine dose to administer it to the correct client. The following should be considered each time a medicine is administered:

3.7.3.1 The six rights:

- Right client
- Right medicine and dose
- Right time
- Right route
- Right for the client at that time e.g. an anti-hypertensive when the client's blood pressure is low, monitoring of blood glucose prior to administering insulin.
- Right allergy status, i.e. is the allergy status documented and is the client allergic to the medicine or one of its constituents (if a combination product).

3.7.3.2 Staff must

- Consider the dosage, method of administration, route and timing of the administration in the context of the condition of the client and co-existing therapies.
- Check that the label on a medicine dispensed by a pharmacist is clearly written and unambiguous and matches the requirements of the Trust medicines record/administration sheet. For blister strips, check the name of the medication on the reverse of the blister strip matches the name of the medication on the label on the box.
- Where available check the expiry date of the medication to be administered.
- Check that the prescribed dose has not already been given e.g. by another staff member, by clients carer or taken by the client themselves. For 'when required medicines' the dose and time of the previous dose administered should be checked to ensure that any prescribed time period has lapsed before further administration.
- If a maximum dose is stated a check should be made to ensure that the total dose given, counting back 24 hours from the current time, is not exceeded.

Belfast Health and Social Care Trust Community Medicines Code 🔲 29

| | • A check must also be made to ensure there has been no duplication of prescribed drugs in any other section of the medicines record/administration sheet or MAR, e.g. paracetamol within more than one product. |
|---------|---|
| | Check if the medication requires further dilution before administration and the correct diluent to be used. |
| | Check the rate of administration, if appropriate. |
| | Record vaccine batch numbers. |
| | Record site of administration where appropriate e.g. vaccines, antipsychotic depot injections. |
| | For the oral administration of liquid medicines, a 5ml spoon must be used for doses of 5mls or multiples of 5mls. For doses less than 5mls or doses that are not complete multiples of 5ml an oral syringe must be used. Medicine pots or measure supplied by a manufacturer may be used. IV or insulin syringes should never be used to measure oral medication. |
| | Community services will almost always use a commercial pen device to administer insulin. Insulin must NEVER be withdrawn from a pen device using a syringe or any other means even if the pen device is faulty. |
| | Make a clear, accurate and immediate record of all medication administered, intentionally withheld or refused by the client, using the medicines record/ administration sheet, MAR chart or other Trust recording sheet. Ensure any written entries and the signature is clear and legible. It is also your responsibility to ensure that a record is made when delegating the task of administering medication. When supervising a student nurse in the administration of medicines, clearly countersign the signature of the student. |
| | • Document any medication that is not administered to the client for any reason with an explanation of reasons for non administration. Every occasion when a critical medicine is omitted or delayed must be escalated to the prescriber/manager/medical practitioner. Examples of critical medicines are given in 3.5.4. |
| | Contact the prescriber or another authorised prescriber without delay if any prescribing or dispensing error is highlighted. |
| | Report any errors in administration using the Trust incident reporting procedure and the contact the client's medical practitioner. |
| | • Contact the prescriber or another authorised prescriber without delay where contra-indications to the prescribed medication are discovered, where the client develops a reaction to the medication, assessment of the client indicates that the medication is no longer suitable or if the medicine is unavailable through a supply shortage. |
| 3.7.3.3 | Staff should |
| | Know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications. |
| | Be aware of the client's care plan. |
| | |

30 Belfast Health and Social Care Trust Community Medicines Code

- If the client appears to be intoxicated with alcohol or other substances, do not administer medicine until discussed with prescriber or a risk assessment has been carried out and a care plan put in place for such clients.
- To avoid missed doses, be aware if administering from a compliance aid the client might have other medication that is not suitable for a compliance aid e.g. Warfarin, liquid medicines, eye drops etc. See also section 2.8.16 compliance aids.
- Contact the prescriber or other authorised prescriber where the medicine has been withheld or refused or if the patient has vomited soon after the dose and advice is required see 3.5 Timing of administration.
- The client or carer should be made aware of the importance and implications of the prescribed treatment to enhance their understanding of the prescribed treatment and its side effects.
- Be aware of medicines whose dose depends on blood results e.g. warfarin. There should be a system in place to let the person or people who provide care know what the correct dose is. The latest information needs to be kept with the medicines record/administration sheet or MAR chart.
- Care should be taken with long acting and slow-release products which are not always equivalent e.g. diltiazem, nifedipine and theophylline. The nurse/midwife should confirm with a pharmacist whether it is appropriate to substitute products. Lithium products are not interchangeable and the client must be maintained on the same branded product. Refer to appendix 1 in the Trust 'Policy for appropriate use of generic names' – BHSCT intranet.

3.8 Administration of medicines by non-registered practitioners

- 3.8.1 A registrant is responsible for the delegation of any aspects of the administration of medicinal products and they are accountable to ensure that the client, carer or non-registered practitioner is competent to carry out the task.
- 3.8.2 Staff other than nursing, medical and registered practitioners, who are engaged in handling or administering specific medicines may only administer medicines to clients by working within their own competencies and following Trust approved training.
- 3.8.3 Non-registered practitioners must adhere to Trust and the local approved local medication policy. The tasks should be designated to them by their manager and clearly defined in the client's care plan.
- 3.8.4 The client should consent to a non-registered practitioner administering or assisting with medication. If a client is unable to communicate informed consent, the client's representative or the prescriber should indicate formally that the treatment is in the best interest of the individual.
- 3.8.5 Clear roles and responsibilities for non-registered practitioners must be identified and agreed.
- 3.8.6 Non-registered practitioners are NOT authorised to put out doses of medicines to be taken at a future time.

Belfast Health and Social Care Trust Community Medicines Code 🔳 🕴 31

| | Medication should be administered from the original container which has been |
|--|--|
| | dispensed and labelled by a pharmacist or dispensing GP. Medication can also |
| | be administered from monitored dosage systems dispensed by a community |
| | pharmacist or dispensing GP – refer to section 3.8.16. |

- 3.8.8 The non-registered practitioner must document, on each occasion, the administration or assistance with medication.
- 3.8.9 If a medicine is refused, the non-registered practitioner must record this in the client's care plan or nursing notes and inform their manager. A client must never be forced to take their medication.
- 3.8.10 Where a non-registered practitioner has observed the self-administration this must be documented in the client's care plan or nursing notes and indicate that administration of medicine was supervised only.
- 3.8.11 Non-registered practitioners must not give advice about medication. Questions must be redirected to a qualified nurse, doctor, pharmacist or line manager.
- 3.8.12 Non-registered practitioners are not responsible for clinically monitoring the effect of a client's medication. However, if in the course of their treatment, it is observed that a client is experiencing possible side effects of drugs, this should be reported to the appropriate doctor, line manager or nurse. Details should be recorded in the client's care plan or nursing notes.
- 3.8.13 Non-registered practitioners must report any signs of clients inadvertently taking additional doses or tampering with medication to the relevant health care professional or line manager. This action should be recorded.

3.8.14 Child service

- 3.8.14.1 When children are supported by a care agency, parents or guardians will normally assume responsibility for the child's medication.
- 3.8.14.2 The non-registered staff may provide 'general support' to the parent or guardian. This may occur as a result of a request from the parent or guardian but also includes situations when the non-registered staff reminds or prompts the parent or guardian to give medication to a child.
- 3.8.14.3 In the care of children with complex needs where an individual care plan has been written and signed off by a registrant and the non-registered practitioner has been assessed by a registrant as competent to undertake the specific administration of medicinal products to a specific named client this may be undertaken e.g. children with complex health needs in community settings, palliative care, clients home or special school. The young person must agree to have the medication and this consent should be documented in the service user plan. Children can give consent themselves providing they are Gillick competent or meet the 'Fraser guidelines' or the parent or guardian can consent if they are not.

3.8.15 Standards for medicines management training for non-registered practitioners working in RQIA regulated premises and services

- 3.8.15.1 Non-registered practitioners and non-registered managers of RQIA registered premises must complete training as defined in the standards outlined in Box 2.
- 32 Belfast Health and Social Care Trust Community Medicines Code

3.8.15.2 Training should be on induction and at least once every 3 years thereafter. Competency assessments should be performed at induction, and reviewed

annually or after an untoward medicines event. The frequency should be reviewed following any untoward medicines event or where a need for update training on the management of medicines has been identified during the home's medicines auditing/monitoring programme.

3.8.15.3 Box 2: Standards for training of non-registered practitioners working in RQIA regulated premises and services;

| Facility/service | Standard/legislative framework* |
|---|--|
| RQIA registered residential care home | Residential Care Homes Regs (NI) 2005 – Reg. 20(1)(a), (c)(1) Residential Care Homes minimum Standards 20.16, 23.4, 30.3 Local Operational Guidelines for the Use, Control and Administration of Medicines |
| RQIA registered nursing home | Nursing Homes Regs (NI) 2005 – Reg. 20(1)(a), (c) (1) Nursing Homes minimum Standards 25.3, 28.4, 37.3 Local Operational Guidelines for the Use, Control and Administration of Medicines |
| RQIA registered day care setting | Regulations 20(1)(a), (c)(1) of The Day care Setting Regulations (NI) 2007 Day Care Setting minimum Standards 17.15, 21.4, 29.3, 19.4 Local Operational Guidelines for the Use, Control and Administration of Medicines |
| RQIA registered children's homes | Children's Homes Regs (NI) 2005 – Reg. 24(1) Local Operational Guidelines for the Use, Control and Administration of Medicines |
| RQIA registered residential family centres | Residential Family Centres Regs (NI) 2007 – Reg. 17(1)(a) Residential Family Centre minimum Standards 12.15,15.3 Local Operational Guidelines for the Use, Control and Administration of Medicines |
| RQIA registered domiciliary care agencies | Domiciliary Care Agencies Regs (NI) 2007 – Reg. 16(1)(a), (2)(a) Domiciliary Care Agencies minimum Standards 7.7,8.17,12.4 Guidelines for the Control and Administration of Medicines, Domiciliary Care Agencies, RQIA, January 2009 Local operational Guidelines for the Use, Control and Administration of Medicines |

*The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 applies to all facilities Iservices registered with RQIA

Belfast Health and Social Care Trust Community Medicines Code

33

3.8.16 Aids to support compliance – multi-compartment compliance aids (MCA)

- 3.8.16.1 Ideally, medication should be administered from a labelled original pack of a medicine dispensed by a pharmacist or dispensing GP. Client medication is not required to be dispensed into a multi-compartment compliance aid (MCA), for a non-registered practitioner to be involved in the administration of medicines to a client.
- 3.8.16.2 Where a MCA is determined to be required for a client, the MCA used must be a sealed system, generally referred to as a multi-compartment compliance aid or monitored dosage system (MDS) and is subject to the labelling and leaflet requirements of 'dispensed medicinal products' and must be labelled in accordance with the legislative requirements.
- 3.8.16.3 The filling of MCAs is classed as dispensing and must only be undertaken by pharmacists or dispensing doctors. Trust community staff must not repackage dispensed medication into a MCA. This is considered 'secondary dispensing'.
- 3.8.16.4 Trust community staff must not administer medicines from a MCA that does not meet the standard specified in 3.8.16.2. Daily/weekly dosing organizers or pill boxes that has been filled by a client or carer must not be used.
- 3.8.16.5 MCA can only be used for tablets and capsules. Some systems are designed for liquid formulations. The following cannot be placed into a MCA without additional stability testing:
 - Medicines that are susceptible to moisture, e.g. effervescent and soluble formulations, medicines which have a desiccant within the packaging and medicines which must be kept stored in their original container
 - · Light-sensitive medicines, e.g. chlorpromazine
 - Medicines that should only be dispensed in glass bottles, e.g. glyceryl trinitrate
 - Medicines that may be harmful when handled, e.g. cytotoxic products like methotrexate.
 - Medicines prescribed on an 'as required' basis.

Refer also to section 3.8.16.8 below.

- 3.8.16.6 It is good practice to be able to positively identify each medicine so that it can be identified from those in the container space for the particular time and day. Ideally, an accurate description of each medicine should accompany an MCA.
- 3.8.16.7 It must be apparent that the compartments (be they blister packs or spaces within a container) have not been tampered with between the closure and sealing by the community pharmacist and the time of administration.
- 3.8.16.8 The NPSA recommends that warfarin is administered from the original packs dispensed for individual clients. MCA are not flexible enough to cope with frequent dose changes and are not recommended for warfarin. They recognise that some people who are cared for in their own homes may rely on compliance aids to manage their medicines. For these people, a risk assessment is essential to decide whether the warfarin should be placed in it and, if it is thought necessary, the person who fills the MCA must ensure that
- 34 Belfast Health and Social Care Trust Community Medicines Code

the tablets in the MCA match the latest prescribed dose. The service provider must have a record of the method by which dose changes will be actioned on the day they are needed e.g. how will dose change be communicated to the person/community pharmacist filling the MCA and how contents of the box will be changed before next dose.

3.9 Single use medication

3.9.1 Medication presented in single use containers i.e. not containing a preservative, must be used for single use only. Do not use single use containers for more than one client. Partially used containers must be discarded.

3.10 Administration of 'as required' medicines (PRNs)

- 3.10.1 The process for administration of medicines as outlined earlier (Section 3.7.3.2) should be followed when administering 'as required' medicines. The local medication policy should state additional actions necessary to ensure that the time and dose of an 'as required' medicine is clear.
- 3.10.2 An additional check must be made to ensure sufficient time has elapsed since the previous dose of the medicine, and that any maximum dose stated for that medicine has not been exceeded. If a variable dose is permitted the dose given must be recorded. If optional routes are permitted, the route used must be recorded. An appropriate entry must be made in the nursing/midwifery notes stating the reasons for, and the outcome of, the 'as required' administration.

3.11 Nil by mouth

- 3.11.1 Clients classified 'nil by mouth' prior to a diagnostic procedure or receiving an anaesthetic must have all their prescribed medicines administered to them in accordance with the prescriber's instructions. Any oral medicines should be taken with a small quantity of water.
- 3.11.2 It is the responsibility of the prescriber to provide clear instructions to nursing/midwifery staff concerning omission of prescribed medicines.
- 3.11.3 Clients may also be 'nil by mouth' for other reasons e.g. vomiting, unable to swallow, treatment of ileus.
- 3.11.4 All medicines should be reviewed and alternative routes and formulations considered where necessary. Special attention should be made where a critical medicine has been prescribed. It is important to clarify the instructions regarding medicine administration with the prescriber.
- 3.11.5 Refer to BHSCT Policy for the insertion and confirmation of position of a nasogastric (feeding) tube in adults, children and neonates.
- 3.11.6 Refer to BHSCT Policy for the use of oral or enteral syringes in the safer measurement and administration of liquid medicines via oral and other enteral routes.

3.12 Crushing tablets or opening capsules

- 3.12.1 Crushing tablets or opening capsules often results in the use of that medicine becoming unlicensed. Tablets should not be crushed or capsules opened unless an alternative formulation or medicine is unavailable. Those involved in the prescribing and administration of unlicensed medicines are likely to carry increased responsibility for their use. In addition, crushing tablets or opening capsules might release some of the medicine into the air and present health and safety issues for staff and clients. Consideration should be given as to whether a COSHH (Control of Substances Hazardous to Health) assessment is required for the medicine involved.
- 3.12.2 Advice should be sought from a pharmacist on the alternative options available and the clinical consequences of crushing tablets or opening capsules. Refer to the medicines information service (direct line: 028 9504 0558) when necessary.

3.13 Covert administration of medicines

- 3.13.1 Clients have the right to refuse medication and this should be respected (see 3.13.3 for clients treated under mental health legislation). However, a distinction must be made between those clients who have the capacity to refuse medication and whose refusal should be respected and those clients who lack this capacity. For clients who lack capacity a further distinction should be made between those who will accept any medication offered because they are not aware they are being given medication and those who would not take the medication if it were not disguised in some way.
- 3.13.2 Administration of medicines to a client who lacks capacity should only take place after a multi-professional assessment has concluded that such administration is in the client's best interests. The prescriber should make an appropriate entry in the client's care plan explaining the rationale for this decision. If the assessment concludes the client is unlikely to take the medication, and therefore benefit from it, unless it is disguised in some way then this must also be documented. Advice should be sought from a pharmacist, preferably from the medicines information service (direct line: 028 9504 0558) on the options available for disguising the medication, including mixing with food.
- 3.13.3 Different rules apply regarding consent to take medication for clients who are detained under mental health legislation. In these cases follow the relevant guidance on the Mental Health Order.
- 3.13.4 Further information can be found at
 - Nursing and Midwifery Council: <u>www.nmc.org.uk</u>
 - Royal College of Psychiatrists: <u>www.rcpsych.ac.uk</u>

3.14 Trust medication record/administration sheets

3.14.1 A Trust medication record/administration sheet must be used to record all medicines administered. It is not a chart for prescribing or supplying medicines. Medicines are prescribed on a prescription form – see 2.2.1 for types of HS21 form or medication kardex e.g. EMI Home.

36 Belfast Health and Social Care Trust Community Medicines Code

- 3.14.2 The Trust medicines record / administration sheet can take several formats depending on local policies e.g. MARs (medicines administration record) used in care homes may look similar to 'prescription' charts used in the hospital setting but the MAR is not equivalent to the hospital's kardex.
- 3.14.3 It is important that it is clear, accurate and up to date as it may be required to be used as evidence in clinical investigations and court cases.

3.15 Specialist medicine therapy for administration in community

- 3.15.1 Wherever possible clients should be trained to self-administer. In certain circumstances, community nurses are asked to administer medicines to clients which have been prescribed by hospital consultants/medical staff and given to the client on discharge (e.g. enoxaparin, filgrastim, and erythropoietin). Community nurses can only administer this medication on receipt of a 'Patient Specific Direction to Administer Form'. These forms are available through the Trust Intranet.
- 3.15.2 The appropriate form must be completed by medical staff before discharge. Staff arranging discharge must ensure the form and medicines accompany the client home as it is the written instruction for the community nurse to administer the prescribed medicine. Refer to section 2.9.3 and 2.17.
- 3.15.3 Where such information is not supplied or where in his/her professional opinion there is a risk of harm to the client a nurse should contact the team looking after the client in secondary care.
- 3.15.4 Local arrangements will apply for discharge of clients from hospitals outside Belfast Trust.

3.16 Administration of medicines in community facilities

- 3.16.1 Where medicines are administered in community facilities each facility must have an approved operational policy for medicines management. This includes procedures for the handling, storage and administration of medicines. Trust employees would act in accordance with the medicines management policy, approved Patient Group Directions and Patient Specific Directions.
- 3.16.2 Further guidance is available from appropriate bodies such as RQIA, Department of Education (DENI) – 'Supporting pupils with Medication needs'.

3.17 Administration of medicines in a client's home or non Trust facility

3.17.1 If a trust employee is working in a client's home or non-BHSCT facility then they must adhere to guidance in the community medicines code.

3.18 Administration of medicines by midwives

3.18.1 Registered midwives may supply and administer, on their own initiative, any of the substances that are specified in medicines legislation under midwives exemptions, provided it is in the course of their professional midwifery practice. They may do so without the need for a prescription or patient-specific written direction from a medical practitioner.

3.18.2 Provided the requirements of any conditions attached to those exemptions are met, a patient-group direction (PGD) is not required. If a medicine is not included in the midwives exemptions, a prescription or PGD will be required.

On 1st July 2011, amending legislation came into force enabling student midwives to administer medicines on the midwives exemptions list, **except controlled drugs**, under the direct supervision of a registered midwife.

Student midwives may not administer controlled drugs but may participate in the checking and preparation of controlled drugs for administration on the midwives exemption list under the direct supervision of a registered midwife.

3.18.3 Midwives will record the administration of a medicine in the appropriate administration record. The administration record must be endorsed 'midwives exemption'.

3.19 Self administration of medicines in a community setting (excluding client's own home)

- 3.19.1 Whenever possible adults and children should take responsibility for their own medicine. This preserves independence regardless of the social care environment.
- 3.19.2 Clients should be encouraged to maintain control of their medicines in non residential settings e.g. day care facilities. This includes responsibility for holding their own medicines and taking them at the appropriate time. Some clients may be able to take their medication at the appropriate time, however, the facility may be required to store their medication. Staff will only undertake administration where it is deemed essential. Operational procedures must be in place to manage client's own medication where it has been deemed that facility staff will be responsible for the client's medication.
- 3.19.3 Clients may self-administer their own medicines in residential facilities following the agreement of the multidisciplinary team, including the client's GP. The multi-disciplinary team and the appointed practitioner in charge must be satisfied that the client has sufficient understanding and ability to self-medicate safely and efficiently.
- 3.19.4 The multidisciplinary team must decide whether the self administration is fully independent or is to be supervised. Self administration must only take place in accordance with an agreed, documented and properly structured multi-stage medicine training and assessment scheme.
- 3.19.5 Clients may self administer certain medications for example creams, ointments and inhalers following the completion of a satisfactory risk assessment. This risk assessment must be agreed with medical staff and documented in the notes.
- 3.19.6 All medicines for self-administration must be kept in an individual client's medicine cabinet (this can be a lock fitted to a drawer), the medicine trolley or other secure storage. If the room is shared, there must be separate storage facilities for each person.

- 3.19.7 Following a risk assessment, if it is felt appropriate, the client may be given custody of a key and a duplicate (or master) will be kept by the designated practitioner. In some circumstances the designated practitioner will retain custody of the keys to a client's individual medicine cabinet.
- 3.19.8 Clients should only self-medicate from fully labelled, named client supplies which have been obtained from the supplying pharmacy specifically for the purpose.
- 3.19.9 When the client is self-administering his or her own medicines, a record must be made of this in the medicines record/administration sheet.
- 3.19.10 The designated practitioner responsible for the care of the client must regularly monitor that the self-administration process is being conducted correctly. If the client is unable to take the medicines as prescribed the self-administration process must be discontinued, although it may be later reintroduced following further training and assessment.
- 3.19.11 Doses administered in addition to or instead of the self-administration must be recorded in the normal way.
- 3.19.12 Where medicines are stored in individual medicines cupboards, it is the responsibility of the assigned practitioner in charge to ensure that such medicines are transferred with the client if they are moved or transferred, and to ensure that client's keys are retained for re-use.
- 3.19.13 It is also the responsibility of the assigned practitioner in charge to ensure that a client's individual medicines cupboard is completely empty following their discharge and prior to re-use by another client.

Belfast Health and Social Care Trust Community Medicines Code 🔳 🕴 39

4 Ordering, supply and receipt of pharmaceuticals

4.1 General

There are a number of service users based in the community examples of which are given below:

4.1.1 Trust based community clinics e.g.

| Podiatry | • Dental |
|--|---|
| Gynae Services | Addictions services |
| Substitute Prescribing | • Glaucoma Clinic |
| Sexual and Reproductive Health | Contact Lens Clinic |
| Tissue Viability Clinic | |

- 4.1.1.1 Clinics may be held in Trust owned premises e.g. Health and Wellbeing centres, Health Centres or non Trust premises e.g. GP premises. Trust medicines stock should not be stored on non Trust premises unless by prior agreement.
- 4.1.1.2 The appointed practitioner in charge for each discipline shall have responsibility for ensuring that there are systems in operation for the ordering, storage and supply of medicines and that these systems are followed.
- 4.1.1.3 Ordering of stock medication for community clinics is from a designated Trust pharmacy department or Victoria Pharmaceuticals (regional specialist manufacturing service for Northern Ireland).

4.1.2 Trust community teams e.g.

- Community children's nursing
- Integrated care teams (ICT)
- · Home care team
- Intensive treatment teams
- 24 hour nursing team

4.1.3 Trust treatment rooms

Treatment rooms, staffed either by Trust or non-Trust nursing staff, obtain their supplies of medicines and adult vaccines from community pharmacies, via the stock prescription system.

4.1.4 Trust residential/nursing nomes and day care centres

Clients in the Trust residential/nursing homes and day care centres obtain all their medicines via prescriptions from their General Practitioners. The local medication policy will detail the process for ordering, receipt and stock control of medicines.

4.1.5 Trust GP Out of Hours centres

- 4.1.5.1 The Trust GP Out of Hours centres obtain patient packs of medicines, with an over-label detailing the dosage instructions and relevant warnings, and patient information leaflet, via a designated Trust pharmacy department or Victoria
- 40 Belfast Health and Social Care Trust Community Medicines Code

Pharmaceuticals (regional specialist manufacturing service for Northern Ireland).

4.1.5.2 Schedule 2 controlled drugs are not included in the formulary of drugs held by Out of Hours Services. All doctors working for the Out of Hours Services requisition a supply of these drugs through their practice using a HS21S.

For doctors not attached to a practice, who do not have access to HS21S, protocols exist whereby they can have access to stock prescriptions supervised by the medical managers of the services.

4.1.5.3 A number of community pharmacies will hold an agreed stock of medicines for palliative care. A list of the members of the Community Pharmacy Palliative Care Network can be accessed via the GP OOH centres, community specialist palliative care nurses and GPs.

4.2 Ordering of medicines other than controlled drugs

4.2.1 Ordering, from a designated Trust pharmacy department, will be either by use of an agreed stock list or by a Trust pharmacy requisition book. Orders are normally delivered to pharmacy in the locked pharmacy box belonging to the clinic or posted directly to pharmacy. Facilities, which order on an occasional basis, may place an order on signed Trust headed paper. Orders are normally posted to the pharmacy. Faxed orders may be processed but not released until the original order has been received. Only in exceptional circumstances will a faxed order be released without the original.

4.3 Using the Trust requisition book

- 4.3.1 The nurse/midwife in charge of a department/facility, senior professional or manager may delegate writing of a pharmacy order in the requisition book, following the instructions at the front of the book, to another nurse/midwife or appropriate person, but the finished order should be signed by the nurse/midwife in charge, senior professional e.g. AHP or manager in charge of the unit/facility.
- 4.3.2 Only one requisition book will be issued at any one time. Each book is uniquely numbered for traceability. Pharmacy will issue a new book only when they receive the last order in the old book which should include an order for a replacement book. A department/facility should ensure that any remaining pages in the book are cancelled.
- 4.3.3 Stationery used to order medicines such as top-up lists and pharmacy requisition books must be stored securely when not in use.
- 4.3.4 The manager in charge must report the loss or theft of the requisition book immediately to the Pharmacy department who supplied the requisition book and complete an incident form. The department/facility will not be issued with a new book unless Pharmacy receives a copy of the incident form or are notified of the incident form reference number. In the event of a missing requisition book, the department/facility will still have access to medicines using a requisition book in Pharmacy or by ordering required items on Trust headed notepaper.

4.3.5 Before ordering:

- 4.3.5.1 Check the departmental/facility stock holding list.
- 4.3.5.2 Previous orders should be checked as the item may have already been ordered.
- 4.3.5.3 When a bank or public holiday falls on the designated day of delivery, the facility should place a double order the week before.

4.3.6 Completion of requisition

- 4.3.6.1 Orders must include the following details:
 - Date
 - Name of department/facility
 - Department/facility contact telephone number
 - Printed name, signature and designation of nurse/midwife in charge or senior professional or facility manager.
 - Name of medicine required, printed and in accordance with Trust 'Policy for appropriate use of the generic names of medicines' including pharmaceutical form e.g. tablets, liquid etc.
 - Strength of medicine.
 - Quantity of medicine required.
- 4.3.6.2 When ordering an unlicensed medicine include the clients name, hospital number and name of the prescriber except if the unlicensed medicine is for use on a number of clients e.g. acetic acid 3% solution.
- 4.3.6.3 Print legibly and complete all sections to ensure a suitable quantity of the correct medicine is dispensed.
- 4.3.6.4 All remaining lines on the requisition should be cancelled by a single diagonal line. This prevents the addition of items to the requisition after it has been signed by the nurse/midwife in charge, senior professional or facility manager.
- 4.3.6.5 Do not write in the 'Pharmacy use only' section.
- 4.3.6.6 Orders should be sent to the nominated Trust pharmacy on the agreed day. The top two copies of the requisition should be sent to Pharmacy and the requisition book retained in the department.
- 4.3.6.7 Urgent orders that arise outside of this time may be faxed only upon agreement of the pharmacy involved see 4.2.1.
- 4.3.6.8 Pharmacy may query any request for medicines if they are medicines liable to diversion/abuse.
- 4.3.6.9 Collection of orders by staff, from the nominated Trust pharmacy, will only be allowed in exceptional circumstances and only upon agreement of the pharmacy involved. The department/facility messenger/member of staff from facility must present photographic Trust ID.

4.4 Using pre-printed top up sheets

- 4.4.1 Departmental managers will have agreed, where appropriate, a suitable list of stock medicines with the Trust pharmacy department to cover the majority of medicines required by that facility.
- 4.4.2 The Pharmacy department will prepare a 'stock holding list/top-up list' which is the department/facility agreed stock holding. This stock holding list should be available in the department/facility. The list runs for 13 weeks. Where amendments to stock holdings are required, contact the pharmacy department via email or Trust headed notepaper.
- 4.4.3 This list is used to order replacement stock. Currently for community clinics this is weekly, where orders are sent to the designated Trust pharmacy, on a designated day and returned on a designated day by means of Trust transport.
- 4.4.4 The nurse/midwife in charge of a department/facility or senior professional may delegate the preparation of the top-up order, to another nurse/midwife or appropriate person, but the finished order should be signed by the nurse/midwife in charge or senior health care professional in charge of the unit/facility.
- 4.4.5 Pharmacy will produce a picking list of the medicines required for that top-up; a copy of the picking list acts as a delivery docket as confirmation that all the items have been received. The picking list also details stock items not currently available. Facilities should spot-check that their top-up stock agrees with the picking list/delivery docket on the day of the top-up.
- 4.4.6 Picking lists must be stored in a designated location at facility level and must be retained for at least one week as a reference to resolve any queries that may arise.

4.5 When the medicine has been supplied:

- 4.5.1 It is the facilities responsibility to have a member of staff available to receive delivery of medicines. Boxes and tamper evident containers must not be left unattended or accessible to clients and visitors and unauthorised staff.
- 4.5.2 Staff unpacking orders, as soon as possible after receipt, must ensure that the delivery has not been tampered. The nurse/midwife or senior professional or facility manager receiving the order must check each item against the order copy and sign the picking list/delivery copy of the requisition.

Any discrepancies must be reported immediately to the supplying Pharmacy Department. Unresolved issues should be documented on an incident form.

4.5.3 The pink copy of an order placed using the Trust requisition book will be returned with the ordered items. Pharmacy will communicate shortages or queries on the comments section of the requisition. The person checking the returned order against the delivery copy of the requisition must read the comments section and take the appropriate action e.g. highlight shortage with the prescriber. This delivery copy of the requisition should be signed and filed so that it is accessible to all and retained at facility level for at least one week.

- 4.5.4 It is the responsibility of the nurse/midwife or senior professional or facility manager to ensure that the medicines received are stored appropriately.
- 4.5.5 Staff in receipt of drugs requiring refrigeration must ensure that cold chain requirements have been complied with during delivery and will ensure that medicines are placed immediately in the fridge.
- 4.5.6 Empty Trust transit containers must be returned to the delivery driver on the appropriate day for return to pharmacy.

4.6 Expiry dates of medicines

- 4.6.1 The nurse/midwife in charge or senior professional in charge is responsible for checking the expiry dates of medicines held in the unit/facility.
- 4.6.2 Liquid medicines should be endorsed with the date of opening and discarded after 6 months unless stated otherwise on the medicine bottle.
- 4.6.3 It is good practice to check the expiry date of medicines when the medicine is removed from or returned to the medicine cupboard.
- 4.6.4 Registered staff are responsible for checking expiry dates of any medicines held in their possession e.g. anaphylaxis shock kit.

4.7 Supply of medicines to community midwives for a home birth

Refer to Trust Policies. e.g.

- Guideline for management of Home Birth
- Thromboprophylaxis during pregnancy, labour and birth http://intranet.belfasttrust.local/policies/Documents/Thromboprophylaxis%20 during%20pregnancy,labour%20and%20delivery.pdf
- · Diamorphine Intramuscular and subcutaneous analgesia in labour

4.8 Ordering of non-formulary dressings

- 4.8.1 NI operates a joint wound care formulary for primary and secondary care, which is accessible from the NI Formulary website. Non-formulary dressings are only allowed in exceptional circumstances.
- 4.8.2 Requests must be made by completing the Trust 'Request for Non-Formulary Wound Products form', which must be signed by an authorised signatory. (Appendix 2) Alternative/Exception Protocol Dressings, for clients in the community, are supplied through Knockbracken Pharmacy Department. An electronic version can be found at http://intranet.belfasttrust.local/directorates/ nue/Documents/Request%20Form%20for%20Non-Formulary%20Wound%20 Products.pdf

4.9 Ordering of child health vaccines

See chapter 9 – refrigerated medicines (including vaccines)

4.10 Ordering of medical gas cylinders

See chapter 10 – medical gases

44 Belfast Health and Social Care Trust Community Medicines Code

4.11 Ordering of clozapine

- 4.11.1 Most clients in the community will receive all their medicines from their GP and will store them in their own home. However, clozapine is a red list drug, which can only be supplied by Trust pharmacy departments in Northern Ireland. For client convenience this can be delivered to a community team base.
- 4.11.2 Clozapine is ordered from the appropriate Trust hospital pharmacy by completion of the Trust community clozapine prescription. This prescription is valid up to six months. (Appendix 3)
- 4.11.3 Clozapine awaiting collection must be held in a locked cupboard accessible only to authorised staff.
- 4.11.4 The nurse for each client should decide whether the client requires counselling on clozapine. If so the nurse should arrange to personally hand over the medicines and provide the necessary advice. A named non-registered practitioner may also undertake this task.
- 4.11.5 Non-registered practitioners should be given a list of people who may be given their clozapine in this manner and a record must be kept for each time a client collects their medicines. The role of the non-registered practitioner is to give the correct bag of medicine to the correct person. They must not provide advice on the drug and all such requests must be passed on immediately to the nurse. Staff who take on this role must be fully briefed and authorised by the Community Mental Health Team (CMHT) manager.
- 4.11.6 A designated person(s) must ensure clozapine is collected for/by each client and alert the appropriate team if this does not occur.
- 4.11.7 If an error occurs the Health and Social care assistant must inform the CPN or manager.

4.12 Control of Substances Hazardous to Health (COSHH)

- 4.12.1 COSHH is the law that requires employers to control substances that are hazardous to health (COSHH).
- 4.12.2 Hazardous substances must be transported to and from Pharmacy using designated COSHH containers.
- 4.12.3 Many pharmaceutical products used within clinical areas in the Trust come under COSHH regulations.
- 4.12.4 Pharmaceutical information is provided in:
 - Trust Policy for Control of Substances Hazardous to Health (COSHH) Belfast Health and Social Care Trust Policy and Procedural Arrangements
 - The COSHH Pharmaceutical Guidance booklet January 2010 http://intranet.belfasttrust.local/policies/Documents/Pharmaceutical%20 Guidance%20on%20COSHH.pdf
 - · Pharmacy COSHH Frequently Asked Questions and Answers July 2010

Belfast Health and Social Care Trust Community Medicines Code 🔳 🕴 45

- 4.12.5 COSHH assessor workshops are within the Corporate Health & Safety Training Portfolio and can be booked via TAS.
- 4.12.6 Further information is available at http://www.hse.gov.uk/coshh/ and http:// www.hse.gov.uk/pubns/indg136.pdf

4.13 Transfer of medicines between containers

4.13.1 The transfer of any medicine from one container to another, other than by pharmacy staff, is strictly forbidden.

4.14 Returns to Pharmacy and recycling

4.14.1 If a medicine is no longer needed, full packs should be returned to the supplying Pharmacy department i.e. supplying hospital or community pharmacy. Returns to a supplying hospital pharmacy should be placed in the pharmacy box and marked as 'Pharmacy return'. Open/partially used packs should be disposed of in accordance with BHSCT waste policy.

4.15 Pharmaceutical samples

- 4.15.1 A sample is defined as a small quantity of a medicinal product provided to a healthcare professional so that he/she may acquire experience in using it. A sample of a medicinal product may only be provided to a healthcare professional permitted to prescribe/supply that particular medicine/dressing/enteral feed.
- 4.15.2 To ensure compliance with Product Liability Legislation, Medicines Act Regulations, DHSSPS Guidelines and the ABPI code, samples of medicines must not be left in clinical or administration areas. All samples must be receipted and issued only from the relevant site Pharmacy Department.
- 4.15.3 All samples must be licensed and have a UK marketing authorisation as appropriate.
- 4.15.4 The relevant section of the Trust policy 'Interfacing with the Pharmaceutical Industry' must be followed including the arrangements for recording, issuing and tracking of samples of medicines. This policy can be found on Trust HUB.

5 Client's own medicines

5.1 General

- 5.1.1 Medications in the client's home are the property of the patient.
- 5.1.2 The Acute Care at Home service should manage medication supplied to manage the episode of care. Local operational procedures must be in place.
- 5.1.3 Where clients are required to bring medication to a community clinic for administration e.g. depot medication clinic run by community psychiatric nurse, they should be encouraged to store their medications in their own homes.
- 5.1.4 The following sections refer to the the management of client's own medication when brought into a Trust facility.
- 5.1.4.1 Local operational procedures must be in place to manage client's own medication in Trust facilities.
- 5.1.4.2 Prior to admission, the facilty manager will request written confirmation of a client's current medicines.
- 5.1.4.3 All medicines brought into a facility by clients remain their own property and normally will not be destroyed or otherwise disposed of without their agreement or, if this is not possible, the client's carers' agreement.
- 5.1.4.4 Medicines may be returned home via an identified adult. Responsibility for security is given to that adult. The client and/or client's carer should be advised if the medicines are not safe and/or appropriate use.
- 5.1.4.5 If it is deemed inappropriate to return a client's medicines to them, this should be recorded in the client's notes and the medicines (other than CDs) may be destroyed according to local procedures.
- 5.1.4.6 Where facilities store client's medication there must be a means to segregate each client's medication e.g. by use of a green Client's Own Drugs bag. Where it is deemed to be in the client's best interest to keep these medicines at the facility they should be clearly labelled and locked, in a separate cupboard or an area of the cupboard separated from facility stocks. This is to avoid the inadvertent administration of one client's property to another client.
- 5.1.4.7 A record should be kept of client's own medicines received and held in stock and when they are administered or supplied. A record should be held of any medicines returned to the client, carer or community pharmacy.
- 5.1.4.8 Trust facilities should record the date of opening on all medicine containers to facilitate the stock reconciliation and audit process.
- 5.1.4.9 Prior to discharge, any medicines stored, by the facility for the client should be reviewed to ensure they are safe for the client to continue taking after discharge. In particular, the client's and/or client's carer attention should be drawn to changes in the dose of prescribed medicines, discontinuation of medicines or the commencement of new medicines. The client and/or carer must give permission for the destruction of medicines that are no longer prescribed.

Belfast Health and Social Care Trust Community Medicines Code 🔲 🕴 47

5.2 Use of client's own medicines

5.2.1 Medicines brought into a Trust facility by a client, client's carer or Northern Ireland Ambulance Service should only be used i.e. administered when they can be positively identified, meet defined quality criteria and are appropriately labelled. They should be approved for use by appropriately trained staff.

5.2.2 The medicine must be clearly labelled with: -

- The name of the client.
- The name and strength of the medication.
- The prescribed dose, frequency of administration and method where appropriate.
- The date dispensed do not use if dispensed more than 6 months ago or the expiry date has passed.
- The name and address of the supplying pharmacy or hospital.
- In addition;
- Medicines such as glyceryl trinitrate and eye drops that have a short shelf life once opened must not be used unless the date that the medicine container was opened is clear and within the accepted expiry date.
- There must be confirmation that the medicines have been stored appropriately, e.g. items that require refrigeration such as insulin have been stored in a refrigerator.
- The overall appearance of the bottle, label and medicine must be acceptable, e.g. the container must be intact and clean. The medicine must be clean, whole and without visible sign of deterioration.
- The medicine in the container must be all of the same type. If the appearance of the medicine is not uniform it must not be used.
- · If the medicine has no dispensing label, it must not be used.
- Controlled drugs must be stored and recorded according to the controlled drug regulations. Refer to Community Controlled Drug policy if clients medicines include controlled drugs.
- 5.2.3 Medicines that cannot be clearly identified or are unfit for use must be placed in a sealed bag and stored in a locked medicines cupboard until either returned to the client/client's carer or destroyed in accordance with local procedures.

5.3 Residential facility

- 5.3.1 Medicines brought into a residential facility by clients must be recorded as per local operational policy, and then reviewed by the doctor who will decide which medications are to continue. Controlled drugs must be stored and recorded in accordance with controlled drug legislation.
- 5.3.2 Non-prescribed medication
- 5.3.2.1 Staff must consult at all times with the GP in relation to non-prescribed medicines, as there can be a risk of interactions between prescribed medicines and medicines bought over the counter. This includes the purchase of supplements such as iron or vitamins and complementary medicines.

- 5.3.2.2 No over the counter medicines should be given by staff unless the GP has given written instruction to do so. They must be documented on the client's medicines record/administration sheet or MAR.
- 5.3.3 Short break and respite services

It must be

- Confirmed with the client's General Practitioner prior to admission the medicines prescribed for the client.
- Confirmed with the carers prior to admission that the necessary medicines to span the period of respite care will be provided. The medicines must be supplied in the original containers, supplied and labelled by the pharmacist.
- If all attempts to receive a supply from the carer fail or the supply of medicines are thought to be unsuitable to use, arrangements must be made to receive further supplies from the GP and/or community pharmacy. Alternatively (and temporarily) facility stock may be used.

5.4 Illicit substances

- 5.4.1 Refer to BHSCT Hospital Medicines Code for guidance.
- 5.4.2 Under the Misuse of Drugs Act 1971, those in charge of premises have a responsibility to inform the police if they believe that anyone is committing an offence (in particular dealing of drugs on the premises).
- 5.4.3 Managers are liable to criminal prosecution if they allow such activity to take place on their premises.
- 5.4.4 Clients and visitors must be informed that the Trust will not tolerate any use of illicit substances in Trust premises.
- 5.4.5 If visitors are seen to be in possession of a suspected illicit substance they must be asked to leave the Trust premises and may return only when they no longer have any illicit substances with them. The police must be informed.
- 5.4.6 If visitors are suspected of passing illicit substances to a client or other visitors the appointed practitioner in charge of the team must discuss the matter with the clinical service manager, and consider banning the visitor from the Trust premises and informing the police.
- 5.4.7 If a member of staff considers that a client may have, or be using, an illicit substance they should seek advice from a senior member of staff before approaching the client.
- 5.4.8 Where a client is suspected of being in possession of an illicit substance staff must discuss the situation with the client. The client must be asked to voluntarily give up the substance in question for the purposes of destruction. When confiscating an illicit (or suspected illicit) substance, staff must always have their actions witnessed by a colleague, must record their actions in the client's notes and complete a BHSCT incident reporting form in line with Trust policy. If the client refuses to hand over the suspected illicit substance, the person in charge should consider involving the police.

- 5.4.9 A search of a client or their belongings may only be conducted if the unit has a written search policy. Where the unit does not have a search policy, a search of the client should not take place and consideration should be given to involving the police.
- 5.4.10 Confiscated illicit substances must be handled and stored in a similar manner to controlled drugs and a clear audit trail must be in place. Under no circumstances should suspected illicit substances be returned to the client.
- 5.4.11 The PSNI must to be asked to collect the illicit substances. Staff should co-operate with any police investigation. When the police attend to remove the substance, then the officer collecting the substance should complete the appropriate part of the form for removal of unauthorised drugs or other suspicious substances. The officer should countersign the unit register of illicit substances to verify the removal. A copy of the completed form should be filed in the client's notes.
- 5.4.12 Domiciliary care providers should devise policies and procedures in relation to clients using illicit drugs. This may include a requirement for care workers to vacate the premises if a client is smoking, consuming or injecting illegal substances. Legal advice should be sought in situations where care workers may be at risk of aiding and abetting a client to perform an illegal act.

5.5 Overdose medicines

5.5.1 Where an overdose occurs any remaining medicines should be quarantined and kept in a secure place. If the client is moved to an acute setting the medicines must be transferred with the client.

6 Storage and security of medicines

6.1 General principles

- 6.1.1 The appointed nurse/midwife or senior non medical professional manager in charge of a department, clinic or facility is responsible at all times for the safe custody of all medicines in the department, clinic or facility.
- 6.1.2 When medicines are issued to staff for use in the community, the storage and security of these medicines becomes the responsibility of the person to whom they are issued.
- 6.1.3 All healthcare practitioners are individually responsible for ensuring medicinal products are stored in accordance with the patient information leaflet and/or summary of product characteristics and in accordance with instructions on the label. The patient information leaflet and/or summary of product characteristics document for UK licensed medicinal products may be found at www.emc. medicines.org.uk.The electronic medicines compendium may also be accessed via BHSCT intranet.
- 6.1.4 The Designated Community Practitioner must keep the medicine:
 - Secure when visiting a client.
 - Secure and out of sight, e.g. within the locked boot of a car, when travelling between visits.

In the event of a loss or theft of medication whilst away from base the line manager must be informed immediately. Police must also be informed of the loss or theft. An incident form must also be completed.

- 6.1.5 Where premises are shared with a number of teams/clinics, each team/clinic must be responsible for their own stock of medicines. The appointed practitioner in charge is ultimately accountable for the storage and security of stock of all medicines held for that discipline.
- 6.1.6 Community teams that supply medicines from base stocks should keep a record and audit trail of all medicines held on base and regular stock checks and running totals should occur.
- 6.1.7 If medicines are stored in readiness for domiciliary visiting, there must be clear procedures for access to these, and for their replacement if used during the visit.
- 6.1.8 Medicines no longer required by community teams should be returned to the pharmacy of origin for destruction.

6.2 Medicine storage units

- 6.2.1 Clinical areas may have some or all of the following medicine storage units depending on the range of pharmaceuticals in stock, which must be kept locked at all times when not in use.
- 6.2.2 There should be lockable cupboards as follows:
 - CD cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973
 - Internal Medicine Cupboard(s)

Belfast Health and Social Care Trust Community Medicines Code 🔲 🕴 51

- External Medicines Cupboard(s)
- Pharmaceutical refrigerator/freezer for medicines
- 6.2.3 The CD cabinet, medicines cupboards and pharmaceutical refrigerator/freezer must be kept locked at all times.
- 6.2.4 Separate storage should be provided as follows:
- 6.2.4.1 Cupboard for diagnostic agents, including urine testing
- 6.2.4.2 Area for intravenous fluids and sterile topical fluids. Intravenous fluids should be stored in the original box/container where possible. Local Anaesthetic Injections should be stored separately from IVs.
- 6.2.4.3 Area(s) separate for flammable fluids and gases
- 6.2.5 Medicine cupboards to be used for internal and external medicines should comply with the current British Standards (BS 2881 (1989) NHS Estates Building Note No 29.
- 6.2.6 Locks for metal cupboards must comply with BS 3621. Locking mechanisms other than keys may be used, except for CD cupboards, provided they comply with BS 3621, where appropriate. Where keypads or swipe cards are used to open medicines cupboards, systems should be in place to ensure codes are regularly changed or swipe cards updated. Doors should lock automatically on closing.
- 6.2.7 Medicine cupboards must not be used to store anything other than medicines i.e. as a safe for keys, money or other valuables or to store food. The only reason to open the medicine cupboard should be to access medicines.
- 6.2.8 Medicines must be stored in a medicine cupboard or a medicine trolley dependent on the facility. Where the term 'cupboard' is used, the word drawer may be substituted provided that the storage space is adequate, compliant with British Standards as above and is not used to store controlled drugs.

6.2.9 Siting of cupboards and trolleys

- 6.2.9.1 Cupboards/trolley must be sited where most convenient for staff and to afford maximum security against unauthorised access.
- 6.2.9.2 The location of medicines cupboards should be based on the following recommendations:-
 - In a room without direct access (i.e. door or window) to the exterior of the building
 - Where it is not obvious to 'prying eyes' i.e. not in front of a window
 - · Adjacent to storage units of similar appearance
 - In a room that can be secured when unattended and to which the general public does not have access.
 - Away from sources of heat and humidity e.g. radiators, windowsills and sinks.
- 52 Belfast Health and Social Care Trust Community Medicines Code

- 6.2.9.3 The medicine trolley must be secured to the wall in a specified location when not in use. When in use, it must not be left unattended, but if this is unavoidable, the trolley must be left locked.
- 6.2.9.4 Where designated trolleys are in use which are specific to a monitored dosage system these must be kept secure to prevent unauthorised access.
- 6.2.9.5 Where schemes for PODs or self-administration are in operation each client involved in the scheme should have a lockable receptacle for medicines e.g. drawer, individual cupboard. This can be a lock fitted to a drawer and does not need to be made of metal or even look like a medicine cupboard. If the room is shared, there must be separate storage facilities for each person.
- 6.2.9.6 The only exceptions to this requirement, that medicines are not in locked storage, are medicines for clinical emergencies. These must be held in a tamper evident box and must not be in a locked cupboard, but at a strategic and accessible site. Once opened the box must be returned to the appropriate pharmacy for replacement.

6.3 Containers

- 6.3.1 All medicines other than medicines dispensed in a monitored dosage system must be stored in their original containers.
- 6.3.2 Under no circumstances may medicines be transferred from one container to another, nor may they be taken out of their container and left loose.
- 6.3.3 Injection ampoules and vials must be stored in the outer packaging in which they are supplied. It is good practice only to remove ampoules from their outer packaging at the time they are required. Ampoules/vials must not be returned to the original pack.

6.4 Custody and loss of medicine keys

- 6.4.1 Only appointed or authorised staff may access the medicines stock storage areas. Those authorised staff in the community teams will require access to the medicines cupboards at different times of day. A key holding policy must be in place. The responsibility for controlling access (by keys or other means) to medicine storage remains with the appointed practitioner in charge even if he/she decides to delegate the duty to someone else. Where locked boxes have been allocated as a means to transport medicines from a Trust pharmacy, the key should be retained with the medicines keys.
- 6.4.2 Keys for controlled drug cupboards must be separate from the keys to the medicine cupboard/trolley.
- 6.4.3 All medicine cupboards (including refrigerators) must be kept locked at all times when not in use.
- 6.4.4 On discovering the loss of keys the member of staff must inform the designated manager immediately and complete an incident report.
- 6.4.5 The designated manager will investigate any loss immediately (including consideration of notifying the police) and follow the incident reporting procedure.

Belfast Health and Social Care Trust Community Medicines Code 🔳 🕴 53

- 6.4.6 If necessary a duplicate set of keys (as per local key holding policy) may be issued to allow continued provision of clinical services, until such time as the original keys are located.
- 6.4.7 If the lost keys are not found the appointed practitioner in charge, should arrange for new locks to be fitted and for the cupboard to be secured effectively.
- 6.4.8 Maintenance staff should not be allowed to work on the cupboard unsupervised.

6.5 Security and storage of stationery used to order medicines

- 6.5.1 Stationery used to order medicines such as top-up lists, non-stock pharmacy requisitions and prescriptions must be stored securely when not in use.
- 6.5.2 Only one top-up file or requisition book is used by a facility/department at any one time. The requisition book is uniquely numbered and Pharmacy will only issue a new book on an order and receipt of the last page in the current requisition book. Two top-up files or requisition books may be held with agreement of Pharmacy to facilitate weekly ordering and delivery by transport.
- 6.5.3 The facility/department must report the loss or theft of any of controlled stationery immediately to Pharmacy and complete an incident form. The facility/department will not be issued with a new book unless Pharmacy receives a copy of the incident form. In the event of a missing requisition book, the facility/department will still have access to medicines using a requisition book in Pharmacy.

6.6 Loss of medicines or unauthorised access

6.6.1 An incident form must be completed when there has been unauthorised access, theft of a medicine, abuse or an unexplained increase in usage of medicines especially that are liable to diversion. If theft is suspected, security, personnel and police will be involved.

For suspected loss/theft of Controlled Drugs refer to BHSCT 'Dealing with discrepancies or concerns involving Controlled Drugs' on BHSCT HUB.

- 6.6.2 When there has been unauthorised access to, or unexplained high usage of medicines, or theft of a facility's medicines stock, this must be reported immediately to the manager/nurse/midwife in charge and the Pharmacy Services manager who will conduct an initial investigation and subsequently inform their line managers. 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, regular unexplained absences from the work area, and loss of stock or excessive ordering.
- 6.6.3 Alternatively, the Pharmacy may ask the manager/nurse/midwife in charge to explain any increase in usage of medicines especially those medicines liable to diversion. It then becomes the responsibility of the Directorate and the Pharmacy Department to investigate the matter enlisting the support of other disciplines and liaising with the police as appropriate. It is the responsibility of the Pharmacy Services manager to contact the police.
- 54 Belfast Health and Social Care Trust Community Medicines Code

6.6.4 Particular care must be taken to ensure that medicines which are liable to diversion or abuse e.g. benzodiazepines, analgesics, steroids, antibiotics, are always stored correctly in order to prevent unauthorised access.

6.7 Pharmaceutical refrigerators

6.7.1 Responsibilities

- 6.7.1.1 Each clinical setting where vaccines and heat sensitive pharmaceutical products are stored must have one trained and designated individual (this may include administrative staff) and one deputy to be responsible and accountable for:
 - Receipt and storage of vaccines/heat sensitive pharmaceutical products
 - · Monitoring and recording of fridge temperatures
 - Audit and evaluation of training needs for staff using or involved in use of these products

The designated person and/or their deputy should be easily identifiable by recording the name on fridge monitoring records.

- 6.7.1.2 The designated person or deputy (in their absence) is responsible for the following:
 - Checking the order and contents of a delivery of vaccines/products for expiry, damage, leakage and correct transportation (i.e. evidence that the cold chain has been maintained).
 - · Signing delivery sheet to acknowledge correct safe receipt.
 - Immediate storage of products in the designated storage refrigerator.
 - Completing the vaccine/product log.
 - Ensure overstocking does not take place.
 - Exercising stock rotation to prevent wastage from out of date vaccines and products.
 - · Removal and safe disposal of expired or damaged stock.
 - Maintaining accurate and legible records of cold chain monitoring for audit purposes.
 - Ensuring **immediate action** is taken if the fridge thermometer reading is or has been outside the recommended range (between 2°C and 8°C).
- 6.7.2. All facilities or departments that use medicines requiring refrigeration must have a suitable refrigerator. Refer to section 8.22 BHSCT Hospital Medicines Code March 2017 for the specification for a pharmaceutical refrigerator in facilities and departments.
- 6.7.2.1 The refrigerator must be kept locked or in a locked room (with no public access) when not occupied by a member of staff, as all prescription only medicines (POMs) must be stored under locked conditions.
- 6.7.2.2 The refrigerator must be sited away from external windows and all heat sources e.g. radiators, direct sunlight.

6.7.3 Purpose, installation, operation and maintenance

- 6.7.3.1 Domestic refrigerators are not suitable for the purpose of storing temperature controlled pharmaceuticals.
- 6.7.3.2 The refrigerator must be of sufficient size, for the quantity of stock to be stored (not more than 50% full) to permit air circulation between stored pharmaceuticals and internal surfaces. Stored pharmaceuticals must not be placed on the floor of the refrigerator or come into contact with the chiller plate, coil or motor. Storage adjacent to freezer packs should also be avoided. An overfilled fridge can also create potential for freezing and lead to poor stock rotation.
- 6.7.3.3 The refrigerator must be installed in an environment where the surrounding ambient temperature does not affect its temperature control. The temperature of the surrounding environment should be between +10°C and +32°C.
- 6.7.3.4 The electricity supply must be safeguarded against inadvertent breaks. The refrigerator should be wired directly to the mains supply. If this is not possible, tape over the plug and label with a recommended cautionary notice e.g. "Pharmacy fridge: Do NOT switch off".
- 6.7.3.5 The refrigerator must remain locked. The keys must be kept by the appointed practitioner in charge of the department/facility or delegated member of staff.
- 6.7.3.6 The refrigerator must only be used to store pharmacy supplies which require storage between +2°C and +8°C. Do not store food, milk, drink or specimens in the refrigerator.
- 6.7.3.7 Any facility or department holding fridge stock with a value of £500 or more, and which is not staffed on a 24 hour, seven-day per week basis, must have their refrigerator alarm signal connected to an emergency engineer so that deviations outside the agreed range may be acted upon.

6.7.4 Pharmaceutical refrigerators must be managed as follows:

- 6.7.4.1 The acceptable temperature range for pharmaceutical refrigerators is +2°C to +8°C. Any deviation must be recorded and remedial action taken.
- 6.7.4.2 The temperature (current, maximum and minimum) of pharmaceutical refrigerators in facilities and departments must be recorded at least once a day, preferably at the same time each day during the working week. A record of the values must be made in the appropriate sections of the Pharmaceutical Refrigerator Temperature Log (Appendix 4). The log must be retained for audit purposes for a minimum of one year and kept close to the fridge.
- 6.7.4.3 Once the temperature has been recorded, the thermometer must be reset. Batteries for digital thermometers should be replaced 6 - 12 monthly. If using a stand-alone thermometer, return it to the refrigerator and ensure that the refrigerator door is closed securely.
- 6.7.4.4 If there is more than one refrigerator in the same room, each one should be clearly labelled and identified (e.g. Fridge 1, Fridge 2 etc) and cross referenced to the appropriate temperature monitoring sheet and operating manuals.
- 56 Belfast Health and Social Care Trust Community Medicines Code

- 6.7.4.5 Any deviation in temperature from +2° to +8°C must be reported to the Appointed Practitioner in charge for urgent remedial action. If a fault is detected during normal monitoring, the temperature log should be checked to ascertain when the refrigerator was last recorded as being in range. If there is concern over the operation of a medicine refrigerator, then Estates department should be contacted.
- 6.7.5 For further advice regarding the stability of the pharmaceuticals affected e.g. if a break in the cold chain, please contact the **Regional Medicines and Poisons Information: 028 950 40558** (Monday-Friday 9am - 5pm)
- 6.7.6 If so advised, all pharmaceuticals must be removed from the refrigerator and disposed of in accordance with the Trust's waste policy. A list of the items wasted (description and quantity) must be made and reported to Pharmacy. Replacement pharmaceuticals will only be issued when the refrigerator has been repaired and is once again functioning according to its specification.
- 6.7.7 If a refrigerator remains out of use for any time, then temperatures must be monitored for at least 24 hours to ensure the correct temperature has been achieved before being used to store medicines.
- 6.7.8 There must be a maintenance contract in place that allows for at least annual servicing and calibration of temperature gauge. The manager in charge of the facility/department or service head is responsible for ensuring that this check takes place.

6.7.9 Refrigerator content / stock control

- 6.7.9.1 All medicines should be stored in the original manufacturer's packaging as this is printed with the expiry date and batch number, contains a patient information leaflet and administration instructions and protects vaccines from light and damage.
- 6.7.9.2 Fridge contents should be evenly distributed to allow air to circulate around items and shelves thus enabling the temperature to remain constant.
- 6.7.9.3 Expired stock must be removed as soon as possible and safely destroyed according to local policy or returned to supplying pharmacy.
- 6.7.9.4 Stock must be rotated according to expiry date and older stock placed at the front of the fridge to use first to minimise potential for unnecessary medicines waste.
- 6.7.9.5 Different types of vaccine must be stored in different parts of the fridge.

6.8 Medical gases

Refer to Chapter 10: Medical Gases for detail on storage.

6.9 Controlled drugs

Refer to BHSCT Community Controlled Drugs Policy (SG 23/15) http://intranet. belfasttrust.local/policies/Documents/Community%20Controlled%20Drugs%20 Policy.pdf

7 Transport of medicines

7.1 General principles

- 7.1.1 There must be systems in place for the transport of medicines that ensure their security, quality and integrity, and maintain the health and safety of the staff and the public.
- 7.1.2 Systems should be in place to ensure there is an audit trail for any medicines issued, received, transferred or delivered including receipt by a client. There should be a signature at each point of transfer.
- 7.1.3 If a delivery has failed e.g. premises closed the medicines must be returned to the supplying pharmacy.
- 7.1.4 All containers and packages are clearly labelled with the final destination.
- 7.1.5 Equipment used in the transport of medicines should be designed to ensure the security, integrity and quality of the medicine is not compromised and where appropriate the cold chain is maintained.
- 7.1.6 Transfer of medicines outside the healthcare organisation e.g. to client's homes, other Trust pharmacies, should always be authorised and receipt acknowledged by the receiving body. Where intermediate carriers (e.g. taxis, couriers, homecare companies) are used, recording of collections should be in place.

Taxis:-

- Must always be ordered as per Trust contract and procedures.
- ID should be provided.
- Taxis must not carry non-Trust passengers while transporting medicines.
- 7.1.7 Trust staff engaged in the transportation of medicines should carry Trust identification.
- 7.1.8 Designated members of Trust transport will undertake deliveries of medicines to community facilities. The delivery driver is responsible for safe delivery of the goods to the correct location. The driver must inform an appropriate member of staff that an order has been delivered. He/she is responsible for ensuring that a signature acknowledging receipt of the goods is obtained. Staff in receipt of drugs must sign the appropriate notice to acknowledge receipt. Containers and packages must be kept securely or under surveillance whilst in transit between pharmacy and the final destination. The driver should always lock their transport when they are in a facility or leaving their vehicle unattended for any time.
- 7.1.9 Community staff (registered practitioners, non registered practitioners or allied health professionals & carers), may deliver medicines in exceptional circumstances, where clients, their carers or representatives are unable to collect them, provided the member of staff is conveying the medication to a client for whom the medicine has been prescribed (for example, from a pharmacy to the client's home). This aspect of care i.e. delivery of medicines, must be documented in the care plan and the client must be known to the member of staff delivering the medicines.

- 7.1.9.1 Staff must be aware of the potential for serious adverse incidents with incorrect delivery of medicines. These risks include but are not limited to
 - · The delivery of incorrect medicines to a client;
 - Inadvertent breach of a client's confidentiality
 - Non-delivery of medicines within a specific time frame.
- 7.1.9.2 An audit trail recording receipt of medicines by community staff for transportation and receipt by the client following delivery of medicines to the client must be maintained.
- 7.1.9.3 Medication must be handed to the client (or the carer if they are known to the team). Clients (or carers) must sign for receipt of the medicines; the record of receipt should be placed in the client's record. Any refusals to accept delivery must be documented in the client's record. If medicines cannot be delivered they must be returned to the issuing pharmacy on the same day.
- 7.1.9.4 Medicines must never be posted through letterboxes or left with a person unknown to the team.
- 7.1.10 Where medicines carried by a community practitioner for administration cannot be administered that day they must be returned to the community base on the same day and stored securely in a designated locked cupboard.
- 7.1.11 It is the responsibility of the service users' family/carers to ensure medications are transported safely transported to day facilities e.g. day care centres, special schools.
- 7.2 Maintaining the cold chain

Refer to chapter 9.

7.3 Medical gas cylinders

Refer to chapter 10.

7.4 Action in the event of a breach of security

- 7.4.1 A breach of security includes any deviation from the procedures that causes actual or potential loss or theft of medicines. Examples of such incidents include:
 - Medicines are left unattended at an insecure location;
 - Medicines have been handled by an unauthorised person;
 - Actual or suspected theft.
- 7.4.2 Any person who discovers a breach of security is responsible for reporting it immediately to the manager of the department concerned, and to the pharmacy.
- 7.4.3 The manager of the department concerned is responsible for investigating the breach of security, and for taking the necessary action according to relevant Trust procedures. This includes informing appropriate personnel within appropriate timescales, and ensuring that a Trust incident form is completed.

Belfast Health and Social Care Trust Community Medicines Code

59

7.5 Posting of medicines

- 7.5.1. Systems should be in place to ensure there is an audit trail for any medicines e.g. specialist (red/amber) medicines posted by hospital pharmacies direct to clients. For instance use of recorded or special delivery.
- 7.5.2 Hospital pharmacies involved must ensure a risk assessment is documented for any system for delivery that identifies and addresses any potential risks to client safety e.g. the risk associated with the medicines being delivered including to anyone who is not the client or the organisation.

60 Belfast Health and Social Care Trust Community Medicines Code

8 Disposal of unwanted medicines

8.1 General principles

8.1.1 Community facilities should not maintain a stock of medicines and dressings that are not required. They are responsible for their own pharmaceutical waste management disposal as per Trust Waste Management procedures.

Pharmaceutical waste includes:

- Waste medicines
- Packaging contaminated with medicines
- Items used to handle and administer medicines

Cytotoxic and cytostatic medicines are medicines that are either: **toxic**, **carcinogenic**, **mutagenic** or **toxic** for reproduction. They include:

- · Most hormonal preparations
- Some anti-viral drugs
- Many antineoplastic agents
- Immunosuppressants
- Some antibiotics

Refer to BHSCT Community Controlled Drugs policy for advice on disposal of controlled drugs

- 8.1.2 Any outer packaging and patient information leaflets may be placed into ordinary paper cardboard waste containers for recycling; however personidentifiable information such as names on labels must be obliterated with permanent black marker pen before disposal.
- 8.1.3 All pharmaceutical waste, including vaccine and cytotoxic waste, either empty or partially used, must be placed for disposal in a burn bin with a purple lid. The additional label 'cytotoxic waste' must be applied.

The details on the burn bin label must state the date and the name of the person who assembled the burn bin, the unit/facility and the name of the person who locked the bin and date of closure. All burn bins must be tagged by the unit/facility using their unique tags.

- 8.1.4 Full packs that have been supplied by a Trust pharmacy department and are still in date may be returned to the appropriate pharmacy where they will be considered for reuse and credit.
- 8.1.5 Partly used drugs such as ampoules of antibiotics, drugs which have been refused or spat out, should be regarded as *clinical* waste and disposed of as such by the facility or in the client's home.
- 8.1.6 Trust staff are not registered as carriers of pharmaceutical waste and should not in normal circumstances remove any medicines from a client's home see below.

8.2 Disposal of medicines by nursing homes

8.2.1 Medicines waste from clients within nursing homes is not included under the definition of household waste, under the Controlled Waste Regulations Northern Ireland 2002. These homes, therefore, should make their own arrangements to have such waste collected by an authorised person and delivered to an authorised facility for its safe disposal. Failure to do so could render the home to commit a number of offences under a range of legislation. Unless community pharmacies have a waste management licence, they cannot accept back unwanted medicines from nursing homes. Guidance is provided by the RQIA.

8.3 Disposal of medicines by residential homes

8.3.1 Residential homes can return medicines to the supplying pharmacy. An audit trail must be maintained for medicines returned. If the medicines cannot for any reason be returned to the supplying pharmacy they can be returned to an alternative community pharmacy.

8.4 Disposal of client's own medicine

- 8.4.1 Refer to Community Controlled Drug policy for advice on controlled drugs.
- 8.4.2 Medicines obtained for a client on a prescription are the property of the client. If they are no longer required or the client has died, the client or client's agent should return them to the community pharmacy for destruction.
- 8.4.3 Clients should be told not to dispose of medicines down the toilet due to contamination of the environment. Medicines should not be disposed of in the dustbin.
- 8.4.4 In **very exceptional** circumstances, where there is deemed to be a 'real concern' in leaving medicines in the clients home e.g. previous evidence of theft/misuse of those drugs in this particular home, a **risk assessment** will normally be in place to identify how this is being managed. Part of the 'risk assessment' must include discussion with the Nurse Lead/Team Manager and notifying a Pharmacy Services Manager (RVH or BCH) and OOH Nursing Team of the risk. In a situation where the risk of leaving the drugs has only been identified and there has not been the opportunity to put a risk assessment in place, staff can remove the drugs, complete the necessary documentation/process and must inform their line manager/on-call manager. An 'exceptional circumstance' **is not** that the patient lives in a particular area.
- 8.4.4.1 The registered nurse will ask the client or carers permission to take the medicine to the nearest pharmacy for destruction. Wherever possible ensure that the action is witnessed by another health professional or the client/carer. The Form: 'Consent for removal of unwanted medicines' is given in Appendix 5. This must be completed and signatures obtained.
- 8.4.4.2 Any medicines removed should be taken directly to the nearest community pharmacy for disposal. Medicines removed from a client's home **must not** be stored at community bases or taken home by staff. The community pharmacist should be requested to sign and date receipt of the medicines. The form then should be filed in the client's notes. This audit trail provides protection for staff when removing medicines from a client's home.
- 62 Belfast Health and Social Care Trust Community Medicines Code

- 8.4.4.3 If a community pharmacy is not open (after 9pm Mon-Fri or after 5pm Sat, Sun and public holiday) the Belfast Trust on-call pharmacist should be contacted via BCH switchboard to accept the controlled drugs for storage and destruction.
- 8.4.4.4 Exceptionally, the medicines may be held in the locked boot of the community nurses car for short periods if they cannot be taken directly to the community or hospital pharmacy.
- 8.4.5 Non registered practitioners or allied health professionals should always refer to a registered practitioner or prescriber prior to removing any medicines from a client's home.
- 8.4.6 Home Treatment Team (HTT) may identify a risk associated with adherence or risk of accidental or deliberate overdose and will follow the same process of local risk assessment and the actions described in section 8.4.4.1 above. Outside community pharmacy hours the medicines must be locked in a safe provided by HTT in the clients home. The following day the medicines can be removed to Community Pharmacy for desctruction.

8.5 Sharps bins

- 8.5.1 Waste medicines and sharps generated by staff should be disposed of in sharps bins then disposed of in appropriate collecting bins and collected by an authorised person.
- 8.5.2 Waste medicines and sharps generated by nurses in clients' homes should be disposed of in sharps bins and transported back to the surgery/trust facility for safe disposal.
- 8.5.3 Sharps bins should be kept in a secure environment in order to prevent unauthorised access to them.

9 Refrigerated medicines (including vaccines)

9.1 General principles

- 9.1.1 The efficacy and safety of medicines requiring storage at controlled low temperature, typically 2-8°C, depends on maintaining this temperature. Failure to store medicines according to manufacturers recommendations can invalidate the expiry date and cause manufacturers to disclaim responsibility for any apparent failure of the medicine as the safety and efficacy of such medicines can be significantly compromised.
- 9.1.2 Sensitivity to changes in temperature varies depending on the medicine. The manufacturer's literature must be consulted and other expert advice must be sought if medicines that require to be stored at temperatures outside normal ambient temperatures i.e. in a fridge or freezer need to be transported.
- 9.1.3 If medicines that are sensitive to temperature changes are to be transported on a **regular basis**, the transport system must be validated and monitored for the duration of the transport time.
- 9.1.4 If medicines that are sensitive to temperature changes are to be transported on an **occasional** basis, the following good practice should be followed.
 - The medicine must be held outside the recommended storage temperature for the minimum time possible. Maximum exposure time allowed depends on the sensitivity of the product.
 - Validated cool boxes or containers should be used.
 - If ice packs are used, they must be evenly distributed. Direct contact with the medicines must be avoided e.g. by using layers of card or bubble wrap between the medicines and the ice packs.
- 9.1.5 Validated cool boxes must be used for transport of vaccines for the purposes of influenza and pneumococcal vaccination programmes where the vaccinations are carried out by community nursing in the patients home for the GP registered population.
- 9.1.6 The supplying Trust pharmacy should ensure that the driver is aware that a delivery contains a fridge item.

9.2 Receiving refrigerated medicines

9.2.1 When expecting a delivery of any medicine requiring storage at 2-8°C the designated accountable person or deputy must ensure that whoever accepts the delivery is aware of the need to check the order for leakage, damage and discrepancies, before signing for them. Pharmaceutical distributors and manufacturers will not accept any refrigerated medicine for return once it has left their control.

If there is any concern that a break in the cold chain has occurred prior to delivery, the delivery should not be accepted but reported to the distributor along with the reason for non-acceptance. A Trust incident report should be completed.

- 9.2.2 All deliveries of refrigerated medicines must be unpacked **immediately** on arrival and placed in a pharmacy/vaccine refrigerator and not left at room temperature. Items must remain in the manufacturer's original packaging to protect them from light.
- 64 Belfast Health and Social Care Trust Community Medicines Code

- 9.2.3 The date and time at which the vaccine was received should be entered into a vaccine log. This information should also include details of vaccine type, brands, quantities, batch numbers and expiry dates.
- 9.2.4 Delivery dockets should be retained for at least a week to resolve any queries that may arise.

9.3 Storage conditions

Refer to Chapter 6.7 Pharmaceutical Refrigerators.

9.4 Vaccines

- 9.4.1 Incorrect storage of vaccines is not only wasteful and costly. The failure to store vaccines correctly, particularly at temperature below the manufacturer's recommendations, can reduce vaccine effectiveness and cause vaccine failures. Freezing can cause deterioration or increased reactogenicity of some vaccines. It can also cause hairline cracks in the ampoule/vial/pre-filled syringe with the potential for contamination of the contents. Excessive heat speeds up the loss of vaccine potency and, as exposure to UV light also decreases potency, they should be protected from light.
- 9.4.2 Domestic cool boxes should not be used to store, distribute or transport vaccines.
- 9.4.3 Vaccines may be given on the specific written instructions of the responsible doctor or under an approved patient group direction.
- 9.4.4 Mechanisms should be in place to reconcile current stock with records of doses administered and stock ordered.

9.4.5 Ordering of vaccines

- 9.4.5.1 Services should have no more than two to four week's supply of vaccines at any time. This will be sufficient for routine provision. Best practice is to order small quantities on a regular, scheduled basis.
- 9.4.5.2 Excess stock may:
 - · Increase the risk of vaccinations with out of date vaccines.
 - Increase wastage and cost of disposal by incineration.
 - Increase the dangers of over-packed refrigerators, leading to poor air flow, potential freezing, poor stock rotation and leads to the potential efficacy of the vaccine being reduced.
 - · Delay the introduction of new vaccines until local supplies have been used.
 - Increase the cost of replacement of stocks if the refrigerator fails.
 - Increase the pressure on clinic refrigerators in periods of high demand, e.g. during the influenza vaccination season.

9.4.6 GPs

9.4.6.1 GPs order vaccines for the Childhood Immunisation Programme from BHSCT partner distributor using an online ordering system. Vaccines will be delivered directly to the GP practice by BHSCT partner distributor.

Belfast Health and Social Care Trust Community Medicines Code

65

| 9.4.6.2 | Each GP is assigned a quota based on their list size for the relevant age and |
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| | the vaccine schedule. This quota is maintained by Knockbracken Pharmacy. |
| | Requests for amendments to quotas must be addressed to pharmacy staff at |
| | Knockbracken. |

- 9.4.6.3 Delivery issues including errors in a delivery must be addressed to the vaccine distributor on the day of delivery.
- 9.4.6.4 If a GP practice has a cold chain breach they should, when possible, keep the vaccines in the fridge but clearly mark them not be used. Notify the Public Health Agency (PHA) duty office and provide details of:
 - The vaccines affected and their batch number
 - The quantity of each vaccine
 - Records of the fridge temperatures including the time and date of the last reading that was within the range 2-8°C
 - The length of time the vaccines were outside the range 2-8°C
 - The maximum temperature that was reached during the time outside the range 2-8°C
 - Based on the information provided, the duty room staff will advise if any vaccines can be used or if they need to be destroyed.
- 9.4.6.5 Vaccines to be destroyed should be disposed of in the practice Waste Bins for Vaccines.
- 9.4.6.6 Certain vaccines (e.g. influenza and shingles) are purchased directly by PHA on behalf of GPs. The Trust is not responsible for these vaccines and they should be ordered according to the direction of the PHA direct from the supplier.

9.4.7 Domiciliary visits

- a) If the vaccine is not administered to the client within 2 hours of being removed from the fridge it should be disposed of in the appropriate sharps bin and **not returned** to the stock supply in the fridge.
- b) Other medicines may only be returned to the fridge if conditions stated in manufacturers' information are met. Each vaccine must be marked 'use first' and marked with the date it was returned to stock (cool boxes must be transported out of direct sunlight).

9.4.8 School immunisation sessions and clinic sessions

- 9.4.8.1 The ordering process for school health vaccines depends on the vaccine required. At the time of writing, influenza vaccine has been purchased directly by PHA and the Trust has no responsibility for this vaccine. The process directed by PHA for ordering influenza should be followed.
- 9.4.8.2 For other vaccines orders are sent by the school health nurse to Knockbracken Pharmacy according to the process below.

66 Belfast Health and Social Care Trust Community Medicines Code

- 9.4.8.3 A process has been agreed with BHSCT partner vaccine distributor to deliver vaccines directly to individual schools on the morning of an immunisation session and to collect later in the day, and store for re-use, unused vaccines.
- 9.4.8.4 The driver will deliver the vaccine porters to an agreed drop-off point at the school where they will be received by a school nurse.
- 9.4.8.5 Stock delivered will be a mix of new stock and re-issue of stock returned from a previous session and the vaccine porters will be marked by BHSCT partner vaccine distributor to identify which porters contain new stock and which contain re-issued stock. Re-issued stock should be used at the start of an immunisation session and porters containing new stock should remain sealed until needed. If any re-issued stock remains at the end of a session it must be destroyed.
- 9.4.8.6 Only a small number of vaccines should be removed from the vaccine porters at a time and the lid replaced immediately to avoid potential wastage. At the end of the session any vaccines remaining outside the porter should be destroyed. The porter should be taken to the agreed collection point for pick up by BHSCT partner vaccine distributor.
- 9.4.8.7 For some smaller schools school health staff will take vaccines from the first session to the next school. They must be transported in a validated vaccine porter. The nurse must confirm with the school the day before the numbers of pupils attending for immunisation and only bring this amount. Any vaccine that is unused must be destroyed.
- 9.4.8.8 Orders for stock are placed taking into consideration returned stock that is held by the BHSCT partner vaccine distributor. An agreed spreadsheet template is used for ordering stock. The completed spreadsheet detailing the names and address of the schools for each day and the quantity of vaccine including the split between new and re-issued stock must be emailed to Knockbracken pharmacy and BHSCT partner vaccine distributor by Wednesday of the week before. A printed signed copy of the spreadsheet must also be sent to pharmacy.
- 9.4.8.9 The school nurse receives regular updates from BHSCT partner vaccine distributor on the quantity of returned stock. On occasion the school nurse may amend an order to use more returned stock and send an order amendment to BHSCT partner vaccine distributor. The school nurse will keep account of the unused new stock and reduce the following weeks order for new stock by this amount.

9.4.9 Vaccine spillage

- 9.4.9.1 Each vaccine has its own COSHH data sheet which is kept by the relevant manufacturer. See 4.12. If a vaccine is spilt contact the manufacturer for instructions on how to clean the area/surface.
- 9.4.9.2 Any materials used should be disposed of as clinical waste.

Belfast Health and Social Care Trust Community Medicines Code 📕 🕴 67

9.5 Incidents

- a) Service managers should have business continuity plans for storing refrigerated medicines, including vaccines, in the event of refrigerator breakdown, loss of electricity supply or other disruptions to the cold chain. This should be implemented immediately to prevent loss of stock.
- b) If there is any breach of the cold chain, i.e. any temperature record falling outside 2°C to 8°C such as refrigerator breakdown or interruption of the electricity supply, a Trust incident form must be completed after the fridge contents have been safeguarded.
- c) If the fridge current temperature is within the range 2°C to 8°C but maximum or minimum readings are outside of this range try to establish how long the temperature may have been outside the acceptable range. Seek advice on further action. See advice below.
- d) If it is necessary to move stock to alternative cold storage, it should be separated from other stock and clearly marked to indicate it should not be used until confirmed as safe to do so. If immediate transfer is not possible, keep the fridge door closed and regularly monitor temperature up to the time of transfer.
- e) If the electricity supply to the fridge has been disconnected record the current fridge temperature. If this and the maximum/minimum readings are between 2°C to 8°C reconnect the power supply, if possible. No further action is necessary. If any reading is outside this range reconnect the power supply and record the time of reconnection. Try to establish how long the temperature has been outside this range and seek advice from the sources in section below. If it is not possible to reconnect the fridge to the power supply consider moving the contents to alternative cold storage.
- f) If the fridge is faulty contact estates services or an engineer to correct the fault and use an independent thermometer to verify it is operating correctly before returning any medicines to it.
- g) If a fridge in a Trust facility or managed by Trust staff has a temperature excursion outside the range 2°C to 8°C for any reason, contact the NI Regional Medicines and Poisons Information: 028 950 40558 (Monday-Friday 9am-5pm) for advice on whether the medicine can be used or destroyed. The medicine should be quarantined until a decision is made. In some cases stock can still be used after a cold chain breach so it is important to keep it quarantined but in the cold chain until a decision is made.
- h) GP practices who report a cold chain breach to Trust staff must be advised to follow the advice issued by the Public Health Agency contained in each issue of Vaccine Update. All breaches of cold chain that have resulted in loss of vaccine must be reported to the Public Health Duty Room. NOTE: Vaccines can sometimes still be used, so it important to keep it quarantined but in the cold chain until a decision is made.
- 68 Belfast Health and Social Care Trust Community Medicines Code

10 Medical gases

10.1 General principles

- 10.1.1. Medical gases are medicinal products under the provision of the Medicines Act 1968.
- 10.1.2 Medical gases should be managed and controlled to the same level as other medicinal products with regard to authorisation to prescribe, ordering, administration, storage and security.
- 10.1.3 Medical gases must be prescribed by a doctor, dentist or Trust non medical authorised prescriber.
- 10.1.4 Clients in Trust residential facilities, who require oxygen and other medical gases as a regular medicine must have it recorded on the medicines record/administration sheet or MAR.
- 10.1.5 Portable oxygen or oxygen cylinders, required in residential/nursing homes or in day care centres must be prescribed and provided by the client's General Practitioner and Community Pharmacist respectively. (Hospital medical gas cylinders cannot be used in the community as they do not fit community regulators.)
- 10.1.6 When an oxygen concentrator is ordered for a client for home use an emergency back-up cylinder must be supplied by the Oxygen Company in case of an electrical power supply or fault with the concentrator. Both verbal and written safety instructions must be given to the client or their caregiver. Other oxygen equipment and devices, which will allow clients to mobilise, will be available following a detailed assessment by the Trust's Respiratory team.
- 10.1.7 If a client transfers from one facility to another the staff member responsible for the transfer must ensure there is sufficient oxygen for the whole journey, allowing for changes in oxygen requirements and delays such as faulty lifts or heavy traffic.
- 10.1.8 Appropriate risk management and operational arrangements are followed for the prescribing, administration, ordering, storage and quality control of medical gas supplies.
- 10.1.9 In the event of a fire, it is stressed that the safety of all personnel must be the first priority. As soon as a fire is discovered, immediately operate the Fire Procedure and notify the Fire Services, warning them of the presence of compressed gas cylinders.
- 10.1.10 For use of liquid nitrogen follow manufacturers data sheet. Liquid nitrogen is very safe under normal usage. However, when it evaporates e.g. due to spillage it undergoes a large volume expansion causing oxygen depletion. Liquid nitrogen oxygen depletion monitors must be used to provide early warning.
- 10.1.11 Staff should be aware of signs and symptoms of low oxygen levels. Asphyxiation as a result of oxygen depletion can take place on a gradual or sudden basis, depending upon the extent of the depletion.

10.1.12 Locations or departments that hold stock and/or use nitrous oxide should be aware of and safeguard against the recreational misuse of nitrous oxide. Further information can be found at: https://www.gov.uk/government/ publications/acmd-advice-on-nitrous-oxide-abuse

10.2 Areas of responsibility

- 10.2.1 The senior nurse/midwife in charge, healthcare professionals, facilities manager, transport manager and estates operational manager should ensure that all staff in their area of responsibility are adequately trained regarding medical gases, both in routine use and in emergency situations.
- 10.2.2 The senior nurse/midwife in charge or facilities manager is responsible for the safe and secure storage, handling and use of medical gases in his/her area of control. This includes ensuring the availability and maintenance of the necessary equipment. They are also responsible for ensuring effective and efficient stock control.

10.3 Storage of medical gas cylinders

- 10.3.1 The senior nurse/midwife in charge or facilities manager is responsible for the safe and secure storage of medical gas cylinders in the department, and for ensuring the following:
 - Cylinders must be located in a safe position and secured so they cannot fall over. Cylinders must not be stored or used freestanding.
 - Cylinders must be located near to an exit so that they can be removed quickly in an emergency such as a fire. However, they must not block the exit, or present any other type of hazard.
 - Cylinder storage areas must be kept clean and dry, well ventilated and free from inflammable material. Rubbish must not be allowed to accumulate.
 - Cylinders must be sited away from storage areas containing highly flammable liquids and other combustible materials, and from sources of heat or ignition.
 - · Medical gas cylinders must not be stored in lift lobbies.
 - Statutory warning notices must be posted prohibiting smoking and naked lights within the vicinity of the cylinders.
 - Cylinders containing liquefiable gases must be stored and used upright with the valve uppermost unless the attached equipment is specifically designed to withdraw liquid from the container.
 - Full and empty cylinders must be segregated in clearly defined areas and empty cylinders should be returned to the supplier as soon as possible.
 - Cylinders should be kept under cover, preferably inside and should not be subject to extremes of temperature.
 - Cylinders must be clearly marked to show what they contain and the hazards associated with their contents. Staff should be aware that no grease or oil should touch a cylinder or fittings.
- 70 Belfast Health and Social Care Trust Community Medicines Code

- Storage should allow for stock rotation of full cylinders to enable the cylinders with the oldest filling date to be used first. The expiry date must be checked before each use.
- The cylinder stores must be kept locked when not in use. Access must be restricted to authorised personnel only e.g. portering and technical services personnel.
- Medical and industrial (non-medical) gases must be stored separately.
- Cylinders of size "F" and greater must be stored secured in the vertical position to prevent toppling. Cylinders of size "E" and smaller must be stacked horizontally on racks to prevent damage to the cylinder paintwork.
- Different sizes and types of medical gas cylinders must be stored in separate racks or defined areas.
- Cylinders must not be defaced by marking with chalk, paint, crayon or other material.
- Cylinders containing oxygen and oxidants must be stored segregated (if possible by a physical barrier) from flammable gases. Flammable gases must not be stored routinely, and if required, quantities must be kept to a minimum.
- The area surrounding the stores must be kept free of vegetation or other combustible materials. If weed killers are required, chemicals which are a potential fire hazard (e.g. sodium chlorate) must not be used.

10.4 Safe handling and use of medical gas cylinders

- 10.4.1 Medical gas cylinders, though robust, should be handled with care and only by personnel who have received training and understand the hazards involved. The details given below are intended to serve as a reminder to staff who regularly handle and transport cylinders and who have received formal training. The guidelines are therefore intended to supplement, and not replace, formal training.
- 10.4.2 Basic medical gases safety training is provided by BHSCT and can be booked via HRPTS.

10.4.3 General guidelines

- Do not smoke or use naked lights in the immediate vicinity of a cylinder or in confined areas where cylinders are kept or stored.
- In the event of a fire, it is stressed that the safety of all personnel must be the first priority. As soon as a fire is discovered, immediately activate the Fire Procedure and notify the Fire Services, warning them of the presence of compressed gas cylinders.
- Do not subject cylinders to temperatures above 45 degrees centigrade.
- Ensure cylinders are kept free from dirt, grease and oil.
- Ensure all equipment used to transport cylinders (e.g. trolleys) is clean and free from dirt, grease and oil.

Belfast Health and Social Care Trust Community Medicines Code 🔲 🕴 71

- Handle cylinders with care. Do not allow them to knock against each other or against other pieces of equipment. Ensure cylinders are secured to prevent them falling or rolling against each other.
- Do not use cylinders as rollers. Do not roll or drag cylinders along the floor.
- Avoid lifting cylinders by their caps or valves where possible.
- Move cylinders only with the appropriate size and type of trolley. Do not use stretchers or wheelchairs.
- When transporting cylinders attached to medical equipment, ensure that the gas supply is switched off and the cylinder valve is closed, unless the equipment is attached to a client. When cylinders are moved with apparatus attached always close the cylinder valve first and vent any residual gas to the atmosphere.
- Use medical gas cylinders for medical treatment only (normally associated with respiratory function) and not for other purposes such as welding, laboratory experiments, etc.
- The name of the medical gas, cylinder size and expiry date must be checked on the collar of the medical gas cylinder before use.

10.5 Equipment for use with medical gases

10.5.1 All administration equipment must comply with the relevant British Standard and must only be used with the gas for which it is designed.

10.6 Precautions for oxygen therapy

- 10.6.1 There is a serious risk of fire when clients smoke or are in close proximity to other forms of ignition when receiving oxygen therapy. Clients and healthcare staff should be aware that skin products containing paraffin based products, for example white soft paraffin, white soft paraffin plus 50% liquid paraffin or emulsifying ointment, in contact with dressings and clothing are easily ignited with a naked flame or a cigarette. For further information go to www.npsa.nhs. uk. Where alcohol wipes or alcohol gel have been used allow enough time for the alcohol to evaporate before using the gas.
- 10.6.2 Oxygen, although not flammable, will increase the burning rate of any combustion. The following precautions must be taken.
 - Fire and safety warning signs must be conspicuously displayed where oxygen is to be administered (available from the Trust Fire Officer).
 - Smoking must not be permitted in the room or area where oxygen is being administered or stored. Other sources of ignition e.g. lighters, matches, open fires, cookers must be removed.

10.7 Safe transport of medical gases

- The nurse/midwife in charge or facility manager must ensure that the risks arising from the transport of gas cylinders around the facility are assessed, and appropriate precautions established and applied.
- 72 Belfast Health and Social Care Trust Community Medicines Code

- Gas cylinders must only be transported using containers and or vehicles which are appropriate for the size and number of the cylinders, and which allow all cylinders to be firmly secured either horizontally or vertically.
- Lifts should be used whenever practicable when gas cylinders are taken from one floor to another. Cylinders of sizes G or larger should never be manually handled up or down stairs.
- When transporting a client receiving oxygen therapy, ensure that the oxygen cylinder is firmly secured and cannot move in transit.
- During transit the client must be accompanied by a member of staff trained in the use of oxygen cylinders.
- The managers of departments which require transporting gas cylinders in motor vehicles must ensure that all such vehicles are equipped so that cylinders can be firmly secured and that drivers are trained in the legal and safety requirements.
- Cylinders must only be carried in motor vehicles if they can be securely fastened in the boot of a car or rear of a van. They need to be secured ideally with a cargo net or fixed with a karabiner and strap. Restrict the number of cylinders being carried to a minimum.
- There should be adequate ventilation when cylinders are transported within a car.
- Members of staff should advise their insurance companies where cylinders are to be carried in their motor vehicles.
- Drivers must carry the appropriate handling information for the gas and be familiar with its contents.
- Any incident that causes a significant impact to a gas cylinder must be reported immediately to the relevant manager.

10.8 Faulty cylinders

- 10.8.1 Cylinders are described as faulty where the complaint is minor and client safety is not at risk. Typical complaints that are classified as faulty are:
 - · Faulty valve operation;
 - · Damaged valve outlet; or,
 - · Minor leaks from valve.
- 10.8.2 If a cylinder is thought to be faulty, the supplying pharmacy or BOC (if a direct delivery) must be contacted with details of the fault and arrangements made for a replacement to be provided.
- 10.8.3 The label of the faulty cylinder must be marked "FAULTY DO NOT USE". The faulty cylinder must be segregated from other cylinders until it can be collected or returned to the pharmacy concerned.

10.9 Ordering of medical gas cylinders

- 10.9.1 Refer to local procedures.
- 10.9.2 Facilities wishing to order medical gas cylinders from their designated pharmacy department should include:
 - · Type of medical gas
 - Size of cylinder
 - Quantity of cylinders required.

A facility may only order the number of medical gas cylinders up to the agreed stock level and must have the corresponding number of used/empty cylinders to return to the designated Pharmacy.

- 10.9.3 It is the responsibility of Trust facilities to arrange with Trust transport for the uplift of empty cylinders.
- 10.9.4 Some facilities have direct accounts with BOC Cryospeed to provide e.g. nitrogen SV1.
- 10.9.5 Trust Pharmacy departments hold records of the number of cylinders that each facility holds in stock. If a cylinder is lost, then the facility must pay for the value of the lost cylinder as the cylinder is rented. An incident form must be completed if a Trust facility loses a cylinder and the Trust Pharmacy must be informed.
- 10.9.6 Pharmacy does not supply cylinder regulators, trolleys or restraints.

10.10 Provision of medical gases for home births

The community midwife in charge is responsible for arranging the provision of Entonox and oxygen for home births.

10.11 Emergency use

- 10.11.1 A prescription is not required for the administration of oxygen in peri-arrest or medical emergencies but a subsequent written record must be made of the oxygen therapy prescribed and administered.
- 10.11.2 A record must be made in the client's notes giving details of the client's clinical condition, the administration of oxygen and the delivery system, and any medical advice given.

11 Medication incident reporting

- 11.1 Refer to Trust 'Adverse Incident Reporting and Management Policy' and procedure including the Trust 'Procedure for Investigating an Adverse Incident' on the Trust intranet.
- 11.2 The Trust is committed to developing a reporting and learning culture so that risks to clients and staff from preventable medication incidents are minimised. This relies on effective reporting and analysis of medication incidents and recognises that to improve safety, risks must first be identified. To ensure identification of medication risks, a Trust incident report should be completed for all medication incidents. Lessons can then be learned and, where appropriate, action taken to reduce recurrence.
- 11.3 A medication incident is defined as any preventable medication related event that could have or did lead to client harm, loss or damage. This definition encompasses 'near misses', that is, those medication related occurrences where the client did not suffer harm, but there was the potential for harm, loss or damage.
- 11.4 Medication incidents can occur in any step of the medicines use process, including prescribing, dispensing and administration of medicines, as well as in the transfer of medicines related information. If a medication incident occurs, where possible the medication should be retained for investigation including the packaging.
- 11.5 The Trust operates a fair and just culture with regard to incidents. Following an incident the focus is on 'what went wrong' rather than 'who went wrong'. This does not mean staff are not accountable for their actions but it is recognised that individuals can and do make mistakes. However, disciplinary action may be required in certain circumstances, for example, where the intention was to cause harm or where there are repeated, unreported errors or violations.
- 11.6 The accountable officer for controlled drugs i.e. the Head of Pharmacy and Medicines Management must be informed of any medication incident involving Controlled Drugs. Refer to BHSCT Trust policy: Dealing with discrepancies or concerns involving controlled drugs.
- 11.7 HSCB Learning Letters and safety alerts are available on the HSCB website. Trust safety newsletters are available on the Trust intranet

12 Adverse drug reaction (ADR) reporting

- 12.1 Any medicine may produce unwanted or unexpected adverse reactions.
- 12.2 DHSSPS defines an adverse reaction as a harmful or non-beneficial symptom or syndrome occurring as a result of the correct clinical use of a product which is not defective.
- 12.3 Detection and recording of these is of vital importance. Serious reactions include those that are fatal, life threatening, disabling, incapacitating or which result in/or prolong hospitalisation and/or are medically significant.
- 12.4 Limited safety information is obtained from clinical trials on new medicines and vaccines and further understanding about the safety of medicines depends on the availability of information from routine practice.
- 12.5 The Yellow Card Scheme is a voluntary scheme, through which healthcare professionals notify the Medicines and Healthcare products Regulatory Agency (MHRA)/Commission on Human Medicines (CHM) of suspected ADRs yellowcard.mhra.gov.uk.
- 12.6 Healthcare professionals are encouraged to report all suspected ADRs electronically. Hard copies of yellow cards are also acceptable and can be found in the back of the BNF or on-line.
- 12.7 When reporting a suspected ADR to a vaccine or biological medicine (such as blood products, antibodies and advanced therapies), in addition to the substance, reporters should provide the brand name (or product licence number and manufacturer), and the specific batch number, on the report.
- 12.8 Newly licensed medicines are monitored intensively by the MHRA/CHM and are identified by a black triangle symbol in the BNF. The MHRA/CHM encourage the reporting of all suspected ADRs to newly licensed medicines as well as ADRs in all other established medicines (including unlicensed products) and vaccines. Other areas of interest include herbal medicines, delayed drug effect and congenital abnormalities. The reporting of all suspected adverse drug reactions in children is strongly encouraged for all medicines.
- 12.9 The Bulletin 'Current Problems in Pharmacovigilance' issued by the MHRA/CHM contains advice and information on drug safety issues. It is available from the MHRA website www.mhra.gov.uk.

76 Belfast Health and Social Care Trust Community Medicines Code

13 Defective medicinal products

13.1 Recall of a defective medicine

13.1.1 Official notification of a defective medicine is issued to both Trust and community Pharmacies from the DHSSPS as a Drug Alert, or from the manufacturer or supplier. The Head of Pharmacy and Medicines Management is responsible for ensuring systems are in place to cascade Drug Alerts as appropriate within the Trust, and to facilities who have obtained the medicine from a Trust pharmacy, with a required timescale for action. The designated manager/appointed practitioner in charge of the department/facility are responsible for actioning Drug Alerts within the required timescale for action.

13.2 Reporting a defective medicine

- 13.2.1 If any member of staff has reason to believe that a medicine is defective, he or she must inform the supplying Trust or community Pharmacy immediately.
- 13.2.2 The person who discovers the defect must ensure that the product, container and other packaging are retained. If the defect has been discovered following reconstitution or mixing with another preparation, then the mixture, remaining unmixed constituents, and all containers and other packaging must also be retained.
- 13.2.3 All retained materials must be placed in a sealed container, clearly marked 'Do not use', and returned to the appropriate incident investigator as soon as possible.

14 Investigational medicinal products (IMPs)

- 14.1 An investigational medicinal product (IMP) is the pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial.
- 14.2 If a client should be on a clinical trial the continued supply of medication will be under the direction of the local hospital or GP. Any specific advice should be sought from those individuals.
- 14.3 Clients will have been provided with full information by the appropriate prescriber.
- 14.4 If a client in a residential setting is on a clinical trial this should be indicated on the medicines record/administration sheet or MAR.

15 Closure of a facility

- 15.1 Pharmacy should receive adequate notice of any temporary or permanent facility/department closure or relocation. Refer to Trust policy on
- 15.2 When a facility/department closes for a short period (<14 days), the medicines other than CDs, may stay in the facility/department provided there is adequate security to prevent unauthorised access to them. CDs must be returned in accordance with the Belfast Trust Community Controlled Drugs Policy.
- 15.3 Where a facility/department is closed for a long period (>14 days), all medicines and stationery used to order medicines from a Trust pharmacy department must be returned that pharmacy.
- 15.4 On permanent closure of a facility/department, medicines obtained from a Trust pharmacy department will be assessed for re-use and credit given. Stationery used to order medicines including current Trust prescription forms and requisition book must be returned to the Trust pharmacy department.
- 15.5 The facility/department manager is responsible for Records management and the retention/disposal of records in accordance with DHSSPS Good Management Good Records Schedule and BHSCT Records management policy.

16 Complementary/alternative therapies, homeopathy and herbal medicines

- 16.1 Service users may wish to receive one or more of homeopathic/herbal and complementary/alternative types of therapy.
- 16.2 It should be made clear to the client and recorded in the client's notes that the Trust cannot accept responsibility for the quality of this group of agents or any such items used by the client.
- 16.3 If a client or their carer, or a child's parent/guardian, wishes to administer or requests administration of complementary or alternative medicines they should discuss this with the doctor responsible for care. This discussion should, if possible, include the pharmacist and nurse looking after the client. It should take into account any possible interactions with prescribed medication and laboratory tests. Any possible contraindications should be explained to the person for the benefit of informed choice. If there is a conflict of interest and the person insists on continuing, the conflict should be documented in the care record.
- 16.4 In a residential setting, they must discuss this with their GP and staff will take directions from the GP in respect of this. It should be recorded on the medicines record/administration sheet or MAR and endorsed 'client's own'. Self administration procedures must be followed.
- 16.5 The Trust does not routinely supply complementary alternative therapies or homeopathy therapies except aromatherapy oils for use in oncology and haematology clients.
- 16.6 Where practitioners may wish to use homeopathic/herbal and complementary/alternative types of therapy to treat client, practitioners must have successfully undertaken appropriate training and be competent to practise such treatments.

17 Regional Medicines and Poisons Information Service

- 17.1 The Regional Medicines and Poisons Information Service, is based in the Trust on the Knockbracken site. It is operated by pharmacists and support staff and aimed at healthcare professionals across both hospital and community sectors.
- 17.2 NI Regional Medicines and Poisons Information: 028 950 40558 (Monday-Friday 9am- 5pm) or email: nirdic.nirdic@belfasttrust.hscni.net The Regional Medicines and Poisons Information Service provides an enquiry answering service on cases of poisoning including non-medicine poisoning e.g. household products, petrol or oil products, agricultural, industrial or garden chemicals and plants. It is part of the UK National Poisons Information Service (NPIS) that provides expert advice on all aspects of acute and chronic poisoning.
- 17.3 UK National Poisons Information Service (NPIS): 0344 892 0111 (this will divert calls to the Belfast centre Monday -Friday 9am- 5pm) and Out-of-Hours will divert to the NPIS providing cover on the national rota.

Belfast Health and Social Care Trust Community Medicines Code 🔲 🕴 79

Glossary of terms

| Administer | To administer to a human being 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). |
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| | Any suitably trained member of staff in health or social care can administer medicines against a valid prescription written by an authorised prescriber for an individual patient. The medicines can then only be given to that named patient. This principle applies to registered and non-registered staff at all levels. However, non-registered staff cannot administer medicines using a PGD and cannot train to prescribe medicines. |
| Adverse drug Reaction | An adverse drug reaction (ADR) is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs and is suspected to be related to the drug. The reaction may be a known side effect of the drug or it may be a new previously unrecognised ADR. |
| Adverse event | An adverse event is any undesirable experience that has happened to the client while taking a drug but may or may not be related to the drug. An adverse event is not always the same as an adverse drug reaction as adverse events encompass ADRs but may also include cases where no association has been or can be made between adverse drug administration and the adverse event experienced. Examples of an adverse event include a client being hit by a car while on a specific medication while an ADR could be a client experiencing anaphylaxis shortly after taking the drug; or a fall whilst taking a drug that can cause hypotension or confusion. |
| AHP | Allied Health Professional |
| Amber drugs (Amber list drugs) | A classification system which categorises therapies as those which should be started by a specialist prescriber, but may be transferred to primary care after the client has been stabilised on treatment. |
| Appointed practitioner in charge | A suitably qualified practitioner appointed in charge of a Team /clinic/ facility. This includes non medical professionals and managers with designated responsibility for the team / clinic / facility. |
| BNF | British National Formulary |
| Client | Any service user or patient who receives medical attention, care, or treatment. |
| Clinical trial | A carefully designed and controlled research study designed to test the safety and / or effectiveness of drugs, devices, treatments, or preventive measures in humans. |

80 Belfast Health and Social Care Trust Community Medicines Code

| Cold chain | Maintenance of the temperature of medicines, including vaccines, between 2 and 8°C at all times during storage and transport. This includes from the time of delivery up to the time of administration. |
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| Community practitioner nurse prescriber | For example district nurse, health visitor or school nurse, can independently prescribe from a limited formulary called the Nurse Prescribers' Formulary for Community Practitioners, which can be found in the British National Formulary (BNF). |
| CPN | Community Psychiatric Nurse |
| Complementary medicines | Complementary therapies, such as herbalism, homoeopathy and aromatherapy, involve the administration of unlicensed products such as herbal medicines, homoeopathic remedies and essential oils (used in aromatherapy). |
| Consultant | A fully trained specialist in a branch of medicine who accepts total responsibility for client care. |
| Controlled drugs (CDs) | Opioid or other medicines liable to misuse which are subject to special controls under the Misuse of Drugs Act 1971. |
| СОЅНН | Regulations covering Control of Substances Hazardous to Health. |
| Designated practitioner | Any registered practitioner identified by the appointed practitioner in charge as competent and appropriate to perform a specific function, (which has been communicated to and accepted by the designated practitioner). |
| Dispense | To make up or give out a clinically appropriate medicine to a client for self administration or administration by another, usually a professional. In the case of prescription only medicines, dispensing must be in response to a legally valid prescription. |
| | The act of dispensing is combined with advice about safe and effective use. OR |
| | To make up or give out a clinically appropriate medicine to a client for self administration or administration by another, usually a professional. In the case of prescription only medicines, dispensing must be in response to a legally valid prescription. |
| | The act of dispensing is combined with advice about safe and effective use. |
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Belfast Health and Social Care Trust Community Medicines Code 🔳 🕴 81

| Doctor | A medical practitioner fully registered with the General Medical Council (GMC). In BHSCT Medicines Code 'doctor' is also used to refer to medical practitioners with limited or provisional registration for whom certain restrictions apply. |
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| HS21 | Northern Ireland NHS prescription |
| Independent prescribers | Prescribing by a practitioner (e.g. doctor, dentist, nurse, and pharmacist) responsible and accountable for the assessment of clients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing. The practitioner can prescribe any licensed medicine within their clinical competence. Nurse and pharmacist independent prescribers can also prescribe unlicensed medicines and controlled drugs. |
| Illicit substance | A substance obtained illegally, that causes addiction, habituation, or a marked change in consciousness. |
| Licensed medicine | A medicine which falls within the definition of a medicinal product and which is granted a marketing authorisation by the Licensing Authority when the safety, quality and efficacy of the product have been satisfactorily demonstrated by the licence holder in accordance with EC directives 65/65. |
| Medicines administration record (MAR) | The client medicines administration record is not a prescription but a direction to administer medication. It authorises the delegation to administer medication on the prescriber's behalf. However, in doing so the registrant is accountable for their actions and for raising any concerns about the direction with the prescriber, for example, in respect to clarity. Also known as client administration chart. |
| Medication administration | a care or support worker - Involvement of the care or support worker in any of the following: helping the service user to identify the medication to be taken or applied; preparing the medication dose; and/or giving or applying the medication dose to the service user. |
| Medication assistance | a care or support worker - The act whereby a care or support worker reminds the service user to take or apply his or her medication. |
| Medication incident | Any preventable medication related event that could have or did lead to client harm, loss or damage. This definition encompasses 'near misses', that is, those medication related occurrences where the client did not suffer harm, but there was the potential for harm, loss or damage. |

82 Belfast Health and Social Care Trust Community Medicines Code

| 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 with a view to making a diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product'. |
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| Medicine | A medicine is defined as a substance introduced into the body, or externally applied to the body, for the purpose of treating disease, preventing disease, diagnosing disease, ascertaining the existence, degree or extent of a physiological condition, contraception, inducing general or regional anaesthesia, or otherwise preventing or interfering with the normal operation of a physiological function. |
| Midwife | A person who has completed a formal program of midwifery education and is registered with the Nursing and Midwifery Council. |
| Non-registered health care worker | A member of the care staff who is not registered with a professional body but who may have attained an NVQ qualification in care, undertaken a medicines module and be deemed competent and appropriate to perform a range of specific tasks. This may include auxiliary nurses, health care assistants or rehabilitation support workers. |
| NPSA | National Patient Safety Agency function has transferred to the NHS Commissioning Board Special Health Authority (the Board Authority) from 1 June 2012. It leads and contributes to improved, safe patient care by informing, supporting and influencing the health sector. |
| Nurse | A person who has completed a formal program of nursing education and is registered with the Nursing and Midwifery Council. |
| Nurse independent prescriber | Formally known as Extended Formulary Nurse Prescribers, are able to prescribe any medicine for any medical condition, including some controlled drugs for specific stated medical conditions. |
| Patient group directive (PGD) | Patient group directions are written instructions that permit certain trained groups of named healthcare professionals to supply and/or administer medicines, including prescription only medicines, without a doctor's prescription in an identified clinical situation. It applies to groups of clients who may not be individually identified before presenting for treatment. |

| Patient specific directive (PSD) | A patient specific direction is a written instruction from a doctor or dentist or other independent prescriber for a medicine to be supplied or administered to a named client e.g. a prescription or simple written instruction in the client's notes. |
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| Pharmaceutical Clinical Effectiveness (PCE) programme | The aim of Product Standardisation is for one brand of a medicine to be preferentially prescribed and dispensed both in primary and secondary care settings thereby promoting continuity of medicines use across the primary/secondary care interface. |
| Pharmacist | A person registered with the Pharmaceutical Society of Northern Ireland who is responsible for the safe, effective and efficient use of medicines. |
| Practitioner | Is a physician or other individual licensed in law to practise their profession. |
| Prescriber | Is a person authorised under the Medicines Act 1968 to order in writing the supply of a prescription only medicine for a named client. |
| Prescription only medicine (POM) | Medicines which may be sold or supplied from pharmacies in accordance with a prescription from a practitioner who is authorised to prescribe them. |
| PSNI | Police Service of Northern Ireland |
| Specialist medicines (red/ amber) | A classification system which categorises therapies which should be prescribed by specialist practitioners only, due to restrictions on the drug, e.g. long-term specialist monitoring required for efficacy or toxicity, designated as 'specialist- only' in the marketing authorisation, some clinical trial material. |
| Supplementary prescribers | Partnership between an independent prescriber (a doctor or a dentist) and a supplementary prescriber to implement an agreed Clinical Management Plan (CMP) for an individual client with that client's agreement. The supplementary prescriber may prescribe any medicine, including controlled drugs, for that client under the terms of the agreed CMP, until the next review by the independent prescriber. |
| Supply | To provide a medicine to a client/carer for administration. |
| Syringe pump | Formerly known as syringe driver |
| Unlicensed medicine | Is the term used to refer to a medicine that has no product licence. If an unlicensed medicine is administered to a client, the manufacturer does not have liability for any harm that ensues. The person who prescribes the medicine carries the liability. |

Belfast Health and Social Care Trust Community Medicines Code 🔳 🕴 85

Appendix 1



caring supporting improving together

Transfer of medicines information between care settings

| Client Details |
|---|
| |
| Client's Surname and Forename: |
| Date of Birth: |
| Gender: Male Female |
| Health and Care No: |
| Address: Tick which is applicable |
| Own home |
| Residential home |
| Nursing home |
| Other: |
| Contact Telephone Number – Tick which is applicable |
| Own |
| and Carer |
| Or Carer |
| |
| GP Details |
| |
| GP Name: GP Practice: |
| GP Practice Address: |
| GP Practice Telephone Number: |
| |
| Conditions (if known and/or appropriate) |
| |
| |
| |
| |
| |

Approved by BHSCT Drug and Therapeutics committee June 2010

| Medication Details - consider all medications (Include herbal, dressings, over the counter medication, oxygen etc.) | | | | | | | | | |
|---|----------------------------------|-------------------------------------|--|--|--|--|--|--|--|
| Medication name (generic name and brand where relevant eg. Nifedipine m/r (Coracten XL) | Dose and frequency eg. 30mg mane | Formulation/Route eg. capsules/oral | Any special storage requirements eg. store in fridge | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

| Medication Changes relat | ting to latest episode of car | е | |
|--------------------------|-------------------------------|---------------|-------------------|
| Drug started | Drug stopped | Dosage change | Reason for change |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| Allergies or adverse reactions to medicines (include any contraindications) | | | | | |
|---|---------------------------|--|--|--|--|
| Name of medicine | Type of reaction eg. rash | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

Additional information

Details of person completing record

Name: _____

Job title:

Date: _____

_____ Time:_____

Signature:____

87

Appendix 2

| atient name | : | | GP name | 9: | | | |
|---------------|---|-------------------|--------------------------------------|--------------|--------------|-------------------|-------------------------|
| Address/ward: | | | | Practice | address: _ | | |
| Post code: | DOB: | | | Post cod | e. | | <u>ع</u> . |
| | eets 'criteria' as listed in | | | | | | |
| Exception | | | | | | | |
| | Normal pathway of goo for >2 weeks and woun | | | | | ormulary dressing | has been in use |
| | Wound type: | | logicoo. | | | | |
| | Wound description and | duration: | | | | | |
| 1. | Signs of localised infect | ion: | | | Y/N - giv | e details: | |
| | Full history of dressings | and length tin | ne used: | | | | |
| | Rationale for dressing of | hange: | | | | | |
| 2. | Adverse reaction to a fo | ormulary dress | ing: | | Y/N - giv | e details: | |
| 3. | Product is required due status/special wound/s | | | ical | | | |
| Name of hos | spital identified to supply | | 5. | | | | |
| | | | | s for delive | | unt Facility | |
| | | | Size: | st be GP pro | actice or Tr | ust Facility | |
| | | | Quantity: | | | | |
| Product req | uested | | Frequency of change: | | | | |
| | | | Estimation of duration of treatment: | | | | |
| | | | Quantity | y requeste | d: | | |
| Name of req | uesting practitioner: | | [| Designatio | n: | Signature | e: |
| Contact Pho | ne No: | | Date: | | | | |
| | | | | | | | |
| Tick box i | if reordering for an existir | g patient | | | | | |
| | e supply of the above dre the Regional Wound Mar | | | | of alternati | ve/exception proc | ducts that have been |
| | - | • | | | | | |
| | norised person: | | - | | | | |
| ignature of a | authorised person: | | | | Date: | Tel. N | lo: |
| or Pharm | nacy use only | | | | | | |
| Item on a | pproval 'Alternative/exce | eptions' list for | wound m | nanageme | nt product | s 🗌 Authori | sed signatory (from lis |
| ate requisiti | ion received: | | | | | | |
| tom oodo | Unit of issue | Quantity a | upplied | Dianana | dby | Charlesd by | Data |
| tem code | Onic of issue | Quantity s | upplied | Dispense | eu by | Checked by | Date |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

Appendix 3

| | t Health an Care Trust | _ | Cloz | apine | e Pro | escri | ptioi | ו | |
|--|---|------------|-------------|---------------------------|------------|-----------------|----------------------------|-----------------------------|--|
| write in CAPI | | | addresso | graph | 774.9 | No [.] | | | |
| Name: | | | | | | | | | |
| Address: | | | | Blood sampling Frequency: | | | | | |
| Health and Care | No: | DOB: | | 414. | | eekly | E For | tnightly 4 Weekly | |
| Health and Care Consultant: | (| Check | Iden | ury | Dispe | nsing Freq | uency: | | |
| CPN Name & Ph | | | | | | eekly | E For | tnightly 4 Weekly | |
| Nard/Facility: _ | | | | | Hospital | /Location: _ | | | |
| Inpatient | Outpat | tient | | | | | | | |
| Clozapine collec | tion arrangem | ents: | | | | | | | |
| Special instructio | ons: | | | | | | | | |
| Drug name | | | | Dose | | Fre | quency | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | Any char | ges to the prescription mus | |
| notified to the di | spensing pha | rmacy imme | ediately ar | nd a new pr | escription | n supplied | | ges to the prescription mus | |
| notified to the di Signature of pre | spensing phanese scriber: | rmacy imme | ediately ar | nd a new pr | escription | Date: _ | | | |
| notified to the di Signature of pre Name in PRINT | spensing phanes | rmacy imme | ediately ar | nd a new pr | GMC No: | Date: _ | | Bleep No: | |
| notified to the di Signature of pre | spensing phan scriber: : tick) | rmacy imme | ediately ar | nd a new pr | GMC No: | Date: _ | | Bleep No: | |
| notified to the di Signature of pre Name in PRINT Grade: (Please | spensing phan scriber: : tick) | rmacy imme | ediately ar | nd a new pr | GMC No: | Date: _ | | Bleep No: | |
| notified to the di Signature of pre Name in PRINT Grade: (Please For Pharmacy | spensing phar scriber: tick) use only No. of 100mg | rmacy imme | ediately ar | Blood Status | GMC No: | Date: _ | gistrar Entered ZTAS | Bleep No: | |
| notified to the di Signature of pre Name in PRINT Grade: (Please For Pharmacy | spensing phar scriber: tick) use only No. of 100mg | rmacy imme | ediately ar | Blood Status | GMC No: | Date: _ | gistrar Entered ZTAS | Bleep No: | |
| notified to the di Signature of pre Name in PRINT Grade: (Please For Pharmacy | spensing phar scriber: tick) use only No. of 100mg | rmacy imme | ediately ar | Blood Status | GMC No: | Date: _ | gistrar Entered ZTAS | Bleep No: | |
| notified to the di Signature of pre Name in PRINT Grade: (Please For Pharmacy | spensing phar scriber: tick) use only No. of 100mg | rmacy imme | ediately ar | Blood Status | GMC No: | Date: _ | gistrar Entered ZTAS | Bleep No: | |
| notified to the di Signature of pre Name in PRINT Grade: (Please For Pharmacy | spensing phar scriber: tick) use only No. of 100mg | rmacy imme | ediately ar | blood Blood Status | GMC No: | Date: _ | gistrar Entered ZTAS | Bleep No: | |
| notified to the di Signature of pre Name in PRINT Grade: (Please For Pharmacy | spensing phar scriber: tick) use only No. of 100mg | rmacy imme | ediately ar | blood Blood Status | GMC No: | Date: _ | gistrar Entered ZTAS | Bleep No: | |
| notified to the di Signature of pre Name in PRINT Grade: (Please For Pharmacy | spensing phar scriber: tick) use only No. of 100mg | rmacy imme | ediately ar | blood Blood Status | GMC No: | Date: _ | gistrar Entered ZTAS | Bleep No: | |

Approved by BHSCT Drug and Therapeutics committee June 2010

HSC

Belfast Health and

Social Care Trust

Pharmaceutical Refrigerator Temperature Log

caring supporting improving together

(The temperature must be recorded at least once each day)

(pp8370-10305 of 20966) (this part 1936 pages)

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08)

| | Action | | | | | |
|---------------------|--------------------|--|--|--|--|--|
| Refrigerator Model: | Signed Ac | | | | | |
| Re | Confirm reset | | | | | |
| | Min temp °C | | | | | |
| ; | Max temp °C | | | | | |
| | Current temp °C | | | | | |
| | Time | | | | | |
| Ward/Department: | Date | | | | | |

Appendix 4



Consent for removal of unwanted medicines

| Client Name: | | |
|-------------------|--|--|
| | | |
| Client address: _ | | |

The medicines listed below are no longer required. To facilitate disposal, please sign this consent form for removal of medication.

I give consent for the medicines listed to be returned to an appropriate pharmacy, ie. community / Trust pharmacy (after 9pm Mon-Fri, after 5pm Sat, Sun and public holidays) for destruction. Yes No

| Signature of client / client's representative: | Date: |
|--|-------|
| Signature and designation of person removing the medicines listed below: | Date: |
| Signature and designation of witness (where available): | |
| | Date: |

| Medication to be removed (Drug name, strength, form) | Quantity | Name and address of receiving pharmacy | Signature of receiving pharmacist | Date received by pharmacy |
|---|----------|--|---|------------------------------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Continue overleaf if insufficient room in the above table.

Please file in client's notes upon completion.

Provide a copy to receiving Trust pharmacy.

MAHI - STM - 101 - 008645



TYPE OF DOCUMENT

Standards and Guidelines Committee

| ΤΙΤLΕ | Northern Ireland Clinical Pharmacy Standards |
|----------------------------|--|
| Summary | N.I. standards on the individual components of a clinical pharmacy services have been developed. |
| | 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. |
| | |
| Operational date | May 10 |
| Review date | December 11 |
| Version Number | Version 1.0 |
| Director Responsible | Jennifer Welsh |
| Lead Author | Contact Eimear McCusker on behalf of N.Ireland clinical pharmacy group |
| Lead Author, Position | Head of Pharmacy and Medicines Management |
| Department / Service Group | Cancer and Therapeutics |
| Contact details | Eimear McCusker |
| | Tel no. |
| Additional Author(s) | N/A |

| Reference Number | SG 27/10 |
|------------------|------------------------------------|
| Supercedes | Legacy site clinical pharmacy SOPs |

Drug and Therapeutics committee Northern Ireland clinical pharmacy standards V.1 – Sept 2010

Version Record

| Date | Version | Author | Comments |
|------------------------------|---------|-----------------|---|
| 4 th June 2010 | 0.1 | Eimear McCusker | Regional standards put into Trust standards template (Regional standards approved by D&T for use in Trust) |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Policy Record

| | | Date | Version |
|----------------------|----------|------|---------|
| Author (s) | Approval | | |
| Director Responsible | Approval | | |

Approval Process – Trust Policies

| Policy Committee | Approval | |
|------------------|-----------|--|
| Executive Team | Authorise | |
| Chief Executive | Sign Off | |

Approval Process – Clinical Standards and Guidelines

| Drug and Therapeutics committee | Approval | 7 th May | 1 |
|------------------------------------|-----------|---------------------|---|
| | | 2010 | |
| Standards and Guidelines Committee | Approval | 12/08/2010 | 1 |
| Policy Committee | Ratify | 20/09/2010 | 1 |
| Executive Team | Authorise | 23/09/2010 | 1 |
| Appropriate Director | Sign Off | 24/09/2010 | 1 |

Local Approval Process

| Approval | |
|----------|--|
| | |

Dissemination

| Areas : | |
|---------|--|
| | |
| | |

Drug and Therapeutics committee Northern Ireland clinical pharmacy standards V.1 – Sept 2010

| Summary | T N.I. standards on the individual components of a clinical pharmacy service have been developed. 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. |
|-------------------------|---|
| Title: | N. Ireland Clinical Pharmacy Standards |
| Purpose: | To standardise delivery of clinical pharmacy services in Belfast Trust |
| Objectives: | 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. |
| Policy Statement(s): | Clinical pharmacy relates to the safe, effective and economic use of medicines to the patient care journey at all stages. |

Jennifer Weish

Grear McCusher.

(p.p. N.Ireland Clinical Pharmacy Group)

Sept 2010

Director Jennifer Welsh

Sept 2010

Author Eimear McCusker

Full Description

| | N. Ireland Clinical Pharmacy Standards | | |
|----|--|--|--|
| 1. | Introduction: N.I. standards on the individual components of a clinical pharmacy service have been developed | | |
| 2. | Purpose Clinical pharmacy relates to the safe, effective and economic use of medicines to the patient care journey at all stages. These policies ensure standardisation of the process | | |
| 3 | The Scope: This standard applies to clinical pharmacy staff | | |
| 4 | Objectives:N.I. standards on the individual components of a clinical pharmacy services have been developed (Appendices 1 and 2).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. | | |
| 5 | Roles and Responsibilities All clinical pharmacy staff should be familiar with this standard. | | |
| 6 | The definition and background of the policy: Clinical pharmacy relates to the safe, effective and economic use of medicines to the patient care journey at all stages. These policies ensure standardisation of the process | | |
| 7 | Policy / Guideline description To standardise clinical pharmacy services in the trust | | |
| 8 | To improve the clinical pharmacy contribution to patient care through the development of a structured systematic approach to clinical pharmacy practice. | | |
| 9 | Implementation / Resource requirements: Standard Operating Procedures (SOPs) based on these Northern Ireland Clinical Pharmacy Standards will be developed by the Trust Pharmacy Executive Team. The Pharmacy Executive Team are currently self- assessing each site against the standards. This will lead to the development of a priority action plan | | |
| 10 | Source(s) / Evidence Base Meets best practice requirements – see references pgs 108-109 | | |

| 11 | References, including relevant external guidelines: |
|----|---|
| | See pages 108-109 |
| 12 | Consultation Process: |
| | Consulted widely throughout N. Ireland hospital pharmacy staff |
| 13 | Equality and Human Rights screening carried out: In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, the Belfast Trust has carried out an initial screening exercise to ascertain if this policy should be subject to a full impact assessment |
| | Screening completed No action required. |

Grear MCCusher.

Chief Executive / Director (delete as appropriate) Date: Author

Date:

24/08/2010

Appendix 1

NORTHERN IRELAND

CLINICAL PHARMACY STANDARDS

February 2009

Review date December 2011

CONTENTS

Introduction

9

No Standards

Acute

| 1 | Medicine History Interview | 10 |
|----|--|----|
| 2 | Medicine Therapy Monitoring | 14 |
| 3 | Prescription Monitoring and Review | 17 |
| 4 | Prevention, Detection, Assessment and Management of Adverse Drug Reactions | 20 |
| 5 | Prevention, Assessment and Management of Drug Interactions | 24 |
| 6 | Therapeutic Drug Monitoring | 27 |
| 7 | Prevention, identification, management and reporting of medication incidents | 30 |
| 8 | Multidisciplinary Working | 33 |
| 9 | Provision of Medicines Information Advice by Pharmacists | 35 |
| 10 | Discharge | 40 |
| 11 | Patient Medicine Education | 45 |
| | General Support | |
| 12 | Continuing Professional Development for pharmacists | 48 |
| 13 | Resources | 52 |
| 14 | Staffing Levels and Structure | 54 |
| 15 | Documentation | 57 |
| 16 | Quality of Clinical Pharmacy Services | 60 |
| 17 | Health Promotion | 63 |
| 18 | Pharmacoeconomic Evaluation of the use of Medicines | 65 |
| 19 | Pharmacist Led Clinics | 68 |
| 20 | Supplementary and Independent Prescribing | 72 |
| 21 | Communication | 75 |
| 22 | Self Administration of Medicines | 77 |

| 23 | Reuse of Patient's Own Medicines | 79 |
|----|---|-----|
| | Appendix 2 Sample Procedures | 81 |
| | Procedure for Medicine History Interview | 82 |
| | Patient Medicine History Tool | 84 |
| | Procedure for Prescription Monitoring and Review | 86 |
| | Procedure for Prevention, Detection, Assessment And Management of Adverse Drug Reactions | 88 |
| | Procedure for Prevention, Assessment and Management of Drug Interactions | 91 |
| | Procedure for Therapeutic Drug Monitoring | 92 |
| | Procedure for Multidisciplinary Working | 94 |
| | Procedure for Provision of Medicines Information Advice by Pharmacists | 95 |
| | Procedure for Discharge | 96 |
| | Procedure for Patient Medicine Education | 98 |
| | Glossary | 100 |
| | References | 101 |

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.

STANDARD 1 Medicine History Interview

Basic Standard Requirements

An accurate medicine history is obtained on admission to hospital.

A pharmacist shall obtain a medicine history from all patients and/ or their carers on admission. Where this is not possible for all patients, a pharmacist shall verify the medicine history obtained by another healthcare professional.

- 1.1 A local SOP exists of how to take a medicine history.
- 1.2 The SOP states where the medicine history is recorded.
- 1.3 A medicine history is documented or verified by a pharmacist by the next working day after admission to hospital.
- 1.4 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
- 1.5 The medicine history documents relevant recent vaccination history where applicable. This will depend on the age and presenting complaint of the patient.
- 1.6 The medicine history documents any known previous adverse drug reactions.
- 1.7 The medicine history documents any known allergies / sensitivities including non drug allergies/ sensitivities. The type of reaction is documented when known.
- 1.8 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

- 1.9 Any possible drug related admissions are identified and recorded.
- 1.10 Any history of previous or current non-concordance with therapy is documented.
- 1.11 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
 - 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:

- Compare the medicine history with the prescription chart(s) and investigate and record 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

An accurate medicine history is obtained on admission to hospital. A pharmacist shall obtain a medicine history on admission. A pharmacist shall verify the medicine history obtained by another healthcare professional.

| Indicators | Audit Result | | | Comments Action to be taken | Target Date | Completed |
|---|--------------|----------|-----|-----------------------------|----------------|-----------|
| Medicine History Interview | Y | <u>N</u> | N/A | | | |
| 1.1 A local SOP exists of how to take a medicine history. | | | | | | |
| 1.2 The SOP states where the medicine history is recorded. | | | | | | |
| 1.3 A medicine history is documented or verified by a pharmacist by the next working day after admission to hospital. | | | | | | |
| 1.4 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. | | | | | | |

| Indicators | Audit Result | | | Comments Action to be taken | Target Date | Completed |
|---|--------------|---|-----|-----------------------------|----------------|-----------|
| Medicine History Interview | Y | N | N/A | | | |
| 1.5 A vaccination history is documented where applicable. This will depend on the age and presenting complaint of the patient. | | | | | | |
| 1.6 The medicine history documents any known previous significant adverse drug reactions. | | | | | | |

| 1.7 The medicine history documents any known allergies / sensitivities including non drug allergies / sensitivities. The type of reaction is documented when known. | | | |
|--|--|--|--|
| 1.8 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. | | | |
| 1.9 Any possible drug related admissions are identified and recorded | | | |
| 1.10 Any history of previous or current non-concordance with therapy is documented. | | | |
| 1.11 The sources used to obtain the medicine history are documented. More than one source should be used. | | | |

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.
 - ACEI/ A11 antagonists
 - Antidepressants (including lithium)
 - Beta blockers
 - Clopidogrel
 - Digoxin
 - Diuretics
 - Injectables
 - Insulin
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Warfarin
 - 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.
- 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, lab 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

Medicine therapy monitoring encompasses a number of clinical pharmacy activities simultaneously including:

- Medicine History Interview (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 | <u>N</u> | N/A | | | |
| 2.1 A local SOP exists for medicine therapy monitoring. | | | | | | |
| 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

All 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
 Rehabilitation wards, community hospital once weekly wards
- Long stay psychiatric/ learning difficulties once a month
- 3.1 A local SOP exists for prescription monitoring and review.
- 3.2 All patients' prescription charts are monitored and reviewed by a pharmacist by the next working day after admission.
- 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
- 3.5 Pharmacists endorse prescriptions to add clarity to the original prescription, if applicable.
- 3.6 A local SOP exists for prescription endorsement by pharmacists.
- 3.7 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.

Advanced requirements

- 3.8 A pharmacist reviews all prescriptions for 'high risk' drugs (except in emergency situations) before the first dose is dispensed or administered.
- 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.

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 | Δ | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|---|----------|-----|-----------------------------|----------------|-----------|
| Prescription monitoring and review | Y | <u>N</u> | N/A | | | |
| 3.1 A local SOP exists for prescription monitoring and review. | | | | | | |
| 3.2 All patients' prescription charts are monitored and reviewed by a pharmacist by the next working day after admission. | | | | | | |
| 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. | | | | | | |
| 3.6 A local SOP exists for prescription endorsement by pharmacists. | | | | | | |

| Indicators | Audit Result | | | Comments Action to be taken | Target Date | Completed |
|--|--------------|----------|-----|-----------------------------|----------------|-----------|
| Prescription monitoring and review | Y | <u>N</u> | N/A | | | |
| 3.7 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. | | | | | | |

| 3.8 A pharmacist reviews all prescriptions for 'high risk' drugs (except in emergency situations) before the first dose is dispensed or administered. | | | |
|--|--|--|--|
| 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 | | ult | Comments Action to be taken | Target Date | Completed |
|--|--------------|----------|-----|-----------------------------|----------------|-----------|
| Prescription monitoring and review | Y | <u>N</u> | 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. | | | | | | |

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
 - ACEI/ A11 antagonists
 - Antidepressants (including lithium)
 - Beta blockers
 - Clopidogrel
 - Digoxin
 - Diuretics
 - Injectables
 - Insulin
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Warfarin

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 All 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 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
- 4.6 ADRs are documented in patients' medical notes or the patient's prescription chart according to local guidance to prevent re-exposure.
- 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 | <u>N</u> | 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 Appropriate ADRs are reported using the Yellow Card Scheme | | | | | | |
| 4.6 ADRs are documented in patients' medical notes or the patient's prescription chart according to local guidance to prevent re-exposure. | | | | | | |

| Indicators | Audit Result | | | Comments Action to be taken | Target Date | Completed |
|---|--------------|----------|-----|-----------------------------|----------------|-----------|
| Adverse Drug Reactions | Y | <u>N</u> | N/A | | | |
| 4.7 GPs are notified on discharge by the doctor or pharmacist of significant ADRs, their patients have experienced, when appropriate. | | | | | | |

| 4.8 Community pharmacists are notified by the pharmacist of significant ADRs, their patients have experienced, when appropriate. | | | |
|---|--|--|--|
| 4.9 Patients who have experienced serious reactions are provided with verbal information and if available written information or 'alert cards'. | | | |

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 | <u>N</u> | 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 | <u>N</u> | 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.
- 6.4 The clinical pharmacy services manager ensures that, where appropriate, TDM is carried out e.g. peer audit.

Advanced requirements

6.5 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 dependent 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 | A | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|---|----------|-----|-----------------------------|----------------|-----------|
| Therapeutic Drug Monitoring | Y | <u>N</u> | 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 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. | | | | | | |
| 6.4 The accountable clinical pharmacy lead ensures that, where appropriate, TDM is carried out e.g. peer audit. | | | | | | |

| Indicators | Audit Result | | | Comments Action to be taken | Target Date | Completed |
|--|--------------|----------|-----|-----------------------------|----------------|-----------|
| Therapeutic Drug Monitoring | Y | <u>N</u> | N/A | | | |
| 6.5 Pharmacists will specialise in TDM as appropriate. | | | | | | |

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 | А | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|---|----------|-----|-----------------------------|----------------|-----------|
| Medication Incidents | Y | <u>N</u> | 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 | <u>N</u> | 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

Wherever possible 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.
- 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.
 - Have clinical and communication skills.
 - 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

Whenever possible the pharmacist shall attend ward rounds and meetings as a member of the healthcare team.

| Indicators | Α | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|---|----------|-----|-----------------------------|----------------|-----------|
| Multidisciplinary Working | Y | <u>N</u> | 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. | | | | | | |
| 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 * | | | | | | |
| 8.3.4 Have clinical and communication skills * | | | | | | |
| 8.3.5 identify pharmaceutical care issues * | | | | | | |

*This is measured by pharmacist activity and intervention data

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 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. Medicines Information enquiry form and/or the patient's medical notes

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 | А | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|---|----------|-----|-----------------------------|----------------|-----------|
| Provision of Medicines Information and Advice | Y | <u>N</u> | 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 | Α | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|---|----------|-----|-----------------------------|----------------|-----------|
| Provision of Medicines Information and Advice | Y | <u>N</u> | N/A | | | |
| 9.5Pharmacists 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) | | | | | | |
| 9.9Pharmacists keep up to date with changes in medicinal products and therapeutic advances.(This is measured from pharmacist CPD records) | | | | | | |

| Indicators | Α | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|---|----------|-----|-----------------------------|----------------|-----------|
| Provision of Medicines Information and Advice | Y | <u>N</u> | 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. Medicines Information enquiry form and/or the patient's medical notes | | | | | | |
| 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

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 liaises 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 The pharmacist ensures that the patient is dispensed an appropriate quantity of medicines according to local guidance.
- 10.6 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

- 10.7 Pharmacists provide 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
 - A copy of this information is filed in the patient's medical notes or within pharmacy.
- 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 | A | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|---|----------|-----|-----------------------------|----------------|-----------|
| Discharge | Y | N | N/A | | | Completed |
| 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 liaises 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 | A | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|---|----------|-----|-----------------------------|----------------|-----------|
| Discharge | Y | <u>N</u> | N/A | | | |
| 10.5 The pharmacist ensures that the patient is dispensed an appropriate quantity of medicines according to local guidance. | | | | | | |
| 10.6 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 | | | | | | |
| 10.7 Pharmacists are involved in the provision of 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 A copy of this information is filed in the patient's medical notes or within the Pharmacy. | | | | | | |

| Indicators | Audit Result | | | Comments Action to be taken | Target Date | Completed |
|---|--------------|----------|-----|-----------------------------|----------------|-----------|
| Discharge | Y | <u>N</u> | 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. | | | | | | |

Patient Medicine Education

Basic Standard Requirements

Medicine education services shall be provided to all 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 Where other health care professionals provide patient medicine education pharmacists should guide and advise as appropriate

Advanced requirements

- 11.5 Medicine education should be documented in the patient's medical or multidisciplinary notes.
- 11.6 Patients are provided with verbal and 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 education eliminate barriers to providing it.

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 Where other health care professionals provide patient medicine education pharmacists should guide and advise as appropriate | | | | | | |
| 11.5 Medicine education is documented in the patient's medical or multidisciplinary notes | | | | | | |
| 11.6 Patients are provided with verbal and written information in a form they can understand | | | | | | |

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), inservice training and formal postgraduate diploma and degree courses.

Examples of CPD include formal courses and work shadowing.

- 12.1 A local SOP exists for the continuous professional development of pharmacists.
- 12.2 Pharmacists participate in and record at least 30 hours of Continuing Professional Development (CPD) each year.
- 12.3 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.
- 12.4 Pharmacists training needs and how these are met must be documented.
- 12.5 Pharmacists starting practice in a ward or department, which is unfamiliar to them should be provided with an orientation and training programme. This programme should be tailored to the experience and practice of the pharmacist and be co-ordinated by a suitably experienced pharmacist. The pharmacist's competency should be assessed.
- 12.6 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.
- 12.7 Where there is a defined role, pharmacists are trained as supplementary and independent prescribers in accordance with local procedure /practice.

Advanced Requirements

12.8 A standard induction programme for each area of clinical practice exists with a written record of competence of each component to ensure consistency of training

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-todate 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. As the regulatory body for pharmacists in Northern Ireland, the Pharmaceutical Society of Northern Ireland is currently considering possible models for revalidation.

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 | ļ | Audit Re | sult | Comments Action to be taken | Target Date | Completed |
|--|---|----------|------|-----------------------------|----------------|-----------|
| CPD | Y | <u>N</u> | 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 | ļ | Audit Re | sult | 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 | | | | | | |
| 12.6 Where there is a defined role pharmacists are trained as supplementary and independent prescribers in accordance with local procedure and practice | | | | | | |
| 12.7 Pharmacist competencies are reviewed on an ongoing basis for each area | | | | | | |

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
- 13.2 Information technology facilities
- 13.3 Appropriate work space and environment as per Estates standards
- 13.4 Support and resources for involvement in CPD activities, training and research
- 13.5 Appropriate staffing levels and structure (Standard 14). Is this considered adequate
- 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 | A | udit Res | ult | 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 has appropriate work space and environment as per Estates standards | | | | | | |
| 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). Is this considered adequate | | | | | | |
| 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 | <u>N</u> | 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 | | | | | | |

| Hospital Area | Pharmacist Ratio | Technician Ratio |
|--|---|--|
| General Medicine Cardiology Paediatrics Acute Psychiatry Acute Elderly Care General Surgery Oncology Inpatients Haematology Inpatients Other comparable specialities | 1 pharmacist per 40 beds (± 10 beds) | 1 technician per 40 beds (± 10 beds) |
| Maternity / Obs & Gynae ENT Orthopaedics Long stay Psychiatric Long stay learning difficulties Long stay Elderly Care Other comparable specialities | 1 pharmacist per 60 beds (± 10 beds) | 1 technician per 60 beds (± 10 beds) |
| ICU / ICCU / HDU PICU / Neonatal Renal Haemodialysis Other comparable specialities | 0.1 pharmacist per bed/ cot station | 0.1 technician per bed/ cot station |
| Accident and Emergency | 1 pharmacist per 100,000 attendances | 1 technician per 100,000 attendances |
| Cystic Fibrosis Patients HIV Patients Other comparable specialities | 0.3 pharmacist per 50 registered patients | 0.3 technician per 50 registered patients |
| Pharmacy led Clinics | 0.2 pharmacist per clinic | - |
| Specialist Teams | 0.5 pharmacist per team | - |
| Clinics - STD | 0.1 pharmacist per 1000 patient visits | - |

Table 1:Clinical Pharmacy Staffing Levels to Provide a Clinical
Pharmacy Service

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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
- · Response to patient specific questions from other members of the healthcare team
- 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 to 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 | Α | udit Res | ult | 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
- 16.2 Quality improvements are shared with other Trusts in Northern Ireland and the United Kingdom. This may be done through publications and presentations at local and national 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 | A | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|---|----------|-----|-----------------------------|----------------|-----------|
| Quality of Clinical Pharmacy Services | Y | <u>N</u> | 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 | <u>N</u> | N/A | | | |
| 16.2 Quality improvements are shared with other Trusts in Northern Ireland and the United Kingdom. This may be done through publications and presentations at local and national conferences. | | | | | | |

STANDARD 17 Health Promotion

Basic Standard Requirements

Pharmacists are involved in health promotion to achieve 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 by educating and ensuring that treatment is optimised to prevent further deterioration in health e.g. 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 wellbeing, 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 achieve health and prevent disease by helping individuals change attitudes to health damaging behaviour and encourage individuals to change their lifestyle.

| Indicators | A | udit Res | ult | 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** Target taken Date Completed Υ N/A Pharmacoeconomic Ν Evaluation of the use of Medicines 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 \square \square \square 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 | <u>N</u> | 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 Led Clinics

Basic Standard Requirements

Pharmacist Led Clinics are managed by pharmacists with appropriate knowledge, experience and training.

- 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 supplementary or independent 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.

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

Pharmacist led clinics encompasses a number of clinical pharmacy activities simultaneously including:

- Medicine History Interview (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 | A | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|---|----------|-----|-----------------------------|----------------|-----------|
| Pharmacist Led Clinics | Y | <u>N</u> | 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 supplementary or independent 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 | <u>N</u> | 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 | | | | | | |

STANDARD 20 Supplementary and Independent Prescribing

Basic Standard Requirements

Pharmacists who work as supplementary or independent 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 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 supplementary or independent 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."

Supplementary and Independent Prescribing

Pharmacists who work as supplementary or independent prescribers must have completed appropriate training and have their Trust's support to work within their field of practice.

| Indicators | Audit Result | | ult | Comments Action to be taken | Target Date | Completed |
|---|--------------|----------|-----|-----------------------------|----------------|-----------|
| Supplementary and Independent Prescribing | Y | <u>N</u> | 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 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 | | sult | Comments Action to be taken | Target Date | Completed |
|--|--------------|----------|------|-----------------------------|----------------|-----------|
| Supplementary and Independent Prescribing | Y | <u>N</u> | 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 | A | Audit Result | | Comments Action to be taken | Target Date | Completed |
|---|---|--------------|-----|-----------------------------|----------------|-----------|
| Communication | Y | <u>N</u> | 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 | Α | udit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|---|----------|-----|-----------------------------|----------------|-----------|
| Self administration of medicines | Y | <u>N</u> | 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 | | ult | Comments Action to be taken | Target Date | Completed |
|---|--------------|----------|-----|-----------------------------|----------------|-----------|
| Self administration of medicines | Y | <u>N</u> | 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 | | sult | Comments Action to be taken | Target Date | Completed |
|--|--------------|----------|------|-----------------------------|----------------|-----------|
| Reuse of Patient's Own Medicines | Y | <u>N</u> | 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 2

Sample Procedures

Procedure for Medicine History Interview

- 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 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.

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

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 | on: | | | |
|---------------------|--|------------------------------------|---|--------------------------------|
| Drugs prescribed I | by doctor: | | | |
| Drug name & form | Strength, dose, frequency, formulation | Information source ₁ | Patient concordant and medicines stored correctly | Supply at home ₂ |
| | | | Y/N | |
| (Continued overlea | af) | 1 | 1 | 1 |

Any additional information:

| Key: 1. GP – General Practitioner | | P – Patient C – Relative/ Carer |
|-----------------------------------|---------------|--|
| CP – Communit | ty 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 & | Strength, dose, | Information | Patient concordant | Supply |
| form | frequency | source ₁ | and medicines stored | at home ₂ |
| | | | correctly | |
| | | | Y/N | |
| | | | | |
| | | | Y/N | |
| | | | | |

| | Y/N | |
|--|-----|--|
| | Y/N | |
| | | |

| Non prescription m | edicine/ self-initiated n | nedicine (including homeopathic & herbal medicine) |
|--------------------|---------------------------|--|
| | | Y/N |
| | | |
| | | Y/N |
| | | Y/N |
| | | |
| | | Y/N |
| | | N/N |
| | | Y/N |

Drug related admission: Y/N

If YES give details:....

| Follow up required: | |
|---------------------|----------------|
| | |
| | |
| | (Diagon print) |

Pharmacist's Name:..... (Please print)

Signature: Date:.....

Procedure for Prescription Monitoring and Review.

The patient's prescription should be reviewed in conjunction with 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 anticoagulant charts, fluid balance chart and all of these must be reviewed. Recent consultations, clinical test 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 medicine 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 digoxin 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 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 as 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.
- 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 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 CP wants to raise
- Prepare the patient pharmaceutical care issues of 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, target patients who would benefit the most. These 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
 - ACEI/ A11 antagonists
 - Antidepressants (including lithium)
 - Beta blockers
 - Clopidogrel
 - Digoxin
 - Diuretics
 - NSAIDs
 - Opiates
 - Prednisolone
 - Warfarin
- 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 a 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 on education:

- 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

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. | | | | | |
| 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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HSC Belfast Health and Social Care Trust

| Title: | Northern Ire | Northern Ireland Clinical Pharmacy Standards | | | | | | | | |
|-------------------------|---|--|----------|-------------------|---|--|--|--|--|--|
| Author(s) | BHSCT | Eimear McCusker, Head of Pharmacy & Medicine Management, BHSCT on behalf of N. Ireland Clinical Pharmacy Group | | | | | | | | |
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| Date | Version | Author | Comments |
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| 20 th August 2012 | V2 | Julia Tolan | Formatted to regional policy template. Extension of review date to August 2013 Approved by Drugs and Therapeutics Committee |



1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

N.I. standards on the individual components of a clinical pharmacy service have been developed.

1.2 Purpose

Clinical pharmacy relates to the safe, effective and economic use of medicines to the patient care journey at all stages. These policies ensure standardisation of the process.

1.3 Objectives

N.I. standards on the individual components of a clinical pharmacy services have been developed (Appendices 1 and 2).

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.

2.0 SCOPE OF THE POLICY

This standard applies to clinical pharmacy staff.

3.0 ROLES/RESPONSIBILITIES

All clinical pharmacy staff should be familiar with this standard.

4.0 KEY POLICY PRINCIPLES

To standardise clinical pharmacy services in the Trust.

To improve the clinical pharmacy contribution to patient care through the development of a structured systematic approach to clinical pharmacy practice.

5.0 IMPLEMENTATION OF POLICY

Standard Operating Procedures (SOPs) based on these Northern Ireland Clinical Pharmacy Standards will be developed by the Trust Pharmacy Executive Team. The Pharmacy Executive Team are currently self-assessing each site against the standards. This will lead to the development of a priority action plan.

6.0 MONITORING

Clinical pharmacy indicators collected by each clinical pharmacist and reviewed by each clinical lead



7.0 <u>EVIDENCE BASE / REFERENCES</u> Meets best practice requirements – see references pgs 84-85

8.0 <u>CONSULTATION PROCESS</u> Consulted widely throughout N. Ireland hospital pharmacy staff.

9.0 <u>APPENDICES / ATTACHMENTS</u> Appendix 1: NI Clinical Pharmacy Standards.

Appendix 1. IN Clinical I narmacy Standar

10.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

Major impact

Minor impact

No impact. X

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

Grear MClusher.

Date: 05/06/2013

Author Head of Pharmacy and Medicines Management

Tenufly Weish

Date: 13/06/2013

Director Cancer & Specialist Services, Pharmacy Group



Appendix 1

NORTHERN IRELAND

CLINICAL PHARMACY STANDARDS

February 2013

Review date February 2015

Drug and Therapeutics committee Northern Ireland Clinical Pharmacy Standards_V2_June 13 BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages) Page 4 of 86 8750 of 10305



CONTENTS

| Intro | oduction |
|-------|--|
| No | Standards |
| | Acute |
| | |
| 1. | Medicine History Interview |
| 2. | Medicine Therapy Monitoring (Pharmaceutical Care) 12 |
| 3. | Prescription Monitoring and Review15 |
| 4. | Prevention, detection, assessment and management of adverse drug reactions |
| 5. | Prevention, Assessment and Management of Drug Interactions |
| 6. | Therapeutic Drug Monitoring23 |
| 7. | Prevention, identification, management and reporting of medication incidents |
| 8. | Multidisciplinary Working27 |
| 9. | Provision of Medicines Information Advice by Pharmacists |
| 10. | Discharge |
| 11. | Patient Medicine Education |

General Support

| 12. | Continuing Professional Development for Pharmacists | 39 |
|-----|---|----|
| 13. | Resources | 42 |
| 14. | Staffing Levels and Structure | 44 |
| 15. | Documentation | 46 |
| 16. | Quality of Clinical Pharmacy Services | 49 |



| 17. | Health Promotion | 51 |
|-----|---|----|
| 18. | Pharmacoeconomic Evaluation of the use of Medicines | 53 |
| 19. | Pharmacist Led Clinics | 55 |
| 20. | Supplementary and Independent Prescribing | 57 |
| 22. | Self Administration of Medicines | 63 |
| 23. | Reuse of Patient's Own Medicines | 65 |

Appendix 2

| Procedure for Discharge 8 | 30 |
|--|----|
| Procedure for Discharge | 30 |
| Procedure for the provision of Medicines Information Advice by Pharmacists 7 | |
| Procedure for Multidisciplinary Working7 | 78 |
| Procedure for Therapeutic Drug Monitoring7 | 77 |
| Procedure for the Prevention, Assessment and Management of Drug Interactions | 76 |
| Procedure for the prevention, detection, assessment and management of adverse drug reactions | 74 |
| Procedure for Prescription Monitoring and Review7 | 72 |
| Procedure for Medicine History Interview | 66 |
| Sample Procedures | 37 |



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 SOP



Belfast Health and Social Care Trust

STANDARD 1 Medicine History Interview

Basic Standard Requirements

An accurate medicine history is obtained on admission to hospital.

A pharmacist shall obtain a medicine history from all patients and/ or their carers on admission. Where this is not possible for all patients, a pharmacist shall verify the medicine history obtained by another healthcare professional.

- 1.1 A local SOP exists of how to take a medicine history.
- 1.2 The SOP states where the medicine history is recorded.
- 1.3 A medicine history is documented or verified by a pharmacist by the next working day after admission to hospital.
- 1.4 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
- 1.5 The medicine history documents relevant recent vaccination history where applicable. This will depend on the age and presenting complaint of the patient.
- 1.6 The medicine history documents any known previous adverse drug reactions.
- 1.7 The medicine history documents any known allergies / sensitivities including non drug allergies/ sensitivities. The type of reaction is documented when known.

1.8 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

- 1.9 Any possible drug related admissions are identified and recorded.
- 1.10 Any history of previous or current non-concordance with therapy is documented.
- 1.11 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
 - 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:

- Compare the medicine history with the prescription chart(s) and investigate and record 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

An accurate medicine history is obtained on admission to hospital. A pharmacist shall obtain a medicine history on admission. A pharmacist shall verify the medicine history

obtained by another healthcare professional.

| Indicators | Αι | udit Res | ult | Comments Action to be taken | Target Date | <u>Completed</u> |
|---|----|----------|-----|-----------------------------|----------------|------------------|
| Medicine History Interview | Y | N | N/A | | | |
| 1.1 A local SOP exists of how to take a medicine history | | | | | | |
| 1.2 The SOP states where the medicine history is recorded | | | | | | |
| 1.3 A medicine history is documented or verified by a pharmacist by the next working day after admission to hospital | | | | | | |
| 1.4 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 | | | | | | |
| 1.5 A vaccination history is documented where applicable. This will depend on the age and presenting complaint of the patient | | | | | | |
| 1.6 The medicine history documents any known previous significant adverse drug reactions | | | | | | |



| Indicators | Αι | ıdit Res | ult | Comments Action to be taken | Target Date | <u>Completed</u> |
|--|----|----------|-----|-----------------------------|----------------|------------------|
| Medicine History Interview | Y | N | N/A | | | |
| 1.7 The medicine history documents any known allergies / sensitivities including non drug allergies / sensitivities. The type of reaction is documented when known | | | | | | |
| 1.8 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. | | | | | | |
| 1.9 Any possible drug related admissions are identified and recorded | | | | | | |
| 1.10 Any history of previous or current non-concordance with therapy is documented | | | | | | |
| 1.11 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.
 - ACEI/ A11 antagonists
 - Antidepressants (including lithium)
 - Beta blockers
 - Clopidogrel
 - Digoxin
 - Diuretics
 - Injectables
 - Insulin
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Warfarin
 - 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.
- 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, lab 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.

Medicine therapy monitoring encompasses a number of clinical pharmacy activities simultaneously including:

- Medicine History Interview (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 | | | | | | |
| 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

All 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
- Intermediate stay wards
- Rehabilitation wards, community hospital wards
- Long stay psychiatric/ learning difficulties

once daily once weekly once weekly once a month

3.1 A local SOP exists for prescription monitoring and review.

3.2 All patients' prescription charts are monitored and reviewed by a pharmacist by the next working day after admission.

- 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.
- 3.5 Pharmacists endorse prescriptions to add clarity to the original prescription, if applicable.
- 3.6 A local SOP exists for prescription endorsement by pharmacists.
- 3.7 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.

Advanced requirements

- 3.8 A pharmacist reviews all prescriptions for 'high risk' drugs (except in emergency situations) before the first dose is dispensed or administered.
- 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.

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 All patients' prescription charts are monitored and reviewed by a pharmacist by the next working day after admission | | | | | | |
| 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 | | | | | | |
| 3.6 A local SOP exists for prescription endorsement by pharmacists | | | | | | |
| 3.7 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 | | | | | | |



| 3.8 A pharmacist reviews all prescriptions for 'high risk' drugs (except in emergency situations) before the first dose is dispensed or administered | | | | | | |
|---|--|--|--|--|--|--|
|---|--|--|--|--|--|--|

| Indicators | Audit Result | | | Comments Action to be taken | Target Date | Completed |
|---|--------------|---|-----|-----------------------------|----------------|-----------|
| Prescription monitoring and review | Y | N | N/A | | | |
| 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 medication related discussions is made in the patient's medical notes / charts or pharmacy records/ profiles as appropriate | | | | | | |



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
 - ACEI/ A11 antagonists
 - Antidepressants (including lithium)
 - Beta blockers
 - Clopidogrel
 - Digoxin
 - Diuretics
 - Injectables
 - Insulin
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Warfarin
 - 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 All 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 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.
- 4.6 ADRs are documented in patients' medical notes or the patient's prescription chart according to local guidance to prevent re-exposure.
- 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 | Αι | ıdit Res | ult | 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 Appropriate ADRs are reported using the Yellow Card Scheme | | | | | | |
| 4.6 ADRs are documented in patients' medical notes or the patient's prescription chart according to local guidance to prevent re-exposure | | | | | | |
| 4.7 GPs are notified on discharge by the doctor or pharmacist of significant ADRs, their patients have experienced, when appropriate | | | | | | |
| 4.8 Community pharmacists are notified by the pharmacist of significant ADRs, their patients have experienced, when appropriate | | | | | | |
| 4.9 Patients who have experienced serious reactions are provided with verbal information and if available written information or 'alert cards' | | | | | | |

Drug and Therapeutics committee Northern Ireland Clinical Pharmacy Standards_V2_June 13 BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)



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 | Au | udit Res | ult | 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 | | | | | | |
| 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.
- 6.4 The clinical pharmacy services manager ensures that, where appropriate, TDM is carried out e.g. peer audit.

Advanced requirements

6.5 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 dependent 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 | Αι | ıdit Res | ult | 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 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 | | | | | | |
| 6.4 The accountable clinical pharmacy lead ensures that, where appropriate, TDM is carried out e.g. peer audit | | | | | | |
| 6.5 Pharmacists will specialise in TDM as appropriate | | | | | | |



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

| Indicators | Au | ıdit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|----|----------|-----|-----------------------------|----------------|-----------|
| Medication Incidents | Ŷ | 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 | | | | | | |
| 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

Wherever possible 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.
- 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
 - have clinical and communication skills
 - 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

Whenever possible the pharmacist shall attend ward rounds and meetings as a member of

| Indicators | Αι | udit Res | ult | 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 | | | | | | |
| 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 * | | | | | | |
| 8.3.4 Have clinical and communication skills * | | | | | | |
| 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 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. Medicines Information enquiry form and/or the patient's medical notes.

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 | Αι | udit Res | ult | 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) | | | | | | |
| 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) | | | | | | |



| Indicators | Audit | Result | | Comments Action to be taken | Target Date | Completed |
|--|-------|--------|-----|-----------------------------|----------------|-----------|
| Provision of Medicines Information and Advice | Y | N | N/A | | | |
| 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) | | | | | | |
| 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. Medicines Information enquiry form and/or the patient's medical notes | | | | | | |
| 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 liaises 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 The pharmacist ensures that the patient is dispensed an appropriate quantity of medicines according to local guidance.
- 10.6 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

- 10.7 Pharmacists provide 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

A copy of this information is filed in the patient's medical notes or within pharmacy.

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

| Indicators | Αι | ıdit Res | ult | 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 liaises 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 The pharmacist ensures that the patient is dispensed an appropriate quantity of medicines according to local guidance | | | | | | |
| 10.6 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 | | | |
| 10.7 Pharmacists are involved in the provision of 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 A copy of this information is filed in the patient's medical notes or within the Pharmacy | | | | | | |
| 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 | | | | | | |



Social Care Trust

STANDARD 11 Patient Medicine Education

Basic Standard Requirements

Medicine education services shall be provided to all patients or their carers where appropriate. If this is not possible categories of patients where maximal benefit is likely should be identified.

- A local SOP exists for patient medicine education. The SOP identifies patients who would 11.1 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.
- Where other health care professionals provide patient medicine education pharmacists should 11.4 guide and advise as appropriate.

Advanced requirements

- 11.5 Medicine education should be documented in the patient's medical or multidisciplinary notes.
- 11.6 Patients are provided with verbal and 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 education eliminate barriers to providing it.



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 | Α | udit Re | sult | 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 Where other health care professionals provide patient medicine education pharmacists should guide and advise as appropriate | | | | | | |
| 11.5 Medicine education is documented in the patient's medical or multidisciplinary notes | | | | | | |
| 11.6 Patients are provided with verbal and 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), inservice training and formal postgraduate diploma and degree courses.

Examples of CPD include formal courses and work shadowing.

- 12.1 A local SOP exists for the continuous professional development of pharmacists.
- 12.2 Pharmacists participate in and record at least 30 hours of Continuing Professional Development (CPD) each year.
- 12.3 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
- 12.4 Pharmacists training needs and how these are met must be documented.
- 12.5 Pharmacists starting practice in a ward or department, which is unfamiliar to them should be provided with an orientation and training programme. This programme should be tailored to the experience and practice of the pharmacist and be co-ordinated by a suitably experienced pharmacist. The pharmacist's competency should be assessed.
- 12.6 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.
- 12.7 Where there is a defined role, pharmacists are trained as supplementary and independent prescribers in accordance with local procedure /practice.

Advanced Requirements

12.8 A standard induction programme for each area of clinical practice exists with a written record of competence of each component to ensure consistency of training.

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-todate and can demonstrate that they continue to meet the requirements of their professional regulator'

HSC Belfast Health and Social Care Trust

(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. As the regulatory body for pharmacists in Northern Ireland, the Pharmaceutical Society of Northern Ireland is currently considering possible models for revalidation.

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 | A | udit Re | sult | 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 | | | | | | |
| 12.5 Education and training outcomes of pharmacists are reflected in practice and improvement in the quality of pharmaceutical care | | | | | | |
| 12.6 Where there is a defined role pharmacists are trained as supplementary and independent prescribers in accordance with local procedure and practice | | | | | | |



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.
- 13.2 Information technology facilities.
- 13.3 Appropriate work space and environment as per Estates standards.
- 13.4 Support and resources for involvement in CPD activities, training and research.
- 13.5 Appropriate staffing levels and structure (Standard 14). Is this considered adequate.
- 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 | Αι | udit Res | ult | 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 has appropriate work space and environment as per Estates standards | | | | | | |
| 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). Is this considered adequate | | | | | | |
| 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.

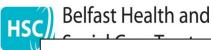
| Indicators | Audit Result | | | Comments Action to be taken | Target Date | Completed |
|--|--------------|---|-----|-----------------------------|----------------|-----------|
| Staffing Structure and Levels | Y | N | N/A | | | |
| 14.1 Adequate staff levels are established and maintained to provide 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 |
|--|---|---|
| General Medicine Cardiology Paediatrics Acute Psychiatry Acute Elderly Care General Surgery Oncology Inpatients Haematology Inpatients Other comparable specialities | 1 pharmacist per 40 beds (± 10 beds) | 1 technician per 40 beds (± 10 beds) |
| Maternity / Obs & Gynae ENT Orthopaedics Long stay Psychiatric Long stay learning difficulties Long stay Elderly Care Other comparable specialities | 1 pharmacist per 60 beds (± 10 beds) | 1 technician per 60 beds (± 10 beds) |
| ICU / ICCU / HDU PICU / Neonatal Renal Haemodialysis Other comparable specialities | 0.1 pharmacist per bed/ cot station | 0.1 technician per bed/ cot station |
| Accident and Emergency | 1 pharmacist per 100,000 attendances | 1 technician per 100,000 attendances |
| Cystic Fibrosis Patients HIV Patients Other comparable specialities | 0.3 pharmacist per 50 registered patients | 0.3 technician per 50 registered patients |
| Pharmacy led Clinics | 0.2 pharmacist per clinic | - |
| Specialist Teams | 0.5 pharmacist per team | - |
| Clinics - STD | 0.1 pharmacist per 1000 patient visits | - |



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
 - response to patient specific questions from other members of the healthcare team
 - 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 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.
- 15.6 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 to 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 | Αι | ıdit Resi | ult | 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
- 16.2 Quality improvements are shared with other Trusts in Northern Ireland and the United Kingdom. This may be done through publications and presentations at local and national 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 | Au | udit Res | ult | 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 | | | |
| 16.2 Quality improvements are shared with other Trusts in Northern Ireland and the United Kingdom. This may be done through publications and presentations at local and national conferences | | | | | | |



STANDARD 17

Health Promotion

Basic Standard Requirements

Pharmacists are involved in health promotion to achieve 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 by educating and ensuring that treatment is optimised to prevent further deterioration in health e.g. 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 wellbeing, 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 achieve health and prevent disease by helping individuals change attitudes to health damaging behaviour and encourage individuals to change their lifestyle.

| Indicators | Au | dit Res | ult | 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 Led Clinics

Basic Standard Requirements

Pharmacist Led Clinics are managed by pharmacists with appropriate knowledge, experience and training.

- 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 supplementary or independent 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.
- 19.7 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.

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

Pharmacist led clinics encompasses a number of clinical pharmacy activities simultaneously including:

- Medicine History Interview (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 | Αι | ıdit Res | ult | 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 supplementary or independent 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 | | | | | | |
| 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 | | | | | | |



STANDARD 20 Supplementary and Independent Prescribing

Basic Standard Requirements

Pharmacists who work as supplementary or independent 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 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 supplementary or independent 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."



Supplementary and Independent Prescribing

Pharmacists who work as supplementary or independent prescribers must have completed appropriate training and have their Trust's support to work within their field of practice.

| Indicators | Αι | ıdit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|----|----------|-----|-----------------------------|----------------|-----------|
| Supplementary and Independent Prescribing | 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 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 | Au | Audit Result | | Comments Action to be taken | Target Date | Completed |
|--|----|--------------|-----|-----------------------------|----------------|-----------|
| Supplementary and Independent Prescribing | 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 | Αι | ıdit Res | ult | 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 adrenoreceptor 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 | Au | dit Res | sult | 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 | | | | | | |
| 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 | Αι | ıdit Res | ult | 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 2

Sample Procedures

Regional Policy Template - V1.2 – 16/04/2012 BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)



Procedure for Medicine History Interview

- 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 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.



MEDICINE HISTORY INTERVIEW TOOL

| Patient name: DOB: | GP name: |
|--|-----------------------|
| Address: | Address: |
| | Community Pharmacist: |
| Hosp. No. | |
| | |
| Patient able to communicate appropriately: V/N | |

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 | |
| (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, | Information | Patient | Supply at home ₂ |
| | frequency | source ₁ | concordant | |
| | | | and medicines | |
| | | | stored correctly | |
| | | | Y/N | |
| | | | | |
| | | | Y/N | |
| | | | | |
| | | | Y/N | |
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| | | | Y/N | |
| | | | | |
| | | | Y/N | |
| | | | | |

| | Y/N | |
|------|-----|--|
| | Y/N | |
| | Y/N | |
| | Y/N | |
| | Y/N | |

Drug related admission: Y/N

If YES give details:....

Follow up required:

Pharmacist's Name:..... (Please print)

Signature: Date:....



Procedure for Prescription Monitoring and Review.

The patient's prescription should be reviewed in conjunction with 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 anticoagulant charts, fluid balance chart and all of these must be reviewed. Recent consultations, clinical test 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 medicine 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 digoxin 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 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 as 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
- 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 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 CP wants to raise.
- Prepare the patient pharmaceutical care issues of 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.

<u>Medicines information enquiries should be recorded and filed according to local policy in an</u> 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:

The information communicated should inclu

- 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, target patients who would benefit the most. These 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:
 - ACEI/ A11 antagonists
 - Antidepressants (including lithium)
 - Beta blockers
 - Clopidogrel
 - Digoxin
 - Diuretics
 - NSAIDs
 - Opiates
 - Prednisolone
 - Warfarin
- 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.

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- 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 drugtest/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 on education:

- 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.



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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. | | |
| 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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Reference No: SG 27/10

| Title: | Northern Ireland Clinical Pharmacy Standards | | | | | |
|-------------------------|--|------------|-------------------|-------------------|--|--|
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| Links to other policies | | | | | | |

| Date | Version | Author | Comments |
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| 20/08/2012 | V2 | Julia Tolan | Formatted to regional policy template. Extension of review date to August 2013. Approved by D&T |
| 15/05/2014 | V3 | Catherine Graham & Caitriona Donnelly | 2013 Northern Ireland Clinical Pharmacy Standards approved by Regional Heads of Pharmacy and formatted into Trust Standards template |

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

The Northern Ireland Standards on the individual components of a clinical pharmacy service were developed in 2010, incorporated into practice and have been subsequently reviewed.

1.2 Purpose

Clinical Pharmacy relates to the safe, effective and economic use of medicines to the patient care journey at all stages. This policy ensures standardisation of the process.

1.3 Objectives

Northern Ireland Standards on the individual components of a clinical pharmacy service were developed in 2010, incorporated into practice and subsequently reviewed.

The principle objective of this document is to improve the clinical pharmacy contribution to patient care through the development of a structured approach to clinical pharmacy practice.

2.0 SCOPE OF THE POLICY

This standard applies to all clinical pharmacy staff and those staff on rotation through clinical pharmacy services.

3.0 ROLES/RESPONSIBILITIES

All clinical pharmacy staff and those on rotation through clinical pharmacy services should be familiar with these standards.

4.0 <u>KEY POLICY PRINCIPLES</u> Policy Principles

4.1 To standardise clinical pharmacy services in the Trust To improve the clinical pharmacy contribution to patient care through the development of a structured systematic approach to clinical pharmacy practice.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

All clinical pharmacy staff and those on rotation through clinical pharmacy services should be familiar with this standard and use the SOPS linked with these standards

5.2 Resources

Trust Clinical Pharmacy Standard Operating Procedures currently in place will be reviewed in light of these new standards. The Trust Clinical Pharmacy Leads will lead on this.

5.3 Exceptions

Not applicable

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6.0 <u>MONITORING</u>

Clinical pharmacy indicators are collected by clinical pharmacy staff on a regular basis and are reviewed by the Clinical Pharmacy Leads.

7.0 EVIDENCE BASE / REFERENCES

These Standards meet best practice requirements – see references pages 116-117

8.0 CONSULTATION PROCESS

A wide consultation was undertaken throughout all hospital pharmacies in Northern Ireland.

9.0 APPENDICES / ATTACHMENTS

Appendix 1: Northern Ireland Clinical Pharmacy Standards 2013

10.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

Major impact

Minor impact

No impact. X

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NORTHERN IRELAND CLINICAL PHARMACY STANDARDS

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3

CONTENTS

Introduction

No Standards

<u>Acute</u>

| 1 | Medicine History Interview and Medicines Reconciliation | 5 |
|------------|--|----|
| 2 | Medicine Therapy Monitoring | 11 |
| 3 | Prescription Monitoring and Review | 14 |
| 4 | Prevention, Detection, Assessment and Management of Adverse Drug Reactions | 19 |
| 5 | Prevention, Assessment and Management of Drug Interactions | 24 |
| 6 | Therapeutic Drug Monitoring | 27 |
| 7 | Prevention, identification, management and reporting of medication incidents | 29 |
| 8 | Multidisciplinary Working | 32 |
| 9 | Provision of Medicines Information Advice by Pharmacists | 34 |
| 10 | Discharge | 40 |
| 11 | Patient Medicine Education | 45 |
| <u>Gen</u> | eral Support | |
| 12 | Education and Training | 49 |
| 13 | Resources | 53 |
| 14 | Staffing Levels and Structure | 56 |
| 15 | Documentation | 60 |
| 16 | Quality of Clinical Pharmacy Services | 63 |
| 17 | Health Promotion | 66 |
| 18 | Pharmacoeconomic Evaluation of the use of Medicines | 68 |

Drugs and Therapeutics Committee_ NI Clinical Pharmacy Standards_V3_2014

Page 5 of 116

| 19 | Pharmacist Led | Clinics | 71 |
|----|------------------------------------|---|-----|
| 20 | Supplementary a | and Independent Prescribing | 75 |
| 21 | Communication | | 79 |
| 22 | Self Administration | on of Medicines | 81 |
| 23 | Reuse of Patient | 's Own Medicines | 84 |
| | Appendix 1 | Sample Procedures | 86 |
| | Procedure for Me | edicine History Interview | 87 |
| | Patient Medicine | e History Tool | 89 |
| | Procedure for Pr | escription Monitoring and Review | 91 |
| | | evention, Detection, Assessment nt of Adverse Drug Reactions | 93 |
| | | evention, Assessment and Drug Interactions | 96 |
| | Procedure for Th | nerapeutic Drug Monitoring | 97 |
| | Procedure for M | ultidisciplinary Working | 99 |
| | Procedure for Pr by Pharmacists | ovision of Medicines Information Advice | 100 |
| | Procedure for Di | scharge | 101 |
| | Procedure for Pa | atient Medicine Education | 104 |
| | Appendix 2 | Northern Ireland timings | 107 |
| | Glossary | | 112 |
| | References | | 114 |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V3_2014

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 | Au | dit Res | sult | 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 | Au | dit Res | sult | 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 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 | Au | dit Res | sult | 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
 - Injectables
 - Insulin/ oral hypoglycaemics
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Anticoagulants/ Warfarin,
 - Antibiotics
 - Antiparkinson drugs
 - Antiepileptics
 - Clozapine
 - Potassium
 - 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
- Prevent omitted does 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 | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|-----|-----------------------------|----------------|-----------|
| Medicine Therapy Monitoring | Y | Ν | 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:

| ٠ | Acute wards | once daily |
|---|--|--------------|
| ٠ | Intermediate stay wards | once weekly |
| • | Rehabilitation wards, community hospital wards | once weekly |
| ٠ | 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 nonadministration 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
 - Injectables
 - Insulin/ oral hypoglycaemics
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Anticoagulants/ Warfarin,
 - Antibiotics
 - Antiparkinson drugs
 - Antiepileptics
 - Clozapine
 - Potassium

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.

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V3_2014

Prescription Monitoring and Review

Patients' prescription charts are monitored and reviewed by a pharmacist at regular intervals.

| Indicators | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|-----|-----------------------------|----------------|-----------|
| Prescription monitoring and review | Y | Ν | 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 | Au | dit Res | sult | 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 | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|-----|-----------------------------|----------------|-----------|
| Prescription monitoring and review | Y | Ν | 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 cotrimoxazole 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
 - Injectables
 - Insulin/ oral hypoglycaemics
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Anticoagulants/ Warfarin,
 - Antibiotics
 - Antiparkinson drugs
 - Antiepileptics
 - Clozapine
 - Potassium
 - 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|------|-----------------------------|----------------|-----------|
| Adverse Drug Reactions | Y | Ν | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Adverse Drug Reactions | Y | Ν | 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 | Aud | dit Res | ult | 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 | Ν | 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 dependent 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 | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|-----|-----------------------------|----------------|-----------|
| Therapeutic Drug Monitoring | Y | Ν | 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 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. | | | | | | |
| 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Medication Incidents | Y | Ν | 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 | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|-----|-----------------------------|----------------|-----------|
| Medication Incidents | Y | Ν | 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 | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|-----|-----------------------------|----------------|-----------|
| Multidisciplinary Working | Y | Ν | 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 | Au | dit Res | sult | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Provision of Medicines Information and Advice | Y | Ν | 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 | Au | dit Res | sult | 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 liaises 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|------|-----------------------------|----------------|-----------|
| Discharge | Y | Ν | 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 liaises 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 | | | | | | |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V3_2014

| Indicators | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Discharge | Υ | Ν | 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 | Ν | 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 | Au | dit Re | sult | Comments Action to be taken | Target Date | Completed |
|--|----|--------|------|-----------------------------|----------------|-----------|
| Patient Medicine Education | Y | Ν | 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 | Ν | 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 | Au | dit Re | esult | Comments Action to be taken | Target Date | Completed |
|---|----|--------|-------|-----------------------------|----------------|-----------|
| CPD | Y | Ν | 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 | Au | dit Re | sult | Comments Action to be taken | Target Date | Completed |
|--|----|--------|------|-----------------------------|----------------|-----------|
| Education and Training | Υ | Ν | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Resources | Y | Ν | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Staffing Structure and Levels | Y | Ν | 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 | Pharmacist time per | Technician time per | NI timings 2012 |
| Orthopaedics | admission 80 minutes | admission 64 minutes | (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 50 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 | 0.1 technician 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 | Ν | 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 | Ν | 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 | Ν | 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 | Ν | 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 | Au | idit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|----|----------|-----|-----------------------------|----------------|-----------|
| Pharmacoeconomic evaluation of the use of medicines | Y | Ν | 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 | Aud | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|-----|---------|------|-----------------------------|----------------|-----------|
| Pharmacoeconomic evaluation of the use of medicines | Y | Ν | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Comple ted |
|---|----|---------|------|-----------------------------|----------------|---------------|
| Pharmacist led clinics | Y | Ν | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Comple ted |
|---|----|---------|------|-----------------------------|----------------|---------------|
| Pharmacist led clinics | Y | Ν | 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 | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|-----|-----------------------------|----------------|-----------|
| Non Medical Prescribing (Pharmacists) | Y | Ν | 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 | Au | dit Res | sult | 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 | | sult | Comments Action to be taken | Target Date | Completed |
|---|--------------|---|------|-----------------------------|----------------|-----------|
| Communication | Y | Ν | 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 | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|-----|-----------------------------|----------------|-----------|
| Self administration of medicines | Y | Ν | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|------|-----------------------------|----------------|-----------|
| Self administration of medicines | Y | Ν | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|------|-----------------------------|----------------|-----------|
| Reuse of Patient's Own Medicines | Y | Ν | 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 | | | | | | |

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Appendix 1

Sample Procedures

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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 medicinerelated 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.

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 & | Strength, dose, | Information | Patient concordant | Supply | | |
| form | frequency, | source ₁ | and medicines | at | | |
| | formulation | | stored correctly | home ₂ | | |
| | | | Y/N | | | |
| | | | | | | |
| | | | Y/N | | | |
| | | | | | | |
| | | | Y/N | | | |
| | | | | | | |
| | | | Y/N | | | |
| | | | | | | |

(Continued overleaf)

Any additional information:

 Key: 1. GP – General Practitioner CP – Community Pharmacist
 P – Patient NH – Nursing Home O – Other

 (please specify)
 2. H – Home W – Ward
 D/C – Discontinued medicine

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| Drugs on Admis | ssion: ed by doctor contin | ued: | | |
|----------------|-------------------------------|---------------------|--------------------|-------------------|
| Drug name & | Strength, dose, | Information | Patient concordant | Supply |
| form | frequency | source ₁ | and medicines | at |
| | | | stored correctly | home ₂ |
| | | | Y/N | |

| Non prescription medicine/ self-initiated medicine (including homeopathic & herbal medicine) | | | | |
|--|-----|--|--|--|
| | Y/N | | | |

Drug related admission: Y/N

If YES give details:

Follow up required:

Pharmacist's/ Technician Name:.....(Please print)

Signature: Date:.....

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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

<u>Medicines information enquiries should be recorded and filed</u> <u>according to local policy in an easily retrievable manner to allow</u> <u>access by other users and to prevent duplication.</u> 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
 - Injectables
 - Insulin/ oral hypoglycaemics
 - -Methotrexate
 - -NSAIDs
 - Opiates
 - Prednisolone
 - -Anticoagulants/Warfarin,
 - -Antibiotics
 - Antiparkinson drugs
 - Antiepileptics
 - Clozapine
 - Potassium

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, drugalcohol 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 Admission28minsInpatient Monitoring5.23 x 6.54 = 34mins (basedon LOS* 6.54days)9Medicines Reconciliation at Discharge + Prep35minsDischarge Counselling5mins

Total

102mins per patient

Technician time spent on a standard medical patient

Drug History on Admission Stocking OSD drawer on Admission Inpatient Kardex Review on LOS* 6.54days) Discharge Prep and check 5mins 10mins 5.186 x 6.54 = 34mins (based

Total

34mins

83mins per patient

79.5mins per patient

Surgical wards (including Trauma & Orthopaedics)

Pharmacist time spent on a standard surgical patient

| Medicines Reconciliation on Admission | 25.5mins |
|--|-----------------------------|
| Inpatient Monitoring | 5.23 x 4.72 = 25mins (based |
| on LOS* 4.72days) Medicines Reconciliation at Discharge + Prep Discharge Counselling | 24mins 5mins |

Total

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Technician time spent on a standard surgical patient

Drug History on Admission Stocking OSD drawer on Admission Inpatient Kardex Review on LOS* 4.72days) Discharge Prep and check

5mins 10mins 5.18 x 4.72 = 24.5mins (based

24mins

Total <u>Gynae wards</u>

Pharmacist time spent on a standard gynae patient

| Medicines Reconciliation on Admission Inpatient Monitoring on LOS* 2.4days) | 25.5mins 5.23 x 2.4 = 12.5mins (based |
|---|--|
| Medicines Reconciliation at Discharge + Prep | 24mins |
| Discharge Counselling | 5mins |

Total

67mins per patient

51mins per patient

24mins

63.5mins per patient

Technician time spent on a standard gynae patient

Drug History on Admission Stocking OSD drawer on Admission Inpatient Kardex Review LOS* 2.4days) Discharge Prep and check 5mins 10mins 5.18 x 2.4 = 12mins (based on

Total

Paediatrics

Pharmacist time spent on a standard paediatric patient

Medicines Reconciliation on Admission4minsInpatient Monitoring6.16 x 3.54 = 21.8mins (basedon LOS* 3.54days)6.6minsMedicines Reconciliation at Discharge + Prep6.6minsDischarge Counselling3mins

Total

Technician time spent on a standard paediatric patient

Dispensing of discharge **Total**

14mins **14mins per patient**

36mins per patient

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V3_2014

Page 110 of 116

Acute Elderly Care

Pharmacist time spent on a standard acute elderly care patient

Medicines Reconciliation on Admission Inpatient Monitoring on LOS* 17.72days) Medicines Reconciliation at Discharge + Prep Discharge Counselling 28mins 5.23 x 17.72 = 92mins (based

35mins 5mins

Total

160mins per patient

141mins 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 | 5.186 x 17.72 = 92mins |
| (based on LOS* 17.72days) | |
| Discharge Prep and check | 34mins |
| | |

Total

Acute Psychiatry

Pharmacist time spent on a standard mental health patient

Medicines Reconciliation on Admission Inpatient Monitoring LOS* 27days) Care plan meeting LOS* 27 days/ 4 weeks) Medicines Reconciliation at Discharge + Prep Discharge Counselling

18mins 3.425 x 27= 92mins (based on

12.5 x 4 =50mins (based on

16mins 5mins

Total

181mins per patient

Technician time spent on a standard mental health patient

Inpatient Monitoring on LOS* 27days) Dispensing of discharge

Total

2.625 x 27 = 71mins (based 13mins 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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caring supporting improving together

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|-------------------------|--|---|-------------------|--|-----------|--|--|--|--|--|
| Author(s) | Catherine G | Catherine Graham, Clinical Pharmacy Co-ordinator | | | | | | | | |
| Ownership: | Caroline Le | Caroline Leonard, Director, Surgery and Specialist Services | | | | | | | | |
| Approval by: | Standards a Policy Com | Therapeutics and Guidelines mittee eam Meeting | Approval date: | 03/05/2017 24/05/2017 07/06/2017 28/06/2017 | | | | | | |
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| 15/05/2014 | V3 | Catherine Graham & Caitriona Donnelly | 2013 Northern Ireland Clinical Pharmacy Standards approved by Regional Heads of Pharmacy and formatted into Trust Standards template |
| 25/04/2017 | V3.1 | Catherine Graham | Consultation with Trust Clinical Pharmacy Steering Group that no changes currently required as no update to 2013 Northern Ireland Clinical Pharmacy Standards |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

8949 of 10305

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

The Northern Ireland Standards on the individual components of a clinical pharmacy service were developed in 2010, incorporated into practice and have been subsequently reviewed.

1.2 Purpose

Clinical Pharmacy relates to the safe, effective and economic use of medicines to the patient care journey at all stages. This policy ensures standardisation of the process.

1.3 Objectives

Northern Ireland Standards on the individual components of a clinical pharmacy service were developed in 2010, incorporated into practice and subsequently reviewed.

The principle objective of this document is to improve the clinical pharmacy contribution to patient care through the development of a structured approach to clinical pharmacy practice.

2.0 SCOPE OF THE POLICY

This standard applies to all clinical pharmacy staff and those staff on rotation through clinical pharmacy services.

3.0 ROLES/RESPONSIBILITIES

All clinical pharmacy staff and those on rotation through clinical pharmacy services should be familiar with these standards.

4.0 KEY POLICY PRINCIPLES

Policy Principles

4.1 To standardise clinical pharmacy services in the Trust

To improve the clinical pharmacy contribution to patient care through the development of a structured systematic approach to clinical pharmacy practice.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

All clinical pharmacy staff and those on rotation through clinical pharmacy services should be familiar with this standard and use the SOPS linked with these standards

5.2 Resources

Trust Clinical Pharmacy Standard Operating Procedures currently in place will be reviewed in light of these new standards. The Trust Clinical Pharmacy Leads will lead on this.

5.3 Exceptions

Not applicable

6.0 MONITORING

Clinical pharmacy indicators are collected by clinical pharmacy staff on a regular basis and are reviewed by the Clinical Pharmacy Leads.

7.0 EVIDENCE BASE / REFERENCES

These Standards meet best practice requirements – see references pages 116-117

8.0 CONSULTATION PROCESS

A wide consultation was undertaken throughout all hospital pharmacies in Northern Ireland.

9.0 APPENDICES / ATTACHMENTS

Appendix 1: Northern Ireland Clinical Pharmacy Standards 2013

10.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

Major impact

Minor impact

No impact. X

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

asherne Walton

Date: ____June 2017_____

Author Clinical Pharmacy Co-ordinator, BCH

Caroline A. Leonard

Date: ____June 2017_____

Director Surgery and Specialist Services, Pharmacy and Medicines Management

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017



NORTHERN IRELAND

CLINICAL PHARMACY STANDARDS

2013

Review date 2015

Authorised by:

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3

CONTENTS

Introduction

No Standards

<u>Acute</u>

| 1 | Medicine History Interview and Medicines Reconciliation | 5 |
|------------|--|----|
| 2 | Medicine Therapy Monitoring | 11 |
| 3 | Prescription Monitoring and Review | 14 |
| 4 | Prevention, Detection, Assessment and Management of Adverse Drug Reactions | 19 |
| 5 | Prevention, Assessment and Management of Drug Interactions | 24 |
| 6 | Therapeutic Drug Monitoring | 27 |
| 7 | Prevention, identification, management and reporting of medication incidents | 29 |
| 8 | Multidisciplinary Working | 32 |
| 9 | Provision of Medicines Information Advice by Pharmacists | 34 |
| 10 | Discharge | 40 |
| 11 | Patient Medicine Education | 45 |
| <u>Gen</u> | eral Support | |
| 12 | Education and Training | 49 |
| 13 | Resources | 53 |
| 14 | Staffing Levels and Structure | 56 |
| 15 | Documentation | 60 |
| 16 | Quality of Clinical Pharmacy Services | 63 |
| 17 | Health Promotion | 66 |
| 18 | Pharmacoeconomic Evaluation of the use of Medicines | 68 |

| 19 | Pharmacist Led | Clinics | 71 | | | | | | |
|----|------------------------------------|--|-----|--|--|--|--|--|--|
| 20 | Supplementary a | and Independent Prescribing | 75 | | | | | | |
| 21 | Communication | 79 | | | | | | | |
| 22 | Self Administrati | 81 | | | | | | | |
| 23 | Reuse of Patient | Reuse of Patient's Own Medicines | | | | | | | |
| | Appendix 1 | Sample Procedures | 86 | | | | | | |
| | Procedure for M | edicine History Interview | 87 | | | | | | |
| | Patient Medicine | e History Tool | 89 | | | | | | |
| | Procedure for Pr | rescription Monitoring and Review | 91 | | | | | | |
| | | revention, Detection, Assessment nt of Adverse Drug Reactions | 93 | | | | | | |
| | | revention, Assessment and Drug Interactions | 96 | | | | | | |
| | Procedure for Th | nerapeutic Drug Monitoring | 97 | | | | | | |
| | Procedure for M | ultidisciplinary Working | 99 | | | | | | |
| | Procedure for Pr by Pharmacists | rovision of Medicines Information Advice | 100 | | | | | | |
| | Procedure for Di | ischarge | 101 | | | | | | |
| | Procedure for Pa | atient Medicine Education | 104 | | | | | | |
| | Appendix 2 | Northern Ireland timings | 107 | | | | | | |
| | Glossary | | 112 | | | | | | |
| | References | | 114 | | | | | | |

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 | Au | dit Res | sult | 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. | | | | | | |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

| Indicators | Au | dit Res | | Comments Action to be taken | Target Date | Completed |
|--|----|---------|-----|--------------------------------|----------------|-----------|
| Medicine History Interview and Medicines Reconciliation | Y | N | N/A | | Date | |
| 1.5 The medicine history includes: current and recently prescribed medicines over the counter medicines clinical trial 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. | | | | | | |

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|---|----|---------|------|--------------------------------|----------------|-----------|--|--|
| Indicators | Au | dit Res | sult | 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
 - Injectables
 - Insulin/ oral hypoglycaemics
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Anticoagulants/ Warfarin,
 - Antibiotics
 - Antiparkinson drugs
 - Antiepileptics
 - Clozapine
 - Potassium

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
- Prevent omitted does 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)

(pp8370-10305 of 20966) (this part 1936 pages)

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08)

Medicine Therapy Monitoring

Pharmacists provide medicine therapy monitoring routinely. Criteria shall exist to identify patients who would benefit most from medicine therapy monitoring.

| Indicators | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|-----|-----------------------------|----------------|-----------|
| Medicine Therapy Monitoring | Y | Ν | 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:

once daily

once a month

- Acute wards
- Intermediate stay wards •
- once weekly Rehabilitation wards, community hospital wards once weekly •
- Long stay psychiatric/ learning difficulties
- 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 patient's administration record is reviewed to determine non-The 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

Drugs and Therapeutics Committee NI Clinical Pharmacy Standards V4 2017

- 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
 - Injectables
 - Insulin/ oral hypoglycaemics
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Anticoagulants/ Warfarin,
 - Antibiotics
 - Antiparkinson drugs
 - Antiepileptics
 - Clozapine
 - Potassium

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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Prescription monitoring and review | Y | Ν | 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. | | | | | | |

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| Indicators | Audit Result | | | Comments Action to | Target | Completed |
|--|--------------|---|-----|--------------------|--------|-----------|
| | | | | be taken | Date | • |
| Prescription monitoring and review | Y | Ν | 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. | | | | | | |

8969 of 10305

MAHI - STM - 101 - 008970

| Indicators | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|------|-----------------------------|----------------|-----------|
| Prescription monitoring and review | Y | Ν | N/A | | Dute | |
| 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. | | | | | | |

8970 of 10305

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 cotrimoxazole 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
 - Injectables
 - Insulin/ oral hypoglycaemics
 - Methotrexate
 - NSAIDs
 - Opiates
 - Prednisolone
 - Anticoagulants/ Warfarin,
 - Antibiotics
 - Antiparkinson drugs
 - Antiepileptics
 - Clozapine
 - Potassium

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.

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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 | | sult | Comments Action to be taken | Target Date | Completed |
|--|--------------|---|------|-----------------------------|----------------|-----------|
| Adverse Drug Reactions | Y | Ν | 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 | | | | | | |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

| Indicators | Au | dit Res | sult | Comments Action to | Target | Completed |
|---|----|---------|------|--------------------|--------|-----------|
| | | | | be taken | Date | |
| Adverse Drug Reactions | Y | Ν | 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 | Au | dit Res | sult | 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 dependent 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 | Ν | 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 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. | | | | | | |
| 6.4 Pharmacists will specialise in TDM in appropriate clinical fields. | | | | | | |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

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.

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

Prevention, identification, management and reporting of medication incidents

Pharmacists contribute to the prevention, identification, management and reporting of medication incidents.

| Indicators | Audit Result | | sult | Comments Action to be taken | Target Date | Completed |
|---|--------------|---|------|-----------------------------|----------------|-----------|
| Medication Incidents | Y | Ν | 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 | Υ | Ν | 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 | Ν | 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.

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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 | Ν | 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 | Au | dit Res | sult | 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 | Ν | 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 liaises 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.

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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|------|-----------------------------|----------------|-----------|
| Discharge | Y | Ν | 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 liaises 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 | Ν | 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 | Ν | 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 | Ν | 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 Target Completed

MAHI - STM - 101 - 008999

| | | | | be taken | Date | |
|--|---|---|-----|----------|------|--|
| Patient Medicine Education | Y | Ν | 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

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)

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

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

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 | Au | idit Re | esult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|-------|-----------------------------|----------------|-----------|
| CPD | Y | Ν | 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 | Ν | 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.

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

| Indicators | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Resources | Y | Ν | 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

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)

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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Staffing Structure and Levels | Y | Ν | 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 | Pharmacist time per admission 102 minutes | Technician time per admission 83 minutes | NI timings 2012 (appendix 2) |
| specialities | | | |
| General Surgery Orthopaedics Gynae | Pharmacist time per admission 80 minutes Pharmacist time per | Technician time per admission 64 minutes Technician time per | NI timings 2012 (appendix 2) NI timings 2012 |
| | admission 67 minutes | admission 51 minutes | (appendix 2) |
| Paediatrics | Pharmacist time per admission 50 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 | 0.1 technician 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 lecnnician Ratio Reference | 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

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Documentation | Y | Ν | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|------|-----------------------------|----------------|-----------|
| Quality of Clinical Pharmacy Services | Y | Ν | 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. | | | | | | |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

| Indicators | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|------|-----------------------------|----------------|-----------|
| Quality of Clinical Pharmacy Services | Y | Ν | 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

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 | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|-----|-----------------------------|----------------|-----------|
| Health Promotion | Y | Ν | 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 | Au | dit Res | ult | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|------|-----------------------------|----------------|-----------|
| Pharmacoeconomic evaluation of the use of medicines | Y | Ν | 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 are managed by pharmacists with appropriate knowledge, experience and training.

| Indicators | Au | dit Res | ult | Comments Action to be taken | Target Date | Comple ted |
|---|----|---------|-----|-----------------------------|----------------|---------------|
| Pharmacist led clinics | Y | Ν | 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 | | | | | | |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

| Indicators | Au | dit Res | sult | Comments Action to be taken | Target Date | Comple ted |
|---|----|---------|------|-----------------------------|----------------|---------------|
| Pharmacist led clinics | Y | Ν | 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 | Aud | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|-----|---------|-----|-----------------------------|----------------|-----------|
| Non Medical Prescribing (Pharmacists) | Y | Ν | 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 | | | | | | |

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| | - | | | | | |
|---|----|---------|------|--------------------------------|----------------|-----------|
| Indicators | Au | dit Res | sult | 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 | | sult | Comments Action to be taken | Target Date | Completed |
|---|--------------|---|------|-----------------------------|----------------|-----------|
| Communication | Y | Ν | 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 | Au | dit Res | ult | Comments Action to be taken | Target Date | Completed |
|---|----|---------|-----|-----------------------------|----------------|-----------|
| Self administration of medicines | Y | Ν | 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 | | sult | Comments Action to be taken | Target Date | Completed |
|--|--------------|---|------|-----------------------------|----------------|-----------|
| Self administration of medicines | Y | Ν | 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 | Au | dit Res | sult | Comments Action to be taken | Target Date | Completed |
|--|----|---------|------|-----------------------------|----------------|-----------|
| Reuse of Patient's Own Medicines | Y | Ν | 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 | | | | | | |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

Appendix 1

Sample Procedures

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

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 medicinerelated 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.

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 prescribe | ed by doctor: | | | |
|-----------------|-----------------|---------------------|--------------------|-------------------|
| Drug name & | Strength, dose, | Information | Patient concordant | Supply |
| form | frequency, | source ₁ | and medicines | at |
| | formulation | | stored correctly | home ₂ |
| | | | Y/N | |
| | | | | |
| | | | Y/N | |
| | | | | |
| | | | Y/N | |
| | | | | |
| | | | Y/N | |
| | | | | |

(Continued overleaf)

Any additional information: Kev: 1. **GP** – General Practitioner **P** – Patient **C** – Relative/ Carer

| Key: 1. GP – General Pr | ractitioner | P – Patient C – Relative/ Carer | | |
|-------------------------|--------------|---|------------------|--|
| CP – Community | / Pharmacist | NH – Nursing Home | O – Other | |
| (please specify) | | _ | | |
| 2. H – Home | W – Ward | D/C – Discontinued m | edicine | |
| Druge on Admission: | | | | |

Drugs on Admission:

| Drugs prescribed by doctor continued: | | | | |
|---------------------------------------|-----------|---------------------|--------------------|-------------------|
| Drug name & | | Information | Patient concordant | Supply |
| form | frequency | source ₁ | and medicines | at |
| | | | stored correctly | home ₂ |
| | | | Y/N | |
| | | | Y/N | |
| | | | 1/1 | |
| | | | Y/N | |

| Non prescription medicine/ se herbal medicine) | If-initiated medicine (including homeopathic & |
|--|--|
| | 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

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- 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

<u>Medicines information enquiries should be recorded and filed</u> <u>according to local policy in an easily retrievable manner to allow</u> <u>access by other users and to prevent duplication.</u>

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
 - Injectables
 - Insulin/ oral hypoglycaemics
 - -Methotrexate
 - -NSAIDs
 - Opiates
 - Prednisolone
 - Anticoagulants/ Warfarin,
 - -Antibiotics
 - -Antiparkinson drugs
 - -Antiepileptics
 - Clozapine
 - Potassium

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, drugalcohol 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

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 Admission28minsInpatient Monitoring5.23 x 6.54 = 34mins (basedon LOS* 6.54days)5.23 x 6.54 = 34mins (basedMedicines Reconciliation at Discharge + Prep35minsDischarge Counselling5mins

102mins per patient

Total

Technician time spent on a standard medical patient

Drug History on Admission Stocking OSD drawer on Admission Inpatient Kardex Review on LOS* 6.54days) Discharge Prep and check 5mins 10mins 5.186 x 6.54 = 34mins (based

Total

83mins per patient

34mins

Surgical wards (including Trauma & Orthopaedics)

Pharmacist time spent on a standard surgical patient

Medicines Reconciliation on Admission Inpatient Monitoring on LOS* 4.72days) Medicines Reconciliation at Discharge + Prep Discharge Counselling 25.5mins 5.23 x 4.72 = 25mins (based

24mins 5mins

79.5mins per patient

Drugs and Therapeutics Committee NI Clinical Pharmacy Standards V4 2017

Total

Technician time spent on a standard surgical patient

Drug History on Admission Stocking OSD drawer on Admission Inpatient Kardex Review on LOS* 4.72days) Discharge Prep and check 5mins 10mins 5.18 x 4.72 = 24.5mins (based

24mins

Total <u>Gynae wards</u>

Pharmacist time spent on a standard gynae patient

Medicines Reconciliation on Admission Inpatient Monitoring on LOS* 2.4days) Medicines Reconciliation at Discharge + Prep Discharge Counselling 25.5mins 5.23 x 2.4 = 12.5mins (based

63.5mins per patient

67mins per patient

51mins per patient

24mins 5mins

Total

Technician time spent on a standard gynae patient

Drug History on Admission Stocking OSD drawer on Admission Inpatient Kardex Review LOS* 2.4days) Discharge Prep and check 5mins 10mins 5.18 x 2.4 = 12mins (based on

24mins

Total

Paediatrics

Pharmacist time spent on a standard paediatric patient

| Total | 36mins per patient |
|---|-------------------------------|
| Discharge Counselling | 3mins |
| on LOS* 3.54days) Medicines Reconciliation at Discharge + Prep | 6.6mins |
| Inpatient Monitoring | 6.16 x 3.54 = 21.8mins (based |
| Medicines Reconciliation on Admission | 4mins |

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 Inpatient Monitoring on LOS* 17.72days) Medicines Reconciliation at Discharge + Prep Discharge Counselling 28mins 5.23 x 17.72 = 92mins (based

35mins 5mins

Total

160mins per patient

Technician time spent on a standard acute elderly care patient

Drug History on Admission Stocking OSD drawer on Admission Inpatient Kardex Review (based on LOS* 17.72days) Discharge Prep and check 5mins 10mins 5.186 x 17.72 = 92mins

141mins per patient

181mins per patient

34mins

Total

Acute Psychiatry

Pharmacist time spent on a standard mental health patient

Total

Technician time spent on a standard mental health patient

| Inpatient Monitoring on LOS* 27days) | 2.625 x 27 = 71mins (based |
|---|----------------------------|
| Dispensing of discharge | 13mins |
| Total | 84mins per patient |

*LOS = average length of stay for all Trusts in Northern Ireland for financial year 2011/12

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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). |

Drugs and Therapeutics Committee_NI Clinical Pharmacy Standards_V4_2017

| 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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HSC Belfast Health and Social Care Trust

Reference no: SG 14/13

| Title: | Non-Medical Prescribing of Medicines | | | |
|-------------------------|--|--|-----------------|-------------------------------------|
| Author(s) | Valerie Hall, Nurse Consultant Unscheduled Care, Oriel Brown Nurse Consultant, Public Health Agency | | | |
| Ownership: | Brenda Creaney, Executive Director of Nursing and User Experience/ Eimear McCusker, Head of Pharmacy & Medicines Management, Cancer & Specialist Services Directorate, BHSCT | | | |
| Approval by: | • | Therapeutics and Guidelines mittee | Approval date: | July 2013 31/7/2013 20/5/2013 |
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| Key Words: | Policy for non medical prescribers | | | |
| Links to other policies | | | | |

| Date | Version | Author | Comments |
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| 21/10/08 | 0.1 | Valerie Hall | Initial draft |
| 21/09/09 | 0.2 | Valerie Hall | Revised following consultation |
| 24/11/10 | 0.3 | Valerie Hall | Consultation with Olive MacLeod, Co- Director Nursing Governance, BHSCT |
| 21/12/10 | 0.4 | Valerie Hall | First draft consultation with Oriel Brown, Nurse Consultant, Service Development and Service Improvement (Prescribing) Public Health Agency |
| 07/01/11 | 0.5 | Valerie Hall | Second draft consultation with Eimear McCusker, Head of Pharmacy and Medicines Management, BHSCT |
| 07/02/11 | 0.6 | Valerie Hall | Third draft consultation with Paula King, Lead Pharmacist, BHSCT |
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| 16/01/2013 | 0.8 | Valerie Hall | Update following comments |
| 25/02/2013 | 0.9 | Valerie Hall | Update following AHP comments |
| 25/03/2013 | 0.10 | Valerie Hall | Update following A Wilson comments |
| 26/06/2013 | 0.11 | Valerie Hall | Update following D Robinson comments |
| 30/07/2013 | 0.12 | Valerie Hall | Update following D Robinson comments |

1.0 INTRODUCTION / PURPOSE OF POLICY

This policy sets out a framework for the development and implementation of nonmedical prescribing of medicines within the Belfast Health and Social Care Trust (BHSCT) and thus establishes a consistent approach for non-medical prescribing. This policy applies to all registered nurses, midwives, specialist community public health nurses, pharmacists and other allied health care professionals registered with the Trust as non-medical prescribers of medicines in accordance with their job descriptions and KSF outlines.

(Where the term 'nurse' is used throughout the remainder of this document it includes midwives and specialist community public health nurses).

This document is underpinned by, and should be read in conjunction with, the documents listed in (Appendix 1).

1.1 Background

This policy sets out a framework for the development and implementation of nonmedical prescribing of medicines within the Belfast Health and Social Care Trust (BHSCT).

1.2 Purpose

- **1.2.1** Ensure professional and statutory obligations are met.
- **1.2.2** Contribute to the provision of holistic care.
- **1.2.3** Provide robust standards for non-medical prescribing of medicines.
- **1.2.4** Clarify accountability and responsibility.
- **1.2.5** Provide a framework under which potential applicants could determine eligibility to undertake an approved prescribing programme.

2.0 DEFINITIONS/SCOPE OF THE POLICY

- **2.1** This policy will apply throughout the Belfast Health and Social Care Trust.
- 2.2 <u>Definition of Independent Prescribing</u> The working definition of independent prescribing is prescribing by a practitioner (e.g. doctor, dentist, nurse or pharmacist) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, included prescribing of medicines. Within medicines legislation the term used is "appropriate prescriber".
- 2.3 <u>Definition of Supplementary prescribing</u> A voluntary partnership between an independent prescriber (a doctor or dentist), who has made the initial assessment and diagnosis, and a supplementary prescriber who may prescribe any medicine, in accordance with the agreed patient-specific clinical management plan with the patient's consent.
- 2.4 <u>Prescribing from the Nurse Prescribers Formulary</u> Community Practitioner Nurse Prescribers (CPNPs) V100 – formerly District Nurse/Health Visitor prescribers must only prescribe items listed within the Nurse Prescribers Formulary for Community Practitioners as outlined in the Northern Ireland Drug Tariff.

3.0 ROLES/RESPONSIBILITIES

All Line Managers and Non-Medical Prescribers (NMP) within the BHSCT must be familiar with this policy.

4.0 KEY POLICY PRINCIPLES

4.1 Policy / Guideline Description

This document outlines the BHSCT policy for non-medical prescribing of medicines by nurses, pharmacists and allied health professionals in accordance with guidance outlined in (Appendix 1).

4.2 Policy Statements

4.2.1 <u>Categories of individuals who can prescribe medicines as independent /</u> supplementary prescribers

Non-Medical staff who have successfully completed a recognised prescribing course, have registered with the appropriate professional body as a prescriber of medicines and have been approved and registered as a non-medical prescriber on the BHSCT register for non-medical prescribers can prescribe as either independent or supplementary prescribers.

Qualified staff transferring from other Trusts cannot practice as a non-medical prescriber in the BHSCT until they have been formally approved and registered on the BHSCT register (Appendix 5).

4.2.2 The categories of nurses who can prescribe medicines are:

- Nurse **Independent Prescribers** can prescribe any medicine for any medical condition within their competence including some controlled drugs.
- Nurse **Supplementary Prescribers** can prescribe any medicine, including some controlled drugs under a Clinical Management Plan in partnership with an independent prescriber (doctor or dentist).
- More detailed information is provided in the British National Formulary (BNF).
- CPNPs must only prescribe items listed within the Nurse Prescriber's Formulary for Community Practitioners as outlined in the Northern Ireland Drug Tariff.

4.2.3 The categories of pharmacists who can prescribe medicines are:

- Pharmacist Independent prescribers can prescribe any medicine for any medical condition within their competence including some controlled drugs.
- Pharmacist Supplementary prescribers can prescribe any medicine, including some controlled drugs under a Clinical Management Plan in partnership with an independent prescriber (doctor or dentist).

4.2.4 <u>The categories of Allied Health Professionals who may prescribe medicines are</u>:

- Optometrist Independent Prescribers can prescribe any licensed medicine for ocular conditions affecting the eye and surrounding tissue, but cannot prescribe any controlled drugs.
- Physiotherapists, Podiatrists, Radiographers and Optometrists are able to prescribe as **supplementary** prescribers under a Clinical Management Plan in partnership with an independent prescriber (doctor or dentist). AHPs can only prescribe controlled drugs as supplementary prescribers when the drugs are clearly defined within the clinical management plan.

4.3 Selection criteria

All entrants to prescribing training must be selected according to the criteria set by the individual prescribing programme and the respective professional body for each of the professional groups. Applicants must have a named medical officer within

the clinical area who will act as a mentor and have the approval of BHSCT to complete the training course. Applicants must have the support of their line manager.

The prescriber must have the opportunity to prescribe within their post following completion of training. The therapeutic areas for prescribing must be identified.

4.4 Admission criteria to the Nurse Independent / Supplementary Prescribing Programme

The Nurse Independent / Supplementary Prescribing course is delivered by Queen's University, Belfast and the University of Ulster, Jordanstown over one academic year. Part time employees must have worked for a sufficient period to be deemed competent by their line manager.

The aim in selection of students to undertake the programme is to identify those who will successfully complete the course and be able to carry out the role of nurse prescriber within their speciality/area of expertise.

The admission criteria checklist is outline in (Appendix 2).

4.5 Admission criteria to the Community Practitioner Nurse Prescribing Programme

At present the nurse prescribing programme is integrated into the BSc (Hons) / PG Diploma Community and Public Health Nursing.

4.6 Admission criteria to the Pharmacist Independent Prescribing Course

The course is over a six month period leading to a Post Grad Certificate in Independent/Supplementary Prescribing for pharmacists. The course is provided jointly by Queens University, Belfast and NICPLD (Northern Ireland Centre for Pharmacy Learning and Development). Part time employees must have worked for a sufficient period to be deemed competent by their line manager.

Applicants must be registered with the Pharmaceutical Society of Northern Ireland (PSNI) (or eligible to register), have 2 years post-registration experience and have experience in the clinical area in which they wish to practice as a pharmacist independent prescriber.

The admission criteria checklist is outline in (Appendix 3).

4.7 Admission criteria to the AHP Supplementary Prescribing Programme

The AHP Supplementary Prescribing Course is delivered by the University of Ulster, Jordanstown. The applicant must be registered with at least one year's experience immediately preceding the application in the clinical area in which they intend to prescribe. Part time employees must have worked for a sufficient period to be deemed competent by their line manager.

The admission criteria checklist is outlined in (Appendix 4).

4.8 Application process

Nursing

Commissioning for nurse independent / supplementary prescribing should be undertaken in line with the framework for the management of nursing and midwifery

post registration education commissioning for the BHSCT. Any nurse wishing to undertake the course may apply, having first discussed with and gained approval from their line manager / Associate Director of Nursing and Midwifery (ADN/M). The NMC circular 29/2007 requires that all nurses have an up-to-date criminal records bureau check i.e. within the last 3 years, before they commence the course.

Pharmacy

Pharmacists must have approval from the Head of Pharmacy and Medicines Management. All expressions of interest must be forwarded to the Head of Pharmacy no later than November to ensure inclusion in the following year's commissioning process.

Allied Health Professionals

The course will be available through the AHP commissioning process. Any AHP within the Trust who wishes to apply must have approval from their Trust Professional Lead.

4.9 Trust Register of Non-Medical Prescribers for medicines

A central register of all non-medical prescribers of medicines within BHSCT will be held by the Head of Pharmacy and Medicines Management.

Each professional lead/line manager should ensure that their non-medical prescribers are fulfilling the role as part of the annual appraisal process. Once placed on the BHSCT register yearly confirmation that the practitioner wishes to remain on the register should be sent to the Head of Pharmacy and Medicines Management (Appendix 6). This will ensure the register remains 'live'.

Failure to comply with this requirement will result in the practitioner being removed from the BHSCT register and a suspension of prescribing rights within BHSCT. Any practitioner wishing to 'rejoin' the BHSCT register will be required to re-submit a full application as set out in (Appendix 5).

Job descriptions must be amended or a letter of confirmation placed in the personal file of non-medical prescribers stating that they are practising with BHSCT.

- (a) **Trust Registration Process for Non-Medical Prescribers (V300 only for nursing)** The non-medical prescriber must complete the application form for inclusion on the BHSCT Register of Non-Medical Prescribers (Appendix 5).
- (b) The form is signed off by the appropriate Professional Lead / ADN/M who will forward this to the Head of Pharmacy and Medicines Management to include the prescriber's details on the Trust register.
- (c) The Head of Pharmacy and Medicines Management will then issue a letter to the individual to authorise that he/she can prescribe as part of their role and will also inform their line manager of this decision. This will be copied to the site pharmacy lead.
- (d) The ADN/M adds the name to the locally held nurse prescribing database.
- (e) The AHP Professional Lead adds the name to the locally held non medical prescribing database.

- (f) The ADN/M or AHP/Pharmacy Professional Lead must ensure that the staff member's job description is updated or a letter of confirmation placed within the personal file, to include a statement that they are practising as a non-medical prescriber within the BHSCT.
- (g) The Line Manager must review and verify annually that the non-medical prescriber is working within their authorised area of expertise. A copy of the Confirmation of re-entry to the BHSCT Register Form (Appendix 6) should be completed and sent to the Head of Pharmacy.
- (h) Specific to Community Practitioners (V100 only for nursing)

The Business Services Organisation (BSO) Regional Web Based Registration system enables HSC organisations to:

- maintain a register of non- medical prescribers who wish to obtain their own HS21 prescription pad in line with DHSSPS guidance
- obtain prescriber cypher numbers for non-medical prescribers in the primary care / community setting
- standardise reports to support governance

All primary care / community non medical prescribers must register with BSO using this system.

4.10 Parameters of prescribing

Initially the parameters of prescribing are agreed with their line manager/professional lead as part of the BHSCT registration process as outlined above. The parameters of prescribing will be reviewed as part of the annual appraisal process. Any changes in prescribing practice must be notified to the Head of Pharmacy and Medicines Management on the full form.

4.11 Continuing professional development (CPD)

Non-medical prescribers will be expected to ensure continuous professional development and to keep up to date with evidence and best practice in the management of the conditions for which they prescribe, and in the use of relevant medicines and any legislative changes.

The non-medical prescriber must discuss learning needs and provide evidence of learning and development as a prescriber, as part of the annual appraisal process. The National Prescribing Centre (NPC) (www.npc.co.uk) has produced the following document which may be used as a tool to reflect on practice and identify CPD needs.

1. "A single competency framework for all prescribers" May 2012

www.npc.co.uk/improving safety/improving quality/resources/single comp framework.pdf

4.13 Legal liability

Non-medical prescribers are individually accountable to their professional body for this aspect of their practice, as for any other, and must act at all times in accordance with same. Non-medical prescribers are advised to ensure that they have sufficient professional indemnity, for instance by means of membership of a professional organisation or trade union which provides this cover.

4.14 Obtaining prescription pads - Community

Community non- medical prescribers (district nurses, health visitors and AHPs) will need to be registered with BSO to obtain a prescription pad. Non-medical prescribers practising in the acute sector are unlikely to require a prescription pad.

4.15 Patient assessment

Non-medical prescribers can only prescribe for patients who they have assessed for care.

4.16 Security and safe handling of prescription forms

For non-medical prescribers employed in community the security of prescription forms is the responsibility of both the prescriber and their employing organisation. Please refer to section 6.5 of BHSCT Community Medicines Code regarding security of stationary.

4.17 Prescription writing

Before writing a prescription the non-medical prescriber should have assessed the patient and have knowledge of:

- Patient's full medication (this should include all prescribed and non-prescribed medication including over the counter and alternative remedies).
- Past medical history.
- Allergy status.
- Patient's current health status.
- A thorough knowledge of the item to be prescribed, i.e. dosage, therapeutic action, side effects, and interactions, frequency of use.
- The current British National Formulary (BNF) or Nurse Prescribers Formulary (NPF) for reference, including guidance on prescription writing.

All non-medical prescribers should prescribe according to the Trust's generic prescribing policy except where this would not be clinically appropriate or where there is no approved generic name. Local formularies should be adhered to in accordance to approved Trust guidelines (BHSCT Medicines Code, February 2011).

Non medical prescribers should clearly annotate that they are a supplementary or independent prescriber.

- Nurses should sign as: Nurse Independent Prescriber (NIP) or Nurse Independent Supplementary Subscriber (NISP)
- Pharmacists should sign as Pharmacist Independent Prescriber (PIP) or Pharmacist Independent Supplementary Subscriber (PISP)

• Allied health prescribers should sign as: Allied Health Independent Supplementary Subscribers (AHISP).

In community settings AHP prescribers will use the prescription form HS21 (N).

Nurses working in family planning clinics may prescribe using the same system as doctors in the clinic.

In hospitals non-medical prescribers will prescribe on the relevant prescription form or medicines kardex.

In OPD Clinics / Day procedure, non medical prescribers will complete a letter of recommendation to GPs. They will also clearly annotate their status as outlined (e.g. NISP / PISP / AHISP).

4.18 Patient information

The non-medical prescriber must inform the patient that they are acting as a non-medical prescriber. The non-medical prescriber will explain the following to the patient:

- Indication for the medication.
- The dosage, frequency and method of administration.
- The common side effects.
- Any precautions they should take.
- What to do if they have any concerns or adverse reactions.
- How to store medicines safely.
- What to do with any leftover medicines at the end of treatment.
- Plan for review if indicated.

4.19 Prescribing and administration / supply / dispensing

Non medical prescribers must ensure separation of prescribing, dispensing and administering activities whenever possible.

PSNI Standards and Guidance for pharmacist prescribing April 2013

The pharmacist must not both prescribe and dispense medicines except in exceptional circumstances e.g. where the need for the medicine is urgent and not to dispense would compromise patient care. The pharmacist must have robust procedures in place to demonstrate the separation of prescribing and dispensing."

NMC Standards of proficiency for nurses and midwife prescribers (2006) state:

Practice Standard 9 Prescribing and administration / supply "You must ensure separation of prescribing and administering activities whenever possible"

"In exceptional circumstances where you are involved in both prescribing and administering and patient / clients controlled drug, a second suitably competent person should be involved in checking the accuracy of medication provided"

4.20 Prescribing controlled drugs

4.20.1 Nurses

Amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 were introduced on 10 May 2012 to allow a nurse independent prescriber and a pharmacist independent prescriber to prescribe controlled drugs (CDs) as described in the Department circular DH1/12/112169 (Appendix 7).

Formerly nurse independent prescribers could only prescribe controlled drugs from a limited formulary for specific conditions or by using supplementary prescribing. Nurse independent prescribers can prescribe any controlled drug listed in schedules 2-5 for any medical condition within their competence except diamorphine, cocaine and dipipanone for the treatment of addiction (nurse independent prescribers are able to prescribe other controlled drugs for the treatment of addiction).

Nurse independent prescribers are able to requisition controlled drugs and are authorised to possess, supply, offer to supply and administer the drugs they are able to prescribe. Persons acting in accordance with the directions of a nurse independent prescriber are authorised to administer any schedule 2-5 drugs that the nurse can prescribe,

Detailed advice on writing a prescription for Controlled Drugs is contained in the BNF.

All nurse prescribers wishing to undertake prescription of CDs under this legislation will be required to:

- gain approval from their professional line manager
- provide parameters of prescribing practice for inclusion on the BSO / Trust Central Register
- provide evidence of successful completion of controlled drugs training
- provide evidence of safe prescribing practice and CPD at annual appraisal.
- adhere to BHSCT Controlled Drug policy
- adhere to BHSCT Dealing with discrepancies and concerns about Controlled Drugs

Non-medical prescribers who need to prescribe controlled drugs a part of their role must specify them individually on the parameters of prescribing section of the application form (Appendix 5) and forward to Head of Pharmacy and Medicines Management with evidence of successful completion of CD training.

Only schedules 2 and 3 are highlighted in the BNF and schedule 4 and 5 are not. A comprehensive list of schedules is available from the Home Office and all non medical prescribers should obtain a copy of this document available from the Home Office Website <u>www.homeoffice.gov.uk/drugs/licensing</u>. A list of schedules is also available in the BHSCT CD policy.

4.19.2 Pharmacists

Pharmacists can prescribe controlled drugs as supplementary prescribers when the drugs are clearly defined within the clinical management plan (Appendix 8).

Pharmacist independent prescribers can prescribe any controlled drug listed in schedules 2-5 for any medical condition within their competence except diamorphine, cocaine and dipipanone for the treatment of addiction (pharmacist Drugs and Therapeutics_Non-Medical Prescribing of Medicines_V1_Sept 13

independent prescribers are able to prescribe other controlled drugs for the treatment of addiction). Pharmacist independent prescribers are able to requisition controlled drugs and are authorised to supply or administer the drugs they are able to prescribe. Persons acting in accordance with the directions of a pharmacist independent prescriber are authorised to administer any schedule 2-5 drug that the pharmacist can prescribe,

Detailed advice on writing a prescription for Controlled Drugs is contained in the BNF. Non-medical prescribers who need to prescribe controlled drugs a part of their role must specify them individually on the parameters of prescribing section of the application form (Appendix 5).

BHSCT pharmacy independent prescribers must:

- Adhere to BHSCT Controlled Drug policy
- Adhere to BHSCT Dealing with discrepancies and concerns about Controlled Drugs

Only schedules 2 and 3 are highlighted in the BNF and schedule 4 and 5 are not.

A comprehensive list of schedules is available from the Home Office and all non medical prescribers should obtain a copy of this document available from the Home Office Website <u>www.homeoffice.gov.uk/drugs/licensing</u>

4.19.3 Allied Health Professionals

AHPs can only prescribe controlled drugs as supplementary prescribers when the drugs are clearly defined within the clinical management plan (Appendix 8).

The clinical management plan should clearly indicate:

- Date of prescription
- Name of prescriber and the category of prescriber
- Name of item prescribed, quantity, dose, frequency, and treatment duration.

In primary/community care the non-medical prescriber should agree the process for accessing medical records and recording prescriptions with the GP. If the non-medical prescriber is using computerised records he/she must ensure that they receive adequate and relevant training. Prescribers wishing to produce computer-generated scripts should contact the Professional Lead in the first instance.

Where there is no direct access to the GP records, the prescriber will ensure:

- Written documentation of prescription is sent to the practice manager or an agreed designated member of staff at the GP practice at time of writing (in exceptional circumstances this may be extended to 48 hours). The duplicate copy pad may be used to facilitate this process. These are available from the Professional Lead.
- This designated member of staff at the GP practice will be responsible for ensuring details of the prescription are entered on the prescribing section of the patient's electronic record.

4.21 Review of prescribing

Each prescription is regularly reviewed and is only re-issued to meet clinical need. Suitable provision for monitoring each patient/client's condition is in place for ensuring that patient/client's who need a further examination or assessment do not receive further prescriptions without being seen by an appropriate prescriber.

4.22 Prescribing unlicensed medicines

From 21st December 2009 legislation allows pharmacist and nurse independent prescribers to prescribe unlicensed medicines in all clinical areas on his / her personal responsibility (Appendix9) in line with BHSCT unlicensed medicines policy.

4.22.1 Mixing of Medicines

From 21st December 2009 legislation allows pharmacist and nurse independent prescribers and supplementary prescribers, when working within the terms of a clinical management plan, to mix medicines to produce an unlicensed medicine to meet the needs of a particular patient (Appendix9). The NMP involved in prescribing and actual mixing of medicines should be competent to do so and take full professional and clinical responsibility for their actions. Pharmacists already have authority to mix any drugs in schedules 2-5. Nurse and pharmacist independent prescribers, as well as supplementary prescribers acting in accordance with the terms of a clinical management plan for an individual patient, are authorised to mix any drugs listed in schedules 2-5 prior to administration. Persons acting in accordance with the terms of a nurse or pharmacist independent prescriber or, a supplementary prescriber when acting in accordance with the terms of a clinical management plan, are authorised to mix drugs listed in schedules 2-5.

4.23 Prescribing medicines for use outside the terms of licence

Nurse and pharmacist independent prescribers may prescribe medicines off licence or off label i.e. for uses outside their licensed indications/ UK marketing authorisation. The non-medical prescriber must accept professional, clinical and legal responsibility for that prescribing and should only prescribe off licence where it is acceptable clinical practice and in accordance with Trust policy.

Nurse prescribers should refer to NMC standards Practice standard 18: Prescribing medicines for use outside the terms of their licence (off-label). NMC standard 18: Standards of Proficiency for Nurse and Midwife Prescribers.

4.24 Discontinuation of medication

Non-medical prescribers may discontinue medication if they have assessed a patient and in their clinical judgement think this is the best course of action for the patient. Non-medical prescribers should always consider themselves part of the team and not undertake actions without considering the prescribing actions of others.

4.25 Adverse drug reactions

Adverse drug reactions are reported to the Medicines and Healthcare products Regulatory Authority (MHRA) via the Yellow Card Scheme. The electronic Yellow Card, together with instructions on how to use it, is available at www.yellowcard.gov.uk alternatively non-medical prescribers can use hard copy Yellow Cards which can be found at the back of the BNF. All non-medical prescribers should notify the GP /consultant accordingly. There is a need to discuss, inform and make clear notes.

4.26 Drug and Appliance Alerts

In the event of a drug or appliance alert being received, the non-medical prescriber is responsible for taking immediate and appropriate action. There is a need to discuss, inform and make clear notes.

4.27 Incident Reporting

Non-medical prescribers must act in accordance with the Trust's Adverse Incident Reporting Policy and Procedure and report any adverse incident they witness or are involved in to their line manager via Trust Incident report form or Datixweb. There is a need to discuss, inform and make clear notes.

4.28 Audit

Review of non-medical prescribing is part of the overall prescribing monitoring arrangements. In primary and community care BSO prescribing information is available. In hospital settings, internal systems will need to include audit of non-medical prescribing practice and medication incidents.

4.29 Prescribing for Self / Family / Friends

Non-medical prescribers must **not** prescribe any medicine for themselves or for anyone with whom they have a close personal or emotional relationship other than in exceptional circumstances.

4.30 Pharmaceutical Industry

Non-medical prescribers need to be familiar with professional standards on interface with the pharmaceutical industry and BHSCT Interfacing with Industry policy.

5.0 IMPLEMENTATION / RESOURCE REQUIREMENTS

All line managers must be aware of the admission criteria for nurses / pharmacists and allied health practitioners wishing to undertake non-medical prescribing.

All non-medical prescribers must be aware of the policy for non-medical prescribing.

6.0 SOURCE (S) / EVIDENCE BASED

The policy and statutory obligations relating to this policy are listed in Appendix 1.

7.0 <u>REFERENCES INCLUDING RELEVANT EXTERNAL GUIDANCE</u> See sources.

8.0 CONSULTATION PROCESS

Executive Director / Co-Directors of Nursing. Associate Directors of Nursing. Head of Pharmacy and Medicines Management. Non Medical Prescribers. Prescribing advisors EHSSB, Standards and Guidelines Committee. Drugs and therapeutics committee.

9.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.

The outcome of the Equality screening for this policy is:

Major impact

| Minor | impact | |
|-------|--------|--|
|-------|--------|--|

| No im | pact. 🗌 |
|-------|---------|
|-------|---------|

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

Val Hall

Author

Date: _____24/9/13_____

Sunda Mae areg.

Date: ______24/9/13_____

Director

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)

Appendix 1 POLICY AND STATUTORY OBLIGATIONS

- BHSCT (2010), Medicines Code
- DHSS (1986) **Neighbourhood Nursing a Focus for care**: Report of the community nursing Review, Cumberlege Report
- Dept of Health (1998) Review of Prescribing, Supply and Administration of Medicines. (Crown Report)
- Dept of Health (1999) Review of Prescribing, Supply and Administration of Medicines. (Crown Report (Final))
- DHSS&PS (2000), Nursing Midwifery Advisory Group- Nurse prescribing guidance for implementation.
- DHSS&PS (2004) -Supplementary Prescribing by Nurses and Pharmacists within the HPSS in Northern Ireland. A Guide for Implementation. April
- DHSS&PS (2004) -Extending Independent Nurse Prescribing within the HPSS in Northern Ireland. A Guide for Implementation. April
- DHSS&PS (2004)-Use and Control of Medicines. April
- NMC (2004) Guidelines for the administration of medicines. August
- NMC (2004)-The NMC code of professional conduct: standards for conduct, performance and ethics. November
- NMC (2005)-Guidelines for records and record keeping. January
- April (2006) Best Practice Guidance for Supplementary Prescribing by nurses within the HPSS in Northern Ireland. April
- NMC (2006) -Standards of proficiency for nurse and midwife prescribers. June
- DHSS&PS (2006) Improving Patients' Access to Medicines: A Guide to implementing Nurse and Pharmacist Independent Prescribing within the HPSS in Northern Ireland. December
- Chartered Society of Physiotherapists (2009) Medicines, Prescribing and Physiotherapy Information Paper PD019 (July)

Legislative changes that facilitated the implementation of Nurse Prescribing are:

Misuse of Drugs Act (1971).

- The Medicine Act (1968).
- The Health and Personal Social Services N.I. Order (1972).
- The Medicinal Products: Prescription by Nurses Act (1992).
- The Pharmaceutical Services N.I. Order (1992).
- The Pharmaceutical Services (1992 Order) Commencement Order N.I. (1997).
- The Pharmaceutical Services Regulation N.I. (1997).
- Health and Social Care Act Section 63 (2001).
- Prescriptions Only Medicines Order (2003).
- Professional Guidance and Standards for Pharmacist Prescribers' (2007).
- The Medicines for Human Use (Prescribing) Order (2005) Statutory Instrument 2005
 No 765
- The Misuse of Drugs (Amendment) Regulations (NI) (2005) No.119
- HPSS (Primary Medical Services) (Miscellaneous Amendments) Regulations (NI) (2005) No 368

- The Misuse of Drugs and the Misuse of Drugs (Notification of & Supply to Addicts) (Amendment) Regulations (NI) (2005) No 564
- The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 Statutory Instrument (2006) No. 915
- The Nurses and Midwives (Parts of and Entries in the Register) Amendment Order of Council (2006) Statutory Instrument 2006 No. 1015
- The Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations (2006) Statutory Instrument(2006) No. 914
- The Misuse of Drugs (Amendment) Regulations (2006) Statutory Instrument 2006 No. 986
- The National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) Regulations Statutory Instrument (2006) No. 913
- The Misuse of Drugs (Amendment) (No.2) Regulations (NI) (2006) No.214
- The HPSS (Primary Medical Services) (Miscellaneous Amendments) Regulations (NI) (2006)
- Misuse of Drugs (Amendment No 2) Regulations 2012 (SI 2012/973),

Appendix 2 ADMISSION TO THE NURSE INDEPENDENT SUPPLEMENTARY PRESCRIBING PROGRAMME (criteria checklist) Applicant's details

| Applicant's details | |
|---|---------------------|
| Admission criteria checklist Ref: NMC Standards | Criteria met Y/N |
| Registered first level nurse, midwife and/or specialist community public health nurse | |
| At least three years post registration experience. The year immediately preceding application must have been in the clinical field in which the applicant intends to prescribe | |
| The nurse has been identified through individual Performance Review Appraisal, the suitability to prescribe before they apply for a training place | |
| The applicant is in a role that enables them to prescribe following completion of training and which has clear benefits for patients clients | |
| The applicant must have had a Pocva completed within 3 years of starting the course | |
| The prospective candidate must either be deemed competent in Health Assessment by his/her professional lead and has successfully undertaken a relevant module in Health Assessment* | |
| Demonstrated ability to study at degree level through: <u>Undergraduate level</u> (60 credits) Successful completion of three modules (60 credits) of study at level 2 with a mark of at least 50%. This will include evidence of the skills necessary for the implementation of evidence based practice | |
| OR | |
| 2. <u>Postgraduate level</u> Pre-registration degree in Nursing or Midwifery Post-registration degree in Nursing, Midwifery or Health Studies/Sciences Degree in any other relevant subject area | |
| In addition written confirmation will be required from The Professional Lead/Line Manager of their support for the nurse to undertake the preparation programme and facilitate ongoing CPD and supervision to support the prescribing role A designated medical practitioner who meets eligibility criteria for | |
| medical supervision of nurse prescribers, and who has agreed to provide the required term of supervised practice. (A guide to help doctors prepare for and carry out the role of designated medical practitioner. Feb 2005. Available at www.npc.co.uk | |

Appendix 3 ADMISSION TO THE PHARMACIST INDEPENDENT / SUPPLEMENTARY PRESCRIBING PROGRAMME (criteria Checklist)

Applicant's details.....

| Admission Criteria Checklist | Criteria met Y/N |
|--|---------------------|
| Registered pharmacist with PSNI | |
| At least two years experience practicing as a pharmacist in a clinical | |
| environment in a hospital setting, following their pre-registration year. | |
| The pharmacist has been identified through Individual Performance | |
| Review/Appraisal, the suitability to prescribe before they apply for a | |
| training place | |
| The applicant is in a role that enables them to prescribe following training | |
| and which has clear benefits for patients/clients or has been identified as | a |
| potential role | |
| In addition written confirmation will be required from: | |
| The Pharmacy Services Manager of their support for the pharmacist to undertake the preparation programme and facilitate ongoing CPD and supervision to support their prescribing role A designated medical practitioner who meets eligibility criteria for medical supervision of pharmacist prescribers, and who has agreed to | |

Applicant signature...... Date......

Head of Pharmacy..... Date.....

Appendix 4 ADMISSION TO THE ALLIED HEALTH PROFESSIONAL INDEPENDENT SUPPLEMENTARY PRESCRIBING PROGRAMME

Applicant's details.....

| Admission Criteria Checklist | Criteria met Y/N |
|--|---------------------|
| HCPC Registered Radiographer, physiotherapist or podiatrist | |
| At least three years post registration experience. The year immediately preceding application must have been in the clinical field in which the applicant intends to prescribe | |
| Before applying for a training place the Radiographer, physiotherapist or podiatrist suitability to become a prescriber has been identified through performance review/appraisal | |
| The applicant is in a role that enables them to prescribe following completion of training and which has clear benefits for patients/clients | |
| The applicant must have had an Access NI assessment which has been completed within the previous 3 years (NB in order to prescribe a registrant is required to have an up to date Access NI Assessment) | |
| In addition written confirmation will be required from: 1. The Line Manager/Professional Lead confirming their support for the Radiographer/physiotherapist/podiatrist to undertake the preparation programme and facilitate ongoing CPD and supervision to support the prescribing role 2. A designated medical practitioner who meets eligibility criteria for medical supervision of Radiographer/podiatrist/physiotherapist prescribers, and who has agreed to provide the required term of supervised practice. (A guide to help doctors prepare for and carry out the role of d3esignated medical practitioner. Feb 2005. Available at www.npc.co.uk | |

Criteria confirmed by (Professional Lead)

Date.....

| Ap | plicant | |
|----|---------|--|
| | | |

| Date | | |
|------|------|------|
| | | |

Signature of Assistant Director AHPs..... Date...... Date.....

Appendix 5

Application for inclusion on the Belfast Health and Social Care Trust Register of Non-Medical Prescribers

| Г | |
|---|---|
| First Name | Surname |
| (Details as per professional register) | |
| Hospital / Base | Job Title |
| REGISTRATION DETAILS | Line Manager: |
| NMC Pin No. / Pharm Soc Reg No AHP Reg No | Verification of prescribing status 1. Copy of NMC "Statement of Entry" |
| Current registration expiry date | attached2. Copy of certificate of completion of pharmacist independent prescribing |
| Date of registration as a prescriber Type of prescriber: Community Practitioner Nurse prescriber V100 • | course attachedCopy of AHP certificate of completion of course attached |
| Nurse Independent / supplementary V300Pharmacist Independent prescriberPharmacist supplementary prescriber | Signature |
| AHP Supplementary Prescriber • | Date (Line Manager) |

| PARAMETERS OF PRESCRIBING (ONLY TO BE COMPLETED BY INDEPENDENT / | | | | | | |
|--|---|--|---|--|--|--|
| SUPPLEMENTA | <u>RY PRESCRIBERS</u> | | 1 | | | |
| Therapeutic area | Groups of drugs to be prescribed (alternatively list exceptions) Controlled drugs schedules 2,3 and 4 must be listed individually | Nature of prescribing (independent / supplementary prescribing | Evidence based prescribing – state local / national guidelines e.g. .NI formulary, NICE | Experience / training to enable delivery of service | | |
| Will prescribing include prescribing of medicines outside the terms of their product licence (off-label) or prescribing of unlicensed medicines Yes / No If yes, please specify: | | | | | | |

LOCATION (please delete as appropriate)

Hospital in-patientsYes / NoPrimary Care / CommunityYes / NoHospital out-patient / interfaceYes / No**If yes please provide more details

PRESCRIPTION PAD

Only non-medical prescribers prescribing in the community will be able to prescribe from the non-medical prescribing budget and therefore require a prescription pad from BSO

Prescription pad required Yes / No

If Yes please refer to the section on obtaining prescription pads – process for registration of Non-medical Prescribers with Central Services Agency (BSO)

| NOTIFICATION OF CHANGES | DATE: |
|---|-------|
| Prescriber employment ends | |
| Prescriber details change (e.g. NAME as per professional registration | |
| Prescribing suspended by professional body | |

Please sign appropriately

| Prescriber (As per professional register) | Name Block Capitals Signature Date: | | Address: |
|---|---|---|---|
| Professional Lead / Associate Director of Nursing | The Trust is in agr will prescribe in an as part of their em above. I am satisfied that undertake this role I will ensure that th | ne professional conform r professional body in r | olementary capacity meters detailed ropriately qualified to as to the standards of |

Original to be kept by Professional Lead/Line Manager.

Completed copy to be sent to Head of Pharmacy and Medicines Management for inclusion on the Trust's Prescribing Register.

Appendix 6 CONFIRMATION OF RE-ENTRY OF NON-MEDICAL PRESCRIBER TO TRUST REGISTER

Non-medical prescribers are required by the Trust to confirm on a yearly basis that they wish to remain on the Trust NMP register (as per NMP Policy). If the areas of practice have not changed then this form should be completed and signed by the practitioner and line manager; if areas of prescribing have changed then the practitioner should complete the form to re-register (Appendix 5).

| Name | |
|----------------------|--|
| Hospital/Base | |
| Job title | |
| NMC pin/AHP | |
| HCPC no./ | |
| Pharmaceutical | |
| Society | |
| registration | |
| number and expiry | |
| date Or other | |
| professional body | |
| (please state) | |
| Date of first | |
| registration as | |
| prescriber | |
| Type of prescriber | Community Practitioner Nurse prescriber V100 |
| (tick one) | Nurse Independent/supplementary V300 |
| | Pharmacist independent prescriber |
| | Pharmacist supplementary prescriber |
| | AHP supplementary prescriber |
| NMP sign and | |
| NMP sign and date | |
| Manager/lead | |
| professional sign | |
| and date | |
| | |

Please send completed for to the Head of Pharmacy and Medicines Management:

| Head of Pharmacy | |
|------------------|--|
| | |

Appendix 7

This email has been forwarded by the PSNI on behalf of DHSSPS. Particular significance for: Registered pharmacists Nurse Independent Prescribers Other relevant individuals and healthcare professionals From: The Chief Pharmaceutical Officer Dr Norman Morrow FPS Room D4.7, Castle Buildings Upper Newtownards Road Belfast, BT4 3SQ Tel:

Our Ref: DH1/12/112169 Date: 30 April 2012 Dear Colleagues

THE MISUSE OF DRUGS (AMENDMENT) REGULATIONS (NORTHERN IRELAND) 2012

The above regulations amend the 2002 Regulations^[1] and come into operation on 10 May 2012.

1. The amendments provide that Pharmacist Independent Prescribers, as defined in the amendment, may prescribe any controlled drug in Schedule 2, 3, 4 and 5 of the 2002 Regulations, as amended. (Prescription of cocaine, diamorphine, dipipanone and their salts, or products containing these substances, for a person addicted to any controlled drug listed in the Schedule to the 1973 Regulations[2] is not permitted, except for the purpose of treating organic disease or injury.) Those who will avail of this provision must ensure that prescribing is undertaken in conjunction with professional standards and guidance particularly as they pertain to prescriber's competence; training; monitoring and governance arrangements, including the role of the Accountable Officer, in both the Health Service and independent settings and the principle of separation of prescribing and dispensing roles.

2. The amendments provide that Nurse Independent Prescribers, as defined in the 2002 Regulations, as amended, may prescribe any controlled drug in Schedule 2, 3, 4 and 5 of the 2002 Regulations, as amended. (Prescription of cocaine, diamorphine, dipipanone and their salts, or products containing these substances, for a person addicted to any controlled drug listed in the Schedule to the 1973 Regulations is not permitted, except for the purpose

of treating organic disease or injury.)

Again, those who will avail of this provision must ensure that prescribing is undertaken in conjunction with professional standards and guidance particularly as they pertain to prescriber's competence; training; monitoring and governance arrangements, including the role of the Accountable Officer, in both the Health Service and independent settings and the principle of separation of prescribing and dispensing roles.

3. The above amendment regulations make provision for Nurse and Pharmacist Independent Prescribers to administer to a patient any controlled drug that they may

prescribe under the regulations, without the directions of a doctor or dentist. They also provide that any person may administer any controlled drug in accordance with the directions of a Nurse Independent Prescriber or Pharmacist Independent Prescriber, provided it is prescribed in accordance with the regulations.

4. A further amendment permits a Nurse Independent Prescriber, or Supplementary Prescriber acting under and in accordance with a Clinical Management Plan, to compound any drug in Schedule 2, 3, 4 or 5 for the purposes of administration under the relevant regulation. Any person acting in accordance with the written directions of a Nurse Independent Prescriber, a Pharmacist Independent Prescriber, or Supplementary Prescriber acting under and in accordance with a Clinical Management Plan, may compound any drug in Schedule

2, 3, 4 or 5 for the purposes of administration under the relevant regulation.

5. The provision previously relating to use of diamorphine under a Patient Group Direction in a coronary care unit or an accident and emergency department has been amended to provide that a registered nurse or a pharmacist, when acting in their capacity as such, may supply or offer to supply, under and in accordance with the terms of a PGD, diamorphine or morphine where administration of such drugs is required for the immediate, necessary treatment of sick or injured persons, in any setting.

6. Nurse Independent Prescribers have been added to the list of those who may supply certain specified articles (paraphernalia, Reg 6A) for administering or preparing controlled drugs.

7. Regulation 4 of the 2002 regulations, relating to exceptions for the import and export of Schedule 4 Part II drugs (e.g. the anabolic steroids), has been amended to the effect that import or export, to be lawful, must be carried out in person for administration of the drug to that person.

8. Pharmacists have been added to Schedule 8 of the 2002 Regulations (those persons who may supply or administer a specified controlled drug under a patient group direction.)

9. The amendment regulations also make the necessary arrangements regarding possession by specified persons, when appropriate, of controlled drugs for the purposes described in the regulations, supply, offer to supply, requisitions and furnishing of information.

10. This letter is for information and guidance and may also indicate to organisations where local policies and procedures for the governance of controlled drugs needs to be updated. It is not a definitive legal account of the effect of the amendments and professionals should consult their respective regulatory or leadership organisations for further guidance. Helpful information may be found in Home Office Circular 009/2012 which relates to the corresponding GB Regulations.

Yours sincerely

Dr Norman Morrow Mrs Angela McLernon

Chief Pharmaceutical Officer Chief Nursing Officer (Acting)

Appendix 8 CLINICAL MANAGEMENT PLAN (CMP)

The Clinical Management Plan is the foundation stone of supplementary prescribing – it must be formally agreed by the Independent Prescriber (Doctor) before prescribing occurs. It is essential that there is an agreed CMP in place (written or electronic) relating to a named patient and to that patient's specific condition to be managed by the supplementary prescriber. This must be included in the patient's record. The CMP must include the following:

- A reference to the medicines (by individual medicine or class of medicines) that may be prescribed for the named patient by the supplementary prescriber.
- The CMP may include references to published national or local guidelines. However they must clearly identify the range of relevant medicinal products to be used in the treatment of the patient and the CMP should draw attention to the relevant part of the guideline. The guidelines must also be accessible.
- The circumstances in which the supplementary prescriber can vary the dosage, frequency and formulation of the specific medicines.
- The circumstances in which the supplementary prescriber should refer back to the independent prescriber.
- Relevant warning about any known sensitivities of the patient to particular medicines and arrangements for the notification of any adverse drug reactions.
- The date on which the supplementary prescribing arrangements commence and the date by which it should be reviewed.
- The formal agreement to the CMP of the independent and supplementary prescribers and of the patient.

TEMPLATE CMP 1 (Blank): for teams that have full co-terminus access to patient records

| Name of Patient: | | | Patient medication sensitivities/allergies: | | | |
|---|----------------|----------|--|---|--------------------------------|--|
| Patient identification e.g. ID number, date of birth: | | | | | | |
| Independent Prescriber(| s): | | Supplementary Prescriber(s) | | | |
| Condition(s) to be treate | d | | Aim of treatment | | | |
| Medicines that may be p | rescribed by | SP: | | | | |
| Preparation Indication | | | Dose schedule | ose schedule Specific indications for referral back to the IP | | |
| Guidelines or protocols s | supporting Cli | nical Ma | anagement Plan: | I | | |
| Frequency of review and | l monitoring b | y: | | | | |
| Supplementary prescriber Supple | | | ementary prescriber and Independent prescriber | | | |
| Process for reporting ADRs: | | | | | | |
| Shared record to be used by IP and SP: | | | | | | |
| | | | d by supplementary iber(s) | Date | Date agreed with patient/carer | |

Drugs and Therapeutics _Non-Medical Prescribing of Medicines_V1_Sept 13

9088 of 10305

TEMPLATE CMP 2 (Blank): for teams where the SP does not have co-terminus access to the medical record

| Name of Patient: | | | Patient medication sensitivities/allergies: | | |
|---|-------------|---------------|---|----------|---|
| Patient identification e.g. ID number, date of birth: | | | | | |
| Current medication: | | | Medical history: | | |
| Independent Prescribe | r(s) | | Supplementary pr | rescribe | r(s): |
| Contact details: (tel/en | ail/addres | s) | Contact details: (tel/email/address) | | |
| Conditions(s) to be treated: | | | Aim of treatment: | | |
| Medicines that may be | prescribed | d by SP: | | | |
| Preparation | Indication | | Dose schedule | | ific indications for al back to the IP |
| Guidelines or protocols | s supportin | g Clinical Ma | anagement Plan: | | |
| Frequency of review a | nd monitor | ing by: | | | |
| Supplementary prescriber Supplementary prescriber and Independent prescrib | | | | | endent prescriber |
| Process for reporting ADRs: | | | | | |
| Shared record to be used by IP and SP: | | | | | |
| Agreed by independent prescriber(s);DateAgreed by supplementary prescribers(s):DateDate agree patient/care | | | | | |

Appendix 9



Department of Health, Social Services and Public Safety

www.dhsspsni.gov.uk

AN ROINN Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

MÄNNYSTRE O Poustie, Resydènter Heisin an Fowk Siccar

Directors of Nursing, Public Health Agency and HSC Trusts Family Practitioner Service Leads. HSC Board (FAO Nurse and Pharmacist Independent Prescribers in General Practice) RQIA **Chief Executive NIPEC** Linda Johnston, Head of School, QUB Owen Barr, Head of School, U.U. **Directors of Pharmaceutical Services, HSC** Trusts **Assistant Director of Pharmacy and Medicines** Management, HSC Board Kathryn Turner, BSO Head of Professional Services, Pharmaceutical **Society of Northern Ireland** Professor Sean Gorman, Head of School of Pharmacy, QUB Professor Paul McCarron, Head of School of Pharmacy, University of Ulster

Room C5.14 Castle Buildings Stormont Estate Belfast BT4 3SQ Tel: Fax: Email: Ref: Our Ref: DH1/10/19728 Date: 4th February 2010

Dear Colleagues,

Non-Medical Prescribing: Changes in legislation regarding mixing of medicines and prescribing unlicensed medicines

Following an MHRA public consultation earlier in the year (Proposal for amendments to medicines legislation to allow mixing of medicines in palliative care) changes to legislation have come into force which allows:

- Nurse and pharmacist independent prescribers, and supplementary prescribers when working
 within the terms of a clinical management plan, to mix medicines for administration and provide
 written directions for others to do so
- Nurse and pharmacist independent prescribers to prescribe unlicensed medicines

The Medicines (Exemptions and Miscellaneous Amendments) Order 2009 and the Medicines for Human Use (Miscellaneous Amendments) (No.2) Regulations 2009 were laid before Parliament on November 25th 2009 and came into force on 21st December 2009.

The above amendments do not extend to controlled drugs although MHRA is working with the Home Office to ensure that this is incorporated.

In the meantime existing good practice should continue in relation to mixing of controlled drugs based on MHRA"s existing statement, of which the Home Office is aware and with which the Drugs and Therapeutics _Non-Medical Prescribing of Medicines_V1_Sept 13

Department would concur. The MHRA statement which is included within "The Public consultation (MLX 356): Proposal for amendments to medicines legislation to allow mixing of medicines in palliative care" may be accessed at:

http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON033523

A number of other useful websites which further detail the changes and which you should find useful include the following:-

- Mixing of medicines- http://www.rpsgb.org/pdfs/LEBmixmedicines.pdf
- Prescribing of unlicensed medicines by Pharmacist and Nurse Independent Prescribers • http://www.rpsqb.org/pdfs/LEBunlicensedmed.pdf

Note that the NPC non-medical prescribing FAQs: http://www.npc.co.uk/prescribers/faq.htm will be amended in due course to reflect these changes in legislation.

I would be grateful if you would bring this to the attention of all nurse and pharmacist Independent Prescribers, supplementary prescribers and relevant areas of practice.

Yours sincerely

MARTIN BRADLEY

Chief Nursing Officer

CC. Christine Jendoubi Directors of Children"s Services, HSC Trusts Nurse Prescribing Advisors:-Oriel Brown **Michelle McCourt** Gillian Plant Rose McHugh Brenda Bradley, HSCB Greg Miller, HSCB Rosario Baxter, U.U. Marie Glackin Loretta Gribben Marie Nesbitt, Educare Maura Devlin, Beeches Management Centre Pat Cullen, Public Health Agency Cathy Harrison Angela McLernon

Norman Morrow **Chief Pharmaceutical Officer**



Reference no: SG 14/13

| Title: | Non-Medical Prescribing (NMP) of medicines | | | | |
|-------------------------|--|--|-------------------|--|------------|
| Author(s) | Eimear McCusker, Head of Pharmacy & Medicines Management Karen Devenney, Senior Manager Central Nursing Paula Cahalan, Allied Health Professional Lead | | | | |
| Ownership: | Caroline Leonard, Director of Surgery and Specialist Services | | | | |
| Approval by: | Drugs and Therapeutics Committee Standards and Guidelines Committee Policy Committee Executive Team | | Approval date: | 02/02/2018 07/03/2018 02/05/2018 09/05/2018 | |
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| Key Words: | Non- Medical Prescribers, NMP | | | | |
| Links to other policies | | | | | |

| Date | Version | Author | Comments |
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| 21/10/2008 | 1.0 | V. Hall | Initial draft |
| 21/09/2009 | 1.1 | V. Hall | Revised following consultation |
| 24/11/2010 | 1.2 | V.Hall | Consultation with Olive MacLeod, Co- Director Nursing Governance, BHSCT |
| 21/12/2010 | 1.3 | V.Hall | First draft consultation with Oriel Brown, Nurse Consultant, Service Development and Service Improvement (Prescribing) Public Health Agency |
| 07/01/2011 | 1.4 | V.Hall | Second draft consultation with Eimear McCusker, Head of Pharmacy and Medicines Management, BHSCT |
| 07/02/2011 | 1.5 | V.Hall | Third draft consultation with Paula King, Lead Pharmacist, BHSCT |
| 15/11/2012 | 1.6 | V.Hall | Updated policy following amendments to controlled drug legislation and NMPs |
| 16/01/2013 | 1.7 | V.Hall | Update following comments |
| 25/02/2013 | 1.8 | V.Hall | Update following AHP comments |
| 25/03/2013 | 1.9 | V.Hall | Update following A Wilson comments |
| 26/06/2013 | 1.10 | V.Hall | Update following D Robinson comments |
| 30/07/2013 | 1.11 | V.Hall | Update following D Robinson comments |
| 19/12/2017 | 2.0 | EMcCusker | Updated with Pharmacy and AHP comments |

1.0 INTRODUCTION / PURPOSE OF POLICY

This policy sets out a framework for the development and implementation of nonmedical prescribing of medicines within the Belfast Health and Social Care Trust (BHSCT) and thus establishes a consistent approach for non-medical prescribing. This policy applies to all registered nurses, midwives, specialist community public health nurses, pharmacists and other allied health professionals registered with the Trust as non-medical prescribers of medicines in accordance with their job descriptions and KSF outlines.

(Where the term 'nurse' is used throughout the remainder of this document it includes midwives and specialist community public health nurses).

This document is underpinned by and should be read in conjunction with the documents listed in Appendix 1.

1.1 <u>Background</u>

This policy sets out a framework for the development and implementation of nonmedical prescribing of medicines within the Belfast Health and Social Care Trust (BHSCT).

1.2 <u>Purpose</u>

- 1.2.1 Ensure professional and statutory obligations are met.
- 1.2.2 Contribute to the provision of holistic care.
- 1.2.3 Provide robust standards for non-medical prescribing of medicines.
- 1.2.4 Clarify accountability and responsibility.
- 1.2.5 Provide a framework under which potential applicants could determine eligibility to undertake an approved prescribing programme.
- 1.2.6 To maintain a live register of NMPs in BHSCT with an agreed annual renewal process.

2.0 DEFINITIONS/SCOPE OF THE POLICY

- **2.1** This policy will apply throughout the Belfast Health and Social Care Trust.
- 2.2 <u>Definition of Independent Prescribing</u> The working definition of independent prescribing is prescribing by a practitioner (e.g. doctor, dentist, nurse, pharmacist or AHP) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, included prescribing of medicines. Within medicines legislation the term used is "appropriate prescriber".
- **2.3** <u>Definition of Supplementary prescribing</u> A voluntary partnership between an independent prescriber (a doctor or dentist), who has made the initial assessment and diagnosis, and a supplementary prescriber who may prescribe any medicine, in accordance with the agreed patient-specific clinical management plan with the patient's consent.

2.4 <u>Prescribing from the Nurse Prescribers Formulary</u> – Community Practitioner Nurse Prescribers (CPNPs) V100 – formerly District Nurse/Health Visitor prescribers must only prescribe items listed within the Nurse Prescribers Formulary for Community Practitioners as outlined in the Northern Ireland Drug Tariff.

3.0 ROLES/RESPONSIBILITIES

All Line Managers and Non-Medical Prescribers (NMP) within the BHSCT must be familiar with this policy.

4.0 KEY POLICY PRINCIPLES

4.1 Policy / Guideline Description

This document outlines the BHSCT policy for non-medical prescribing of medicines by nurses, pharmacists and allied health professionals in accordance with guidance outlined in Appendix 1.

4.2 Policy Statements

4.2.1 <u>Categories of individuals who can prescribe medicines as independent /</u> <u>supplementary prescribers</u>

Non-Medical staff who have successfully completed a recognised prescribing course, have registered with the appropriate professional body as a prescriber of medicines and have been approved and registered as a non-medical prescriber on the BHSCT register for non-medical prescribers can prescribe as either independent or supplementary prescribers.

Qualified staff transferring from other Trusts cannot practice as a non-medical prescriber in the BHSCT until they have been formally approved and registered on the BHSCT register (Appendix 5).

4.2.2 The categories of nurses who can prescribe medicines are:

- Nurse **Independent Prescribers** can prescribe any medicine for any medical condition within their competence including some controlled drugs.
- Nurse **Supplementary Prescribers** can prescribe any medicine, including some controlled drugs under a Clinical Management Plan in partnership with an independent prescriber (doctor or dentist).
- More detailed information is provided in the British National Formulary (BNF).
- CPNPs must only prescribe items listed within the Nurse Prescriber's Formulary for Community Practitioners as outlined in the Northern Ireland Drug Tariff.

4.2.3 <u>The categories of pharmacists who can prescribe medicines are</u>:

- Pharmacist Independent prescribers can prescribe any medicine for any medical condition within their competence including some controlled drugs.
- Pharmacist **Supplementary prescribers** can prescribe any medicine, including some controlled drugs under a Clinical Management Plan in partnership with an independent prescriber (doctor or dentist).

4.2.4 The categories of Allied Health Professionals who may prescribe medicines are:

Non-Medical Prescribing of Medicines_v2_March_2018

- Optometrist Independent Prescribers can prescribe any licensed medicine for ocular conditions affecting the eye and surrounding tissue, but cannot prescribe any controlled drugs.
- Physiotherapy, Therapy Radiography and Podiatry Independent Prescribers can prescribe any medicine for any medical condition within their competence including some controlled drugs
- Physiotherapy, Podiatry, Radiography, Dietetics and Optometry Supplementary prescribers can prescribe under a Clinical Management Plan in partnership with an independent prescriber (doctor or dentist). AHPs can only prescribe controlled drugs as supplementary prescribers when the drugs are clearly defined within the clinical management plan.

4.3 Selection criteria

All entrants to prescribing training must be selected according to the criteria set by the individual prescribing programme and the respective professional body for each of the professional groups. Applicants must have a named medical officer within the clinical area who will act as a mentor and have the approval of BHSCT to complete the training course. Applicants must have the support of their line manager.

The prescriber must have the opportunity to prescribe within their post following completion of training. The therapeutic areas for prescribing must be identified.

4.4 Admission criteria to the Nurse Independent / Supplementary Prescribing Programme

The Nurse Independent / Supplementary Prescribing course is delivered by Queen's University, Belfast and the University of Ulster, Jordanstown over one academic year. Part time employees must have worked for a sufficient period to be deemed competent by their line manager.

The aim in selection of students to undertake the programme is to identify those who will successfully complete the course and be able to carry out the role of nurse prescriber within their speciality/area of expertise.

Appendix 2 details the admission criteria checklist.

4.5 Admission criteria to the Community Practitioner Nurse Prescribing Programme

At present the nurse prescribing programme is integrated into the BSc (Hons) / PG Diploma Community and Public Health Nursing.

4.6 Admission criteria to the Pharmacist Independent Prescribing Course

The course is over a six month period leading to a Post Grad Certificate in Independent/Supplementary Prescribing for pharmacists. The course is provided jointly by Queens University, Belfast and NICPLD (Northern Ireland Centre for Pharmacy Learning and Development). Part time employees must have worked for a sufficient period to be deemed competent by their line manager/Professional Lead. Applicants must be registered with the Pharmaceutical Society of Northern Ireland (PSNI) (or eligible to register), have 2 years post-registration experience and have experience in the clinical area in which they wish to practice as a pharmacist independent prescriber.

Candidates may also complete the Pharmacist Independent Prescribing Course as part of the MSc in Advanced Clinical Pharmacy Practice

Appendix 3 outlines the admission criteria checklist.

4.7 Admission criteria to the AHP Independent / Supplementary Prescribing Programme

The AHP Independent / Supplementary Prescribing Course is delivered by the University of Ulster, Jordanstown. The applicant must be registered with at least one year's experience immediately preceding the application in the clinical area in which they intend to prescribe. Part time employees must have worked for a sufficient period to be deemed competent by their line manager/ Professional Lead, as appropriate.

Appendix 4 outlines the admission criteria checklist.

4.8 Application process

Nursing

Commissioning for nurse independent / supplementary prescribing should be undertaken in line with the framework for the management of nursing and midwifery post registration education commissioning for the BHSCT. Any nurse wishing to undertake the course may apply, having first discussed with and gained approval from their line manager / Associate Director of Nursing and Midwifery (ADN/M). The NMC circular 29/2007 requires that all nurses have an up-to-date criminal records bureau check i.e. within the last 3 years, before they commence the course.

Pharmacy

Pharmacists must have approval from the Pharmacy Post-graduate Application Working Group. All applications must be forwarded by 31st January to the Pharmacy Services Manager.

Allied Health Professionals

The course will be available through the AHP commissioning process. Any AHP within the Trust who wishes to apply must have approval from their Trust Professional Lead.

4.9 Trust Register of Non-Medical Prescribers for medicines

A central register of all non-medical prescribers of medicines within BHSCT will be held by the Head of Pharmacy and Medicines Management.

Each professional lead/line manager should ensure that their non-medical prescribers are fulfilling the role as part of the annual appraisal process. Once placed on the BHSCT register yearly confirmation that the practitioner wishes to

remain on the register should be sent to the Head of Pharmacy and Medicines Management (Appendix 6). This will ensure the register remains 'live'.

Failure to comply with this requirement will result in the practitioner being removed from the BHSCT register and a suspension of prescribing rights within BHSCT. Any practitioner wishing to 'rejoin' the BHSCT register will be required to re-submit a full application as set out in Appendix 5.

- (a) **Trust Registration Process for Non-Medical Prescribers (V300 only for nursing)** The non-medical prescriber must complete the application form for inclusion on the BHSCT Register of Non-Medical Prescribers (Appendix 5).
- (b) The form is signed off by the appropriate Professional Lead / ADN/M who will forward this to the Head of Pharmacy and Medicines Management to include the prescriber's details on the Trust register.
- (c) The Head of Pharmacy and Medicines Management will then issue a letter to the individual to authorise that he/she can prescribe as part of their role and will also inform their line manager of this decision.
- (d) The ADN/M adds the name to the locally held nurse prescribing database.
- (e) The AHP Professional Lead adds the name to the locally held non medical prescribing database.
- (f) The ADN/M or AHP/Pharmacy Professional Lead must ensure the job descriptions states the applicant will work as a non-medical prescriber in BHSCT or a letter of confirmation must be placed in the personal file of non-medical prescribers indicating the change in practice. Parameters of Prescribing should also be held in this file
- (g) The Line Manager must review and verify annually that the non-medical prescriber is working within their authorised area of expertise. A copy of the Confirmation of re-entry to the BHSCT Register Form (Appendix 6) should be completed and sent to the Head of Pharmacy.
- (h) Specific to Community Practitioners (V100 only for nursing)

The Business Services Organisation (BSO) Regional Web Based Registration system enables HSC organisations to:

- maintain a register of non- medical prescribers who wish to obtain their own HS21 prescription pad in line with DoH guidance
- obtain prescriber cypher numbers for non-medical prescribers in the primary care / community setting
- standardise reports to support governance

All primary care / community non medical prescribers must register with BSO using this system.

4.10 Parameters of prescribing and expanding parameters of prescribing

Initially the parameters of prescribing are agreed with the line manager/professional lead as part of the BHSCT registration process as outlined above. The parameters of prescribing will be reviewed as part of the annual appraisal process.

Any changes in prescribing practice must be notified to the Head of Pharmacy and Medicines Management on the full form appendix 5 and must be held in the NMP's personal file.

4.11 Continuing professional development (CPD)

Non-medical prescribers are responsible for ensuring continuous professional development (which should address their prescribing role) and keeping up to date with evidence and best practice in the management of the conditions for which they prescribe, and in the use of relevant medicines and any legislative changes.

The non-medical prescriber must discuss learning needs and provide evidence of learning and development as a prescriber, as part of the annual appraisal process. The Royal Pharmaceutical Society has produced a competency framework for all prescribers -RPS competency framework for all prescribers 2016 - which should be used as a tool to reflect on practice and identify CPD needs.

https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/ Professional%20standards/Prescribing%20competency%20framework/prescribingframework-template.docx

4.12 Legal liability

Non-medical prescribers are individually accountable to their professional body for this aspect of their practice, as for any other, and must act at all times in accordance with the same. Non-medical prescribers are advised to ensure that they have sufficient professional indemnity, for instance by means of membership of a professional organisation or trade union which provides this cover.

4.13 Obtaining prescription pads - Community

Community non- medical prescribers (district nurses, health visitors and AHPs) will need to be registered with BSO to obtain a prescription pad. Non-medical prescribers practising in the acute sector are unlikely to require a prescription pad.

4.14 Patient assessment

Non-medical prescribers can only prescribe for patients who they have assessed for care.

4.15 Security and safe handling of prescription forms

For non-medical prescribers employed in community the security of prescription forms is the responsibility of both the prescriber and their employing organisation. Please refer to section 6.5 of BHSCT Community Medicines Code regarding security of stationary.

4.16 **Prescription writing**

Before writing a prescription the non-medical prescriber should have assessed the patient and have knowledge of:

- Patient's full medication (this should include all prescribed and non-prescribed medication including over the counter and alternative remedies).
- Past medical history.
- Allergy status.
- Patient's current health status.
- A thorough knowledge of the item to be prescribed, i.e. dosage, therapeutic action, side effects, and interactions, frequency of use.
- The current British National Formulary (BNF) or Nurse Prescribers Formulary (NPF) for reference, including guidance on prescription writing.

All non-medical prescribers should prescribe according to the Trust's generic prescribing policy except where this would not be clinically appropriate or where there is no approved generic name. The N.Ireland Formulary should be adhered to as well as Trust approved policies e.g. BHSCT Medicines Code. Non medical prescribers should clearly annotate that they are a supplementary or independent prescriber.

- Nurses should sign as: Nurse Independent Prescriber (NIP) or Nurse Independent Supplementary Subscriber (NISP)
- Pharmacists should sign as Pharmacist Independent Prescriber (PIP) or Pharmacist Independent Supplementary Subscriber (PISP)
- Allied health prescribers should sign as: Allied Health Independent Supplementary Subscribers (AHISP).

In community settings AHP prescribers will use the prescription form HS21 (N).

Nurses working in family planning clinics may prescribe using the same system as doctors in the clinic.

In hospitals non-medical prescribers will prescribe on the relevant prescription form or medicines kardex.

In OPD Clinics / Day procedure, non medical prescribers will complete a letter of recommendation to GPs. They will also clearly annotate their status as outlined (e.g. NISP / PISP / AHISP).

4.17 Patient information

The non-medical prescriber must inform the patient that they are acting as a non-medical prescriber. The non-medical prescriber will explain the following to the patient:

- Indication for the medication.
- The dosage, frequency and method of administration.
- The common side effects.

Non-Medical Prescribing of Medicines_v2_March_2018

- Any precautions they should take.
- What to do if they have any concerns or adverse reactions.
- How to store medicines safely.
- What to do with any leftover medicines at the end of treatment.
- Plan for review if indicated.
- And test their understanding of the information provided

4.18 Prescribing and administration / supply / dispensing

Non medical prescribers must ensure separation of prescribing, dispensing and administering activities whenever possible.

PSNI Standards and Guidance for pharmacist prescribing April 2013

"The pharmacist must not both prescribe and dispense medicines except in exceptional circumstances e.g. where the need for the medicine is urgent and not to dispense would compromise patient care. The pharmacist must have robust procedures in place to demonstrate the separation of prescribing and dispensing."

NMC Standards of proficiency for nurses and midwife prescribers (2006) state: Practice Standard 9: Prescribing and administration / supply

"You must ensure separation of prescribing and administering activities whenever possible"

"In exceptional circumstances where you are involved in both prescribing and administering and patient / clients controlled drug, a second suitably competent person should be involved in checking the accuracy of medication provided"

4.19 Prescribing controlled drugs

4.19.1 Nurses

Amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 were introduced on 10 May 2012 to allow a nurse independent prescriber and a pharmacist independent prescriber to prescribe controlled drugs (CDs) as described in the Department circular DH1/12/112169 (Appendix 7).

Formerly nurse independent prescribers could only prescribe controlled drugs from a limited formulary for specific conditions or by using supplementary prescribing. Nurse independent prescribers can prescribe any controlled drug listed in schedules 2-5 for any medical condition within their competence except diamorphine, cocaine and dipipanone for the treatment of addiction (nurse independent prescribers are able to prescribe other controlled drugs for the treatment of addiction).

Nurse independent prescribers are able to requisition controlled drugs and are authorised to possess, supply, offer to supply and administer the drugs they are able to prescribe. Persons acting in accordance with the directions of a nurse independent prescriber are authorised to administer any schedule 2-5 drugs that the nurse can prescribe,

Detailed advice on writing a prescription for Controlled Drugs is contained in the BNF.

All nurse prescribers wishing to undertake prescription of CDs under this legislation will be required to:

• gain approval from their professional line manager

- provide parameters of prescribing practice for inclusion on the BSO / Trust Central Register provide evidence of successful completion of controlled drugs training
- provide evidence of safe prescribing practice and CPD at annual appraisal
- adhere to BHSCT Controlled Drug policy
- adhere to BHSCT Dealing with discrepancies and concerns about Controlled Drugs

Non-medical prescribers who need to prescribe controlled drugs as part of their role must specify them individually on the parameters of prescribing section of the application form (Appendix 5) and forward to Head of Pharmacy and Medicines Management with evidence of successful completion of CD training.

Schedules are highlighted in the BNF.A comprehensive list of schedules is available from the Home Office and all non-medical prescribers should obtain a copy of this document available from the Home Office Website www.homeoffice.gov.uk/drugs/licensing. A list of schedules is also available in

www.homeoffice.gov.uk/drugs/licensing. A list of schedules is also available in the BHSCT CD policy.

4.20.2 Pharmacists

Pharmacists can prescribe controlled drugs as supplementary prescribers when the drugs are clearly defined within the clinical management plan (Appendix 8).

Pharmacist independent prescribers can prescribe any controlled drug listed in schedules 2-5 for any medical condition within their competence except diamorphine, cocaine and dipipanone for the treatment of addiction (pharmacist independent prescribers are able to prescribe other controlled drugs for the treatment of addiction). Pharmacist independent prescribers are able to requisition controlled drugs and are authorised to supply or administer the drugs they are able to prescribe. Persons acting in accordance with the directions of a pharmacist independent prescriber are authorised to administer any schedule 2-5 drug that the pharmacist can prescribe,

Detailed advice on writing a prescription for Controlled Drugs is contained in the BNF. Non-medical prescribers who need to prescribe controlled drugs a part of their role must specify them individually on the parameters of prescribing section of the application form (Appendix 5).

BHSCT pharmacy independent prescribers must:

- Adhere to BHSCT Controlled Drug policy
- Adhere to BHSCT Dealing with discrepancies and concerns about Controlled Drugs

Schedules are highlighted in the BNF.A comprehensive list of schedules is available from the Home Office and all non-medical prescribers should obtain a copy of this document available from the Home Office Website

www.homeoffice.gov.uk/drugs/licensing. A list of schedules is also available in the BHSCT CD policy.

4.20.3 Allied Health Professionals

AHPs can only prescribe controlled drugs as supplementary prescribers when the drugs are clearly defined within the clinical management plan (Appendix 8).

The clinical management plan should clearly indicate:

- The dates all parties [IP, AHPISP, and patient] agree the Clinical Management Plan
- Name of prescriber and the category of prescriber
- Name of item prescribed, quantity, dose, frequency, and treatment duration.

In primary/community care the non-medical prescriber should agree the process for accessing medical records and recording prescriptions with the GP. If the non-medical prescriber is using computerised records he/she must ensure that they receive adequate and relevant training. Prescribers wishing to produce computer-generated scripts should contact the Professional Lead in the first instance.

Where there is no direct access to the GP records, the prescriber will ensure:

- Written documentation of prescription is sent to the practice manager or an agreed designated member of staff at the GP practice at time of writing (in exceptional circumstances this may be extended to 48 hours). The duplicate copy pad may be used to facilitate this process. These are available from the Professional Lead.
- This designated member of staff at the GP practice will be responsible for ensuring details of the prescription are entered on the prescribing section of the patient's electronic record.

4.21 Review of prescribing

Each prescription is regularly reviewed and is only re-issued to meet clinical need. Suitable provision for monitoring each patient/client's condition is in place for ensuring that patient/client's who need a further examination or assessment do not receive further prescriptions without being seen by an appropriate prescriber.

4.22 Prescribing unlicensed medicines

From 21st December 2009 legislation allows pharmacist and nurse independent prescribers to prescribe unlicensed medicines in all clinical areas on his / her personal responsibility (Appendix 9) in line with BHSCT unlicensed medicines policy.

4.23 Mixing of Medicines

From 21st December 2009 legislation allows pharmacist and nurse independent prescribers and supplementary prescribers, when working within the terms of a clinical management plan, to mix medicines to produce an unlicensed medicine to meet the needs of a particular patient (Appendix 9). The NMP involved in prescribing and actual mixing of medicines should be competent to do so and take full professional and clinical responsibility for their actions. Pharmacists already have authority to mix any drugs in schedules 2-5. Nurse and pharmacist independent prescribers, as well as supplementary prescribers acting in accordance with the terms of a clinical management plan for an individual patient, are authorised to mix any drugs listed in schedules 2-5 prior to administration. Persons acting in accordance with the written directions of a nurse or pharmacist

independent prescriber or, a supplementary prescriber when acting in accordance with the terms of a clinical management plan, are authorised to mix drugs listed in schedules 2-5.

4.24 Prescribing medicines for use outside the terms of licence

Nurse and pharmacist independent prescribers may prescribe medicines off licence or off label i.e. for uses outside their licensed indications/ UK marketing authorisation. The non-medical prescriber must accept professional, clinical and legal responsibility for that prescribing and should only prescribe off licence where it is acceptable clinical practice and in accordance with Trust policy.

Nurse prescribers should refer to NMC standards Practice standard 18: Prescribing medicines for use outside the terms of their licence (off-label). NMC standard 18: Standards of Proficiency for Nurse and Midwife Prescribers.

4.25 Discontinuation of medication

Non-medical prescribers may discontinue medication if they have assessed a patient and in their clinical judgement think this is the best course of action for the patient. Non-medical prescribers should always consider themselves part of the team and not undertake actions without considering the prescribing actions of others.

4.26 Adverse drug reactions

Adverse drug reactions are reported to the Medicines and Healthcare products Regulatory Authority (MHRA) via the Yellow Card Scheme. The electronic Yellow Card, together with instructions on how to use it, is available at www.yellowcard.gov.uk alternatively non-medical prescribers can use hard copy Yellow Cards which can be found at the back of the BNF. All non-medical prescribers should notify the GP /consultant accordingly. There is a need to discuss, inform and make clear notes.

4.27 Drug and Appliance Alerts

In the event of a drug or appliance alert being received, the non-medical prescriber is responsible for taking immediate and appropriate action. There is a need to discuss, inform and make clear notes.

4.28 Incident Reporting

Non-medical prescribers must act in accordance with the Trust's Adverse Incident Reporting Policy and Procedure and report any adverse incident they witness or are involved in to their line manager via Trust Incident report form or Datixweb. There is a need to discuss, inform and make clear notes.

4.29 Audit

Review of non-medical prescribing is part of the overall prescribing monitoring arrangements. In primary and community care BSO prescribing information is available. In hospital settings, internal systems will need to include audit of non-medical prescribing practice and medication incidents.

4.30 Prescribing for Self / Family / Friends

Non-medical prescribers must **not** prescribe any medicine for themselves or for anyone with whom they have a close personal or emotional relationship other than in exceptional circumstances.

4.31 Pharmaceutical Industry

Non-medical prescribers need to be familiar with professional standards on interface with the pharmaceutical industry and BHSCT Interfacing with Industry policy.

5.0 IMPLEMENTATION / RESOURCE REQUIREMENTS

All line managers must be aware of the admission criteria for nurses / pharmacists and allied health practitioners wishing to undertake non-medical prescribing.

All non-medical prescribers must be aware of the policy for non-medical prescribing.

6.0 SOURCE (S) / EVIDENCE BASED

The policy and statutory obligations relating to this policy are listed in Appendix 1.

7.0 <u>REFERENCES INCLUDING RELEVANT EXTERNAL GUIDANCE</u> See sources.

8.0 CONSULTATION PROCESS

Executive Director / Co-Directors of Nursing. Associate Directors of Nursing. Head of Pharmacy and Medicines Management. Non Medical Prescribers. Prescribing advisors EHSSB, Standards and Guidelines Committee. Drugs and therapeutics committee.

9.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.

The outcome of the Equality screening for this policy is:

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08)

Major impact

Minor impact

No impact.

(pp8370-10305 of 20966) (this part 1936 pages)

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

Smear Musher

Author

Date: _____

Caroline A. Leonard

Date: _____

Director

Appendix 1 POLICY AND STATUTORY OBLIGATIONS

- BHSCT (2017) Medicines Code
- DHSS (1986) **Neighbourhood Nursing a Focus for care**: Report of the community nursing Review, Cumberlege Report
- Dept of Health (1998) Review of Prescribing, Supply and Administration of Medicines. (Crown Report)
- Dept of Health (1999) Review of Prescribing, Supply and Administration of Medicines. (Crown Report (Final))
- DHSS&PS (2000) Nursing Midwifery Advisory Group- Nurse prescribing guidance for implementation.
- DHSS&PS (2004) Supplementary Prescribing by Nurses and Pharmacists within the HPSS in Northern Ireland. A Guide for Implementation. April
- DHSS&PS (2004) Extending Independent Nurse Prescribing within the HPSS in Northern Ireland. A Guide for Implementation. April
- DHSS&PS (2004) Use and Control of Medicines. April
- April (2006) Best Practice Guidance for Supplementary Prescribing by nurses within the HPSS in Northern Ireland. April
- NMC (2006) Standards of proficiency for nurse and midwife prescribers. June
- DHSS&PS (2006) Improving Patients' Access to Medicines: A Guide to implementing Nurse and Pharmacist Independent Prescribing within the HPSS in Northern Ireland. December
- NMC (2007) Standards for medicines management.
- Pharmaceutical Society of Northern Ireland (2013) Standards & Guidance for pharmacist prescribing
- NMC (2015) The Code: professional standards of practice and behaviour for nurses and midwives. March
- Chartered Society of Physiotherapists (2016) Medicines, Prescribing and
 Physiotherapy Information Paper PD019. October
- British National Formulary (2018). **Medicines guidance: Non-medical prescribing.** Available at: <u>https://bnf.nice.org.uk/guidance/non-medical-prescribing.html</u>.
- NHS England. Allied Health Professionals: Supplementary prescribing by Dieticians. Available at: <u>https://www.england.nhs.uk/ahp/med-project/dietitians/</u>

Legislative changes that facilitated the implementation of Non-Medical Prescribing are:

- Misuse of Drugs Act (1971)
- The Medicine Act (1968)
- The Health and Personal Social Services N.I. Order (1972)
- The Medicinal Products: Prescription by Nurses Act (1992)
- The Pharmaceutical Services N.I. Order (1992)
- The Pharmaceutical Services (1992 Order) Commencement Order N.I. (1997)
- The Pharmaceutical Services Regulation N.I. (1997)
- Health and Social Care Act Section 63 (2001)
- Prescriptions Only Medicines Order (2003)
- Professional Guidance and Standards for Pharmacist Prescribers' (2007)
- The Medicines for Human Use (Prescribing) Order (2005) Statutory Instrument 2005
 No 765
- The Misuse of Drugs (Amendment) Regulations (NI) (2005) No.119
- HPSS (Primary Medical Services) (Miscellaneous Amendments) Regulations (NI) (2005) No 368
- The Misuse of Drugs and the Misuse of Drugs (Notification of & Supply to Addicts) (Amendment) Regulations (NI) (2005) No 564
- The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 Statutory Instrument (2006) No. 915
- The Nurses and Midwives (Parts of and Entries in the Register) Amendment Order of Council (2006) Statutory Instrument 2006 No. 1015
- The Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations (2006) Statutory Instrument(2006) No. 914
- The Misuse of Drugs (Amendment) Regulations (2006) Statutory Instrument 2006 No. 986
- The National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) Regulations Statutory Instrument (2006) No. 913
- The Misuse of Drugs (Amendment) (No.2) Regulations (NI) (2006) No.214
- The HPSS (Primary Medical Services) (Miscellaneous Amendments) Regulations (NI) (2006)
- Misuse of Drugs (Amendment No 2) Regulations 2012 (SI 2012/973)

Appendix 2 ADMISSION TO THE NURSE INDEPENDENT SUPPLEMENTARY PRESCRIBING PROGRAMME (criteria checklist)

| Applicant's details Admission criteria checklist Ref: NMC Standards | Criteria met Y/N |
|--|---------------------|
| Registered first level nurse, midwife and/or specialist community public | |
| nealth nurse | |
| At least three years post registration experience. The year immediately | |
| preceding application must have been in the clinical field in which the | |
| applicant intends to prescribe | |
| The nurse has been identified through individual Performance Review | |
| Appraisal, the suitability to prescribe before they apply for a training place | |
| The applicant is in a role that enables them to prescribe following | |
| completion of training and which has clear benefits for patients clients | |
| The applicant must have had a Pocva completed within 3 years of | |
| starting the course | |
| The prospective candidate must either be deemed competent in Health | |
| Assessment by his/her professional lead and has successfully | |
| undertaken a relevant module in Health Assessment* | |
| Demonstrated ability to study at degree level through: | |
| <u>Undergraduate level</u> (60 credits) | |
| Successful completion of three modules (60 credits) of study at level 2 | |
| with a mark of at least 50%. This will include evidence of the skills | |
| necessary for the implementation of evidence based practice | |
| OR | |
| 2. <u>Postgraduate level</u> | |
| Pre-registration degree in Nursing or Midwifery | |
| Post-registration degree in Nursing, Midwifery or Health | |
| Studies/Sciences | |
| Degree in any other relevant subject area | |
| n addition written confirmation will be required from | |
| I. The Professional Lead/Line Manager of their support for the nurse to | |
| undertake the preparation programme and facilitate ongoing CPD and | |
| supervision to support the prescribing role | |
| 2. A designated medical practitioner who meets eligibility criteria for | |
| medical supervision of nurse prescribers, and who has agreed to | |
| provide the required term of supervised practice. (A guide to help | |
| doctors prepare for and carry out the role of designated medical | |
| practitioner. Feb 2005. | |
| Available at www.npc.co.uk | |

*The Health Assessment module for prescribing will be offered concurrently with the NISP programme for approximately the first two years of the new programme (commencing autumn 2007). After that students will be expected to have evidence of successful completion of the relevant Health Assessment module in advance of the programme.

| Checklist confirmed by | (Line Manager) Date |
|--|---------------------|
| Applicant | Date |
| Associate Director of Nursing | Date |
| Non-Medical Prescribing of Medicines_v2_March_2018 | Page 17 of 30 |

Appendix 3 ADMISSION TO THE PHARMACIST INDEPENDENT / SUPPLEMENTARY PRESCRIBING PROGRAMME (criteria Checklist)

Applicant's details.....

| Admission Criteria Checklist | Criteria met Y/N |
|--|---------------------|
| Registered pharmacist with PSNI | |
| At least two years experience practicing as a pharmacist in a clinical | |
| environment in a hospital setting, following their pre-registration year. | |
| NMP has been identified through Staff Development Appraisal as appropriate in this role | |
| The applicant is in a role that enables them to prescribe following training and which has clear benefits for patients/clients or has been identified as a potential role | |
| In addition written confirmation will be required from: The Pharmacy Services Manager of their support for the pharmacist to undertake the preparation programme and facilitate ongoing CPD and supervision to support their prescribing role A designated medical practitioner who meets eligibility criteria for medical supervision of pharmacist prescribers, and who has agreed to provide the required term of supervised practice | |

| Criteria confirmed: (Line Manager) | Date |
|------------------------------------|------|
| Applicant signature | Date |
| Head of Pharmacy | Date |

Appendix 4 ADMISSION TO THE ALLIED HEALTH PROFESSIONAL INDEPENDENT SUPPLEMENTARY PRESCRIBING PROGRAMME

Applicant's details.....

| Admission Criteria Checklist | Criteria met Y/N |
|---|---------------------|
| HCPC registered radiographer, physiotherapist, podiatrist, optometrist or dietitian | |
| At least three years post registration experience. The year immediately preceding application must have been in the clinical field in which the applicant intends to prescribe | |
| Before applying for a training place the radiographer, physiotherapist, podiatrist, optometrist or dietitian's suitability to become a prescriber has been identified through performance review/appraisal | |
| The applicant is in a role that enables them to prescribe following completion of training and which has clear benefits for patients/clients | |
| The applicant must have had an Access NI assessment which has been completed within the previous 3 years (NB in order to prescribe a registrant is required to have an up to date Access NI Assessment) | |
| In addition written confirmation will be required from: The Line Manager/Professional Lead confirming their support for the radiographer/physiotherapist/podiatrist/optometrist/dietitian to undertake the preparation programme and facilitate ongoing CPD and supervision to support the prescribing role | |
| 2. A designated medical practitioner who meets eligibility criteria for medical supervision of radiographer/podiatrist/physiotherapist/optometrist/dietitian prescribers, and who has agreed to provide the required term of supervised practice. (A guide to help doctors prepare for and carry out the role of designated medical practitioner. Feb 2005. Available at www.npc.co.uk. | |

Criteria confirmed by (Professional Lead)

Date.....

Applicant.....

Date.....

Signature of Designated Professional Head of Service or Trust AHP Lead

..... Date.....

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)

Appendix 5

Application for inclusion on the Belfast Health and Social Care <u>Trust Register of Non-Medical Prescribers</u> (Details as per professional register)

| First Name | Surname |
|-----------------|-----------|
| Hospital / Base | Job Title |

| Registration Details | |
|---|--|
| NMC Pin No. / Pharm Soc Reg No /AHP HCPC no : | |
| Type of prescriber: (Please circle) | |
| Nurse Independent / supplementary V300 • | |
| Pharmacist Independent/Supplementary prescriber • | |
| AHP Supplementary Prescriber AHP Independent Prescriber | |
| | |

| Location (please delete as appropriate) | | | | |
|---|----------|--|--|--|
| Hospital in-patients | Yes / No | | | |
| Primary Care / Community | Yes / No | | | |
| Hospital out-patient / interface | Yes / No | | | |
| Prescription Pad: | | | | |
| Only non-medical prescribers prescribing in the community will be able to prescribe from the non-medical prescribing budget and therefore require a prescription pad from BSO | | | | |
| Prescription pad required | Yes / No | | | |
| If Yes please refer to the section on obtaining prescription pads – process for registration of Non-medical Prescribers with Central Services Agency (BSO) | | | | |

Parameters of Prescribing

| Therapeutic | Groups of | Evidence based | Please demonstrate |
|-------------|--|---|---|
| area | drugs to be prescribed (Controlled drugs schedules 2,3 | prescribing – state local / national guidelines e.gNI formulary, NICE | how competency was gained in this area |
| | and 4, 5 must be listed individually | | |
| | | | |
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Please sign appropriately:

| Prescriber (As per professional register) | I confirm I will work as a NMP within my agreed parameters of prescribing and in line with trust policy. I have developed and attained competencies specific to my role. | Name (Block Capitals) | Address: |
|--|--|--------------------------|----------|
| | Date: | Signature | |
| | | | |
| Professional Lead AHP / Associate Director of Nursing/ Pharmacy Team Lead (8B and above) | The Trust is in agreement that the above named professional will prescribe in an Independent and Supplementary capacity as part of their employed role for the parameters detailed above. I am satisfied that the professional is appropriately qualified to undertake this role. I will ensure that the professional conforms to the standards of proficiency for their professional body in relation to prescribing in his/her area of competence. Verification of prescribing status Copy of NMC "Statement of Entry" attached Copy of certificate of completion of pharmacist independent prescribing course attached Copy of AHP certificate of completion of course attached | | |
| | Name Block Capitals | | Date: |
| | Signature | | 20101 |

Original to be kept by Professional Lead/Line Manager.

Completed copy to be sent to Head of Pharmacy and Medicines Management for inclusion on the Trust's Prescribing Register.

Appendix 6 CONFIRMATION OF RE-ENTRY OF NON-MEDICAL PRESCRIBER TO TRUST REGISTER

Non-medical prescribers are required by the Trust to confirm on a yearly basis that they wish to remain on the Trust NMP register (as per NMP Policy). If the areas of practice have not changed then this form should be completed and signed by the practitioner and line manager; if areas of prescribing have changed then the practitioner should complete the form to re-register (Appendix 5).

| Name | |
|-------------------------------------|--|
| Hospital/Base | |
| Job title | |
| NMC pin/AHP HCPC no./ | |
| Pharmaceutical Society registration | |
| number | |
| Date of first registration as | |
| prescriber | |

Non-medical prescribers will be expected to ensure continuous professional development and to keep up to date with evidence and best practice in the management of the conditions for which they prescribe, and in the use of relevant medicines and any legislative changes.

The non-medical prescriber must discuss learning needs and provide evidence of learning and development as a prescriber, as part of the annual appraisal process. The Royal Pharmaceutical Society has produced a competency framework for all prescribers -RPS competency framework for all prescribers 2016 - which should be used as a tool to reflect on practice and identify CPD needs.

https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/ Professional%20standards/Prescribing%20competency%20framework/prescribingframework-template.docx

| NMP confirm sign and date | |
|---|--|
| Line Manager/Professional Lead confirm, | |
| sign and date | |

Please send completed form to the Head of Pharmacy and Medicines Management:

| Head of Pharmacy | |
|------------------|--|
| | |

Non-Medical Prescribing of Medicines_v2_March_2018

Appendix 7

This email has been forwarded by the PSNI on behalf of DHSSPS. Particular significance for: Registered pharmacistsNurse Independent Prescribers Other relevant individuals and healthcare professionals

From: The Chief Pharmaceutical Officer Dr Norman Morrow FPS Room D4.7, Castle Buildings Upper Newtownards Road Belfast, BT4 3SQ Tel: _____/Fax: ______/Fax: _____

Our Ref: DH1/12/112169 Date: 30 April 2012

Dear Colleagues

THE MISUSE OF DRUGS (AMENDMENT) REGULATIONS (NORTHERN IRELAND) 2012

The above regulations amend the 2002 Regulations^[1] and come into operation on 10 May 2012.

1. The amendments provide that Pharmacist Independent Prescribers, as defined in the amendment, may prescribe any controlled drug in Schedule 2, 3, 4 and 5 of the 2002 Regulations, as amended. (Prescription of cocaine, diamorphine, dipipanone and their salts, or products containing these substances, for a person addicted to any controlled drug listed in the Schedule to the 1973 Regulations[2] is not permitted, except for the purpose of treating organic disease or injury.) Those who will avail of this provision must ensure that prescribing is undertaken in conjunction with professional standards and guidance particularly as they pertain to prescriber's competence; training; monitoring and governance arrangements, including the role of the Accountable Officer, in both the Health Service and independent settings and the principle of separation of prescribing and dispensing roles.

2. The amendments provide that Nurse Independent Prescribers, as defined in the 2002 Regulations, as amended, may prescribe any controlled drug in Schedule 2, 3, 4 and 5 of the 2002 Regulations, as amended. (Prescription of cocaine, diamorphine, dipipanone and their salts, or products containing these substances, for a person addicted to any controlled drug listed in the Schedule to the 1973 Regulations is not permitted, except for the purpose of treating organic disease or injury.) Again, those who will avail of this provision must ensure that prescribing is undertaken in conjunction with professional standards and guidance particularly as they pertain to prescriber's competence; training; monitoring and governance arrangements, including the role of the Accountable Officer, in both the Health Service and independent settings and the principle of separation of prescribing and dispensing roles.

3. The above amendment regulations make provision for Nurse and Pharmacist Independent Prescribers to administer to a patient any controlled drug that they may prescribe under the regulations, without the directions of a doctor or dentist. They also

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08)

(pp8370-10305 of 20966) (this part 1936 pages)

provide that any person may administer any controlled drug in accordance with the directions of a Nurse Independent Prescriber or Pharmacist Independent Prescriber, provided it is prescribed in accordance with the regulations.

4. A further amendment permits a Nurse Independent Prescriber, or Supplementary Prescriber acting under and in accordance with a Clinical Management Plan, to compound any drug in Schedule 2, 3, 4 or 5 for the purposes of administration under the relevant regulation. Any person acting in accordance with the written directions of a Nurse Independent Prescriber, a Pharmacist

Independent Prescriber, or Supplementary Prescriber acting under and in accordance with a Clinical Management Plan, may compound any drug in Schedule 2, 3, 4 or 5 for the purposes of administration under the relevant regulation.

5. The provision previously relating to use of diamorphine under a Patient Group Direction in a coronary care unit or an accident and emergency department has been amended to provide that a registered nurse or a pharmacist, when acting in their capacity as such, may supply or offer to supply, under and in accordance with the terms of a PGD, diamorphine or morphine where administration of such drugs is required for the immediate, necessary treatment of sick or injured persons, in any setting.

6. Nurse Independent Prescribers have been added to the list of those who may supply certain specified articles (paraphernalia, Reg 6A) for administering or preparing controlled drugs.

7. Regulation 4 of the 2002 regulations, relating to exceptions for the import and export of Schedule 4 Part II drugs (e.g. the anabolic steroids), has been amended to the effect that import or export, to be lawful, must be carried out in person for administration of the drug to that person.

8. Pharmacists have been added to Schedule 8 of the 2002 Regulations (those persons who may supply or administer a specified controlled drug under a patient group direction.)

9. The amendment regulations also make the necessary arrangements regarding possession by specified persons, when appropriate, of controlled drugs for the purposes described in the regulations, supply, offer to supply, requisitions and furnishing of information.

10. This letter is for information and guidance and may also indicate to organisations where local policies and procedures for the governance of controlled drugs needs to be updated. It is not a definitive legal account of the effect of the amendments and professionals should consult their respective regulatory or leadership organisations for further guidance. Helpful information may be found in Home Office Circular 009/2012 which relates to the corresponding GB Regulations.

Yours sincerely

Dr Norman Morrow Chief Pharmaceutical Officer (Acting) Mrs Angela McLernon Chief Nursing Officer

Appendix 8 CLINICAL MANAGEMENT PLAN (CMP)

The Clinical Management Plan is the foundation stone of supplementary prescribing – it must be formally agreed by the Independent Prescriber (Doctor) before prescribing occurs. It is essential that there is an agreed CMP in place (written or electronic) relating to a named patient and to that patient's specific condition to be managed by the supplementary prescriber. This must be included in the patient's record. The CMP must include the following:

- A reference to the medicines (by individual medicine or class of medicines) that may be prescribed for the named patient by the supplementary prescriber.
- The CMP may include references to published national or local guidelines. However they must clearly identify the range of relevant medicinal products to be used in the treatment of the patient and the CMP should draw attention to the relevant part of the guideline. The guidelines must also be accessible.
- The circumstances in which the supplementary prescriber can vary the dosage, frequency and formulation of the specific medicines.
- The circumstances in which the supplementary prescriber should refer back to the independent prescriber.
- Relevant warning about any known sensitivities of the patient to particular medicines and arrangements for the notification of any adverse drug reactions.
- The date on which the supplementary prescribing arrangements commence and the date by which it should be reviewed.
- The formal agreement to the CMP of the independent and supplementary prescribers and of the patient.

TEMPLATE CMP 1 (Blank): for teams that have full co-terminus access to patient records

| Name of Patient: | | | Patient medication sensitivities/allergies: | | | |
|--|-----------------|-----|--|---|--------------------------------|--|
| Patient identification e.g. ID number, date of birth: | | | | | | |
| Independent Prescriber(s): | | | Supplementary Prescriber(s) | | | |
| Condition(s) to be treated | | | Aim of treatment | | | |
| Medicines that may be | prescribed by | SP: | | | | |
| Preparation Indication | | | Dose schedule | Specific indications for referral back to the IP | | |
| Guidelines or protocols supporting Clinical Management Plan: | | | | | | |
| Frequency of review ar | nd monitoring t | by: | | | | |
| Supplementary prescriber Supple | | | ementary prescriber and Independent prescriber | | | |
| Process for reporting ADRs: | | | | | | |
| Shared record to be used by IP and SP: | | | | | | |
| Agreed by independent prescriber(s) | t Date | - | d by supplementary iber(s) | Date | Date agreed with patient/carer | |

TEMPLATE CMP 2 (Blank): for teams where the SP does not have co-terminus access to the medical record

| Name of Patient: | | | Patient medication sensitivities/allergies: | | |
|--|------------|--|---|--|---|
| Patient identification e.g. ID number, date of birth: | | | | | |
| Current medication: | | | Medical history: | | |
| Independent Prescriber(s) | | | Supplementary prescriber(s): | | |
| Contact details: (tel/email/address) | | | Contact details: (tel/email/address) | | |
| Conditions(s) to be trea | ted: | | Aim of treatment: | | |
| Medicines that may be | prescribed | by SP: | | | |
| | Indication | | Dose schedule | | ific indications for al back to the IP |
| Guidelines or protocols supporting Clinical Management Plan: | | | | | |
| Frequency of review and monitoring by: | | | | | |
| Supplementary prescriber Supplementary prescriber and Independent prescriber | | | | | bendent prescriber |
| Process for reporting ADRs: | | | | | |
| Shared record to be used by IP and SP: | | | | | |
| Agreed by independent prescriber(s); | Date | Date Agreed by supplementary prescribers(s): | | | Date agreed with patient/carer |

Appendix 9



Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

Poustie, Resydènter Heisin an Fowk Siccar

Room C5.14

Tel:

Fax:

Email:

Castle Buildings

Stormont Estate

Belfast BT4 3SQ

Directors of Nursing, Public Health Agency and HSC Trusts Family Practitioner Service Leads, HSC **Board (FAO Nurse and Pharmacist Independent Prescribers in General Practice)** RQIA **Chief Executive NIPEC** Linda Johnston, Head of School, QUB Owen Barr, Head of School, U.U. **Directors of Pharmaceutical Services, HSC** Trusts **Assistant Director of Pharmacy and** Medicines Management, HSC Board Kathryn Turner, BSO Head of Professional Services, **Pharmaceutical Society of Northern Ireland** Professor Sean Gorman, Head of School of Pharmacy, QUB Professor Paul McCarron, Head of School of Pharmacy, University of Ulster

Ref: Our Ref: DH1/10/19728 Date: 4th February 2010

Dear Colleagues,

Non-Medical Prescribing: Changes in legislation regarding mixing of medicines and prescribing unlicensed medicines

Following an MHRA public consultation earlier in the year (Proposal for amendments to medicines legislation to allow mixing of medicines in palliative care) changes to legislation have come into force which allows:

- Nurse and pharmacist independent prescribers, and supplementary prescribers when working within the terms of a clinical management plan, to mix medicines for administration and provide written directions for others to do so
- Nurse and pharmacist independent prescribers to prescribe unlicensed medicines

The Medicines (Exemptions and Miscellaneous Amendments) Order 2009 and the Medicines for Human Use (Miscellaneous Amendments) (No.2) Regulations 2009 were laid before Parliament on November 25th 2009 and came into force on 21st December 2009.

Non-Medical Prescribing of Medicines_v2_March_2018

The above amendments do not extend to controlled drugs although MHRA is working with the Home Office to ensure that this is incorporated.

In the meantime existing good practice should continue in relation to mixing of controlled drugs based on MHRA"s existing statement, of which the Home Office is aware and with which the Department would concur. The MHRA statement which is included within "The Public consultation (MLX 356): Proposal for amendments to medicines legislation to allow mixing of medicines in palliative care" may be accessed at:

http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON033 <u>52</u>3

A number of other useful websites which further detail the changes and which you should find useful include the following:-

- Mixing of medicines- http://www.rpsgb.org/pdfs/LEBmixmedicines.pdf •
- Prescribing of unlicensed medicines by Pharmacist and Nurse Independent Prescribers • http://www.rpsgb.org/pdfs/LEBunlicensedmed.pdf

Note that the NPC non-medical prescribing FAQs: http://www.npc.co.uk/prescribers/fag.htm will be amended in due course to reflect these changes in legislation.

I would be grateful if you would bring this to the attention of all nurse and pharmacist Independent Prescribers, supplementary prescribers and relevant areas of practice.

Yours sincerely

MARTIN BRADLEY

Chief Nursing Officer

CC.

Christine Jendoubi Directors of Children's Services. HSC Trusts Nurse Prescribing Advisors:-Oriel Brown Michelle McCourt Gillian Plant Rose McHugh Brenda Bradley, HSCB Greg Miller, HSCB Rosario Baxter, U.U. Marie Glackin Loretta Gribben Marie Nesbitt, Educare Maura Devlin, Beeches Management Centre Pat Cullen, Public Health Agency Cathy Harrison Angela McLernon

Norman Morrow **Chief Pharmaceutical Officer**

Non-Medical Prescribing of Medicines_v2_March_2018



caring supporting improving together

Reference No: SG 14/13

| Title: | Non-Medical Prescribing of Medicines Policy | | | | |
|----------------|---|---------------|-------------|--|--|
| Author(s) | Eimear McCusker, Head of Pharmacy & Medicines Management | | | | |
| | Tel: | | | | |
| | Karen Devenney, Senior Manager Cent | tral Nursing | | | |
| | Tel: Paula Cahalan, Allied Health Profession | nallead | | | |
| | Tel: | | | | |
| | Katie Graham, Optometrist | | , , | | |
| | Tel: | | | | |
| Ownership: | Caroline Leonard, Director of Surgery a | ind Specialis | st Services | | |
| Approval by: | Drugs and Therapeutics Committee | Approval | 14/02/2020 | | |
| | Standards and Guidelines Committee | date: | 09/06/2020 | | |
| | Executive Team Meeting05/08/2020 | | | | |
| Operational | August 2020 | Next | August 2025 | | |
| Date: | | Review: | | | |
| Version No. | 3 Supercedes V2 – March | 2018 | | | |
| Key Words: | Non-Medical Prescribers, NMP, Medicines | | | | |
| Links to | All BHSCT Controlled Drug Acute and Community Policies | | | | |
| other policies | BHSCT Dealing with discrepancies or concerns involving controlled | | | | |
| | <u>drugs (SG 18/11) 2019</u> | | | | |
| | BHSCT Acute and Community Medicines Code (SG 09/11) 2020 | | | | |
| | BHSCT Clinical monitoring of patients prescribed controlled drugs | | | | |
| | <u>(SG 64/16) 2016</u> | | | | |

| Date | Version | Author | Comments | |
|------------|---------|--|--|--|
| 21/10/2008 | 1 | V Hall | Initial draft | |
| 21/09/2009 | 1.1 | V Hall | Revised following consultation | |
| 19/12/2017 | 2 | E McCusker Updated with Pharmacy and AHP com | | |
| 10/10/2019 | 2.1 | E McCusker | Updated with legislation changes and governance arrangements | |

Drugs and Therapeutics Committee_Non-Medical Prescribing (NMP) of Medicines Policy_V3_August 2020 Page 1 of 21

Table of Contents

| | Content Description | Page |
|------|---|------|
| 1.0 | Introduction / Purpose of Policy | 3 |
| 2.0 | Scope of the Policy | 3 |
| 3.0 | Roles / Responsibilities | 3 |
| 4.0 | Key Policy Principles and Application Process | 4 |
| 5.0 | BHSCT and Regional Registration Process | 7 |
| 6.0 | Guidance on Prescribing | 9 |
| 7.0 | CPD and Governance Arrangements | 12 |
| 8.0 | Implementation of Policy | 14 |
| 9.0 | Monitoring | 14 |
| 10.0 | Evidence Base / References | 14 |
| 11.0 | Consultation Process | 14 |
| 12.0 | Appendices / Attachments | 14 |
| 13.0 | Equality and Human Rights Screening | 14 |
| 14.0 | Data Protection Impact Assessment | 15 |
| 15.0 | Rural Impact Assessments | 15 |
| 16.0 | Reasonable Adjustments Assessment | 15 |

1.0 INTRODUCTION / PURPOSE OF POLICY

This policy sets out a framework for the development and implementation of nonmedical prescribing (NMP) of medicines within the Belfast Health and Social Care Trust (BHSCT) and thus establishes a consistent approach for NMP. This policy applies to all registered nurses, midwives, specialist community public health nurses, pharmacists, optometrists, and other allied health professionals registered with the Trust as non-medical prescribers of medicines in accordance with their job descriptions and KSF outlines.

(Where the term 'nurse' is used throughout the remainder of this document it includes midwives and specialist community public health nurses).

1.1 <u>Background</u>

1.2

This policy is required to establish a framework for the development and implementation of NMP of medicines within the Belfast Health and Social Care Trust (BHSCT).

1.3 <u>Purpose</u>

- Ensure professional and statutory obligations are met.
- Contribute to the provision of holistic care.
- Provide robust standards for non-medical prescribing of medicines.
- Clarify accountability and responsibility.
- Provide a framework under which potential applicants could determine eligibility undertake an approved prescribing programme.
- To maintain a live register of NMPs in BHSCT with an agreed annual renewal process.

2.0 SCOPE OF THE POLICY

2.1 This policy will apply throughout the Belfast Health and Social Care Trust for all NMPs.

3.0 ROLES/ RESPONSIBILITIES

3.1 <u>NMPs</u>

NMPs are individually responsible and accountable for their prescribing practice and must adhere to trust policies. NMPs are also responsible for:

- Ensuring that they provide appropriate, evidence based, safe, and cost effective prescribing to service users
- Adhering to their professional codes of conduct (see below) and only practice within their own level of competence and parameters of prescribing.
- Completion of an annual declaration of continued competence.
- Participating in timely annual audit of prescribing practice.

- **3.2** Line Managers and Professional Leads are responsible for the monitoring of the daily prescribing activities of NMPs in relation to their job description. They are also responsible for ensuring that systems are in place to facilitate prescribing practice to include:
 - Ensuring the duties of the NMP are included in job description
 - Ensuring that NMPs are supported to attend CPD within the Trust to maintaining their competencies in line with their job description.
 - Informing the Trust Professional lead if an NMP leaves the Trust or there is concern about the prescribing practice of the NMP.
 - Ensuring NMPs are compliant with any audit requirements.

4.0 KEY POLICY PRINCIPLES

4.1 <u>Definitions</u>

- <u>Definition of Independent Prescribing</u> The working definition of independent prescribing is prescribing by a practitioner (e.g. doctor, dentist, nurse, pharmacist, optometrist, or AHP) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, included prescribing of medicines. Within medicines legislation the term used is "appropriate prescriber".
- <u>Definition of Supplementary prescribing</u> A voluntary partnership between an independent prescriber (a doctor or dentist), who has made the initial assessment and diagnosis, and a supplementary prescriber who may prescribe any medicine, in accordance with the agreed patient-specific clinical management plan with the patient's consent.
- <u>Prescribing from the Nurse Prescribers Formulary</u> Community Practitioner Nurse Prescribers (CPNPs) V100 – formerly District Nurse/Health Visitor prescribers must only prescribe items listed within the Nurse Prescribers Formulary for Community Practitioners as outlined in the Northern Ireland Drug Tariff.

4.2 Key Policy Statements

4.2.1 <u>Categories of individuals who can prescribe medicines as independent /</u> supplementary prescribers

Non-Medical staff who have successfully completed a recognised prescribing course, have registered with the appropriate professional body as a prescriber of medicines and have been approved and registered as a NMP on the BHSCT NMP register can prescribe as either independent or supplementary prescribers (As appropriate).

Qualified staff transferring from other Trusts must apply to register as a NMP in BHSCT.

4.2.2 The categories of nurses who can prescribe medicines are:

• Nurse Independent Prescribers can prescribe any medicine for any medical condition within their competence including some controlled drugs.

- Nurse Supplementary Prescribers can prescribe any medicine, including some controlled drugs under a Clinical Management Plan in partnership with an independent prescriber (doctor or dentist).
- CPNPs must only prescribe items listed within the Nurse Prescriber's Formulary for Community Practitioners as outlined in the Northern Ireland Drug Tariff. More detailed information is provided in the British National Formulary (BNF).
- 4.2.3 The categories of pharmacists who can prescribe medicines are:
 - Pharmacist Independent prescribers can prescribe any medicine for any medical condition within their competence including some controlled drugs.
 - Pharmacist Supplementary prescribers can prescribe any medicine, including some controlled drugs under a Clinical Management Plan in partnership with an independent prescriber (doctor or dentist).

4.2.4 The categories of Allied Health Professionals who may prescribe medicines are:

- Physiotherapy, Therapy Radiography, Paramedics and Podiatry Independent Prescribers can prescribe any medicine for any medical condition within their competence including some controlled drugs (Confirm for each profession)
- Physiotherapy, Podiatry, Paramedics, Radiography and Dietetics prescribers can prescribe under a Clinical Management Plan in partnership with an independent prescriber (doctor or dentist). AHPs can only prescribe controlled drugs as supplementary prescribers when the drugs are clearly defined within the clinical management plan.

4.2.5 The categories of Optometrists who may prescribe medicines are:

• Optometrist independent prescribers can prescribe any licensed medicine for ocular conditions, affecting the eye and adnexa, within their recognised area of expertise and competence of the optometrist. Optometrist Independent Optometrists cannot prescribe controlled drugs.

4.2.6 Application process for Independent/Supplementary Prescribing Programme

All entrants must be selected according to the criteria set by the individual prescribing programme and the respective professional body for each of the professional groups. Applicants must have a named medical officer within the clinical area who will act as a mentor and have the approval of BHSCT to complete the training course. Applicants must have the support of their line manager. The prescriber must have the opportunity to prescribe within their post following completion of training. The therapeutic areas for prescribing must be identified.

4.3.1 Application and Admission to the Nurse Independent / Supplementary Prescribing Programme

The Nurse Independent / Supplementary Prescribing course is delivered by Queen's University, Belfast and the University of Ulster, Jordanstown over one academic year. Part time employees must have worked for a sufficient period to be deemed competent by their line manager.

The aim in selection of students to undertake the programme is to identify those who will successfully complete the course and be able to carry out the role of nurse prescriber within their speciality/area of expertise.

Commissioning for nurse independent / supplementary prescribing should be undertaken in line with the framework for the management of nursing and midwifery post registration education commissioning for the BHSCT. Any nurse wishing to undertake the course may apply, having first discussed with and gained approval from their line manager /Divisional Nurse Lead. The NMC circular 29/2007 requires that all nurses have an up-to-date criminal records bureau check i.e. within the last 3 years, before they commence the course.

Appendix 1 details the admission criteria checklist.

4.3.2 Admission criteria to the Community Practitioner Nurse Prescribing Programme

At present the nurse prescribing programme is integrated into the BSc (Hons) / PG Diploma Community and Public Health Nursing.

4.3.3 Admission criteria to the Pharmacist Independent Prescribing Course

The course is over a six month period leading to a Post Grad Certificate in Independent/Supplementary Prescribing for pharmacists. The course is provided jointly by Queens University, Belfast and NICPLD (Northern Ireland Centre for Pharmacy Learning and Development). Part time employees must have worked for a sufficient period to be deemed competent by their line manager/Professional Lead. Candidates may also complete the Pharmacist Independent Prescribing Course as part of the MSc in Advanced Clinical Pharmacy Practice

Applicants must be registered with the Pharmaceutical Society of Northern Ireland (PSNI) (or eligible to register), have 2 years post-registration experience and have experience in the clinical area in which they wish to practice as a pharmacist independent prescriber.

Pharmacists must have approval from the Pharmacy Post-graduate Application Working Group. All applications must be forwarded by 31st January to the Pharmacy Services Manager for consideration.

Appendix 2 outlines the admission criteria checklist.

4.3.4 Admission criteria to the AHP Independent / Supplementary Prescribing Programme

The AHP Independent / Supplementary Prescribing Course is delivered by the Ulster University. The applicant must be registered with at least one year's experience immediately preceding the application in the clinical area in which they intend to prescribe. Part time employees must have worked for a sufficient period to be deemed competent by their line manager/ Professional Lead, as appropriate.

Allied Health Professionals

The course will be available through the AHP commissioning process. Any AHP within the Trust who wishes to apply must have approval from their Trust Professional Lead.

Drugs and Therapeutics Committee_Non-Medical Prescribing (NMP) of Medicines Policy_V3_August 2020 Page 6 of 21

Appendix 3 outlines the admission criteria checklist.

4.3.5 Admission criteria to the Optometrist Independent Prescribing Programme

The Optometrist Independent Prescribing Course is delivered by a number of institutions across the UK. The Optometrist must have been practising as a qualified Optometrist for at least 2 years in order to commence this course. Approval by line manager or Professional Lead is required prior to commencing if funding is available from the BHSCT, or if study leave is being applied for. Optometrists preparing to become independent prescribers will undertake a specific General Optical Council (GOC) approved programme of training, and must successfully complete the Common Final Assessment of Competence

Optometrists require prior approval from their line manager or Professional Lead in order to commence an Independent Prescribing course, if funding is available from BHSCT or if study leave is required. These are provided by a number of University Optometry departments in the UK, and the Optometrist may be required to self-fund their training and Independent Prescriber qualification.

5.0 BHSCT AND REGIONAL REGISTRATION PROCESS

5.1 Application for inclusion on the BHSCT NMP Register

- A central live register of all non-medical prescribers of medicines within BHSCT can be located at: <u>http://intranet.belfasttrust.local/directorates/css/MedicinesManagement/Pages/N</u><u>MPC.aspx</u>
- The NMP must complete the application form for inclusion on the BHSCT NMP Register. (Appendix 4).
- The Head of Pharmacy and Medicines Management will review the application and if approved issue a letter to the NMP to authorise that he/she can prescribe as part of their role.
- The Divisional Nurse/ AHP Professional Lead/ Optometry Professional Lead will add the name to the locally held database and ensures the individual's job description details the applicant will work as a non-medical prescriber in BHSCT.
- The Line Manager must review and verify annually that the non-medical prescriber is working within their authorised parameters of prescribing. A copy of the Confirmation of re-entry to the BHSCT Register Form (Appendix 5) The annual renewal form should be completed and returned to the Head of Pharmacy.
- Failure to comply with this requirement within the time-frame will result in the practitioner being removed from the BHSCT register and a suspension of prescribing rights within BHSCT. Any practitioner wishing to 'rejoin' the BHSCT register will be required to re-submit a full application as set out in Appendix 4.

5.1.1 Parameters of prescribing and expanding parameters of prescribing

Initially the parameters of prescribing are agreed with the line manager/professional lead as part of the BHSCT registration process as outlined above. The parameters of prescribing will be reviewed as part of the annual appraisal process. It is the

Drugs and Therapeutics Committee_Non-Medical Prescribing (NMP) of Medicines Policy_V3_August 2020 Page 7 of 21

Department of Health's policy in Northern Ireland to extend prescribing responsibilities to a range of non-medical professions. Further information is available at:

<u>https://www.health-ni.gov.uk/articles/pharmaceutical-non-medical-prescribing</u> Professional Leads who approve application forms and parameters of prescribing should ensure applications are in line with this policy and DOH guidance at the link above.

Any changes in prescribing practice must be notified to the Head of Pharmacy and Medicines Management by forwarding a new appendix 4.

5.1.2 Maternity Leave and annual registration

It is the responsibility of the individual NMP to advise the Head of Pharmacy before commencing maternity leave – Upon receipt of this information the Head of Pharmacy will annotate *"Maternity leave"* besides the registrant name for a period of 15 months on the trust register. An annual renewal form must be completed within the 15 months to remain on the register.

It is the responsibility of the line manager to advise the Head of Pharmacy when a prescriber has left the trust or is no longer practicing.

5.2 <u>Application for inclusion on the regional Web Based Registration for</u> prescribing in primary care

5.2.1 The Business Services Organisation (BSO) Regional Web Based Registration system maintains a register of non- medical prescribers who wish to obtain their own HS21 prescription pad in line with DoH guidance. All primary care / community non medical prescribers must register with BSO using this system in order to obtain a cipher number. Before commencing the online registration process, please refer to the 'Northern Ireland Non-Medical Prescriber Registration Manual' which is available at the link below:

http://intranet.belfasttrust.local/directorates/css/MedicinesManagement/Documents/ Non-Medical%20Prescriber%20Registration%20Manual%20-%20Jun%202013.pdf

6.0 GUIDANCE ON PRESCRIBING

6.1 Patient assessment

Before writing a prescription the non-medical prescriber should have assessed the patient and have knowledge of:

- Patient's full medication (this should include all prescribed and non-prescribed medication including over the counter and alternative remedies).
- Past medical history.
- Allergy status.
- Patient's current health status.
- A thorough knowledge of the item to be prescribed, i.e. dosage, therapeutic action, side effects, and interactions, frequency of use.
- The current British National Formulary (BNF) or Nurse Prescribers Formulary (NPF) for reference, including guidance on prescription writing.

All non-medical prescribers should prescribe according to the Trust's generic prescribing policy except where this would not be clinically appropriate or where there is no approved generic name. The N.Ireland Formulary should be adhered to as well as Trust approved policies e.g. BHSCT Medicines Code-Non medical prescribers should clearly annotate that they are a supplementary or independent prescriber. <u>http://niformulary.hscni.net/Pages/default.aspx</u>

Prescriptions should be regularly reviewed and only re-issued to meet clinical need. Suitable provision for monitoring each patient/client's condition should be in place for ensuring that patient/client's who need a further examination or assessment do not receive further prescriptions without being seen by an appropriate prescriber.

Non-medical prescribers may discontinue medication if they have assessed a patient and in their clinical judgement think this is the best course of action for the patient. Non-medical prescribers should always consider themselves part of the team and not undertake actions without considering the prescribing actions of others.

6.2 <u>Patient information</u>

The non-medical prescriber must inform the patient that they are acting as a non-medical prescriber. The non-medical prescriber will explain the following to the patient:

- Indication for the medication.
- The dosage, frequency and method of administration.
- The common side effects.
- Any precautions they should take.
- What to do if they have any concerns or adverse reactions.
- How to store medicines safely.
- What to do with any leftover medicines at the end of treatment.
- Plan for review if indicated.
- And test their understanding of the information provided

Information will be communicated to the patient/service user in a way that is easily understood. This may include the need to use a professional interpreter or the provision of information in alternative formats for people with a disability.

6.3 Prescribing and administration / supply / dispensing

Wherever possible, the actions of prescribing, dispensing/supply and administration are performed by separate healthcare professionals. Exceptionally, where clinical circumstances make it necessary and in the interests of the patient, the same healthcare professional can be responsible for the prescribing and supply/administration of medicines. Where this occurs, an audit trail, documents and processes are in place to limit errors.

https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/ Professional%20standards/SSHM%20and%20Admin/Admin%20of%20Meds%20pr of%20guidance.pdf?ver=2019-01-23-145026-567

6.4 Prescribing for Self / Family / Friends

Non-medical prescribers must **not** prescribe any medicine for themselves or for anyone with whom they have a close personal or emotional relationship other than in exceptional circumstances.

6.5 <u>Prescribing controlled drugs</u>

6.5.1 <u>Nurses</u>

Amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 were introduced on 10 May 2012 to allow a nurse independent prescriber and a pharmacist independent prescriber to prescribe controlled drugs (CDs) as described in the Department circular DH1/12/112169 (Appendix 7).

Formerly nurse independent prescribers could only prescribe controlled drugs from a limited formulary for specific conditions or by using supplementary prescribing. Nurse independent prescribers can prescribe any controlled drug listed in schedules 2-5 for any medical condition within their competence except diamorphine, cocaine and dipipanone for the treatment of addiction (nurse independent prescribers are able to prescribe other controlled drugs for the treatment of addiction).

Nurse independent prescribers are able to requisition controlled drugs and are authorised to possess, supply, offer to supply and administer the drugs they are able to prescribe. Persons acting in accordance with the directions of a nurse independent prescriber are authorised to administer any schedule 2-5 drugs that the nurse can prescribe,

Detailed advice on writing a prescription for Controlled Drugs is contained in the BNF.

All nurse prescribers wishing to undertake prescription of CDs under this legislation will be required to:

- gain approval from their professional line manager
- provide parameters of prescribing practice for inclusion on the BSO / Trust Central Register provide evidence of successful completion of controlled drugs training
- provide evidence of safe prescribing practice and CPD at annual appraisal
- adhere to BHSCT Controlled Drug policy
- adhere to BHSCT Dealing with discrepancies and concerns about Controlled Drugs

Non-medical prescribers who need to prescribe controlled drugs as part of their role must specify them individually on the parameters of prescribing section of the application form (Appendix 5) and forward to Head of Pharmacy and Medicines Management with evidence of successful completion of CD training.

Schedules are highlighted in the BNF.A comprehensive list of schedules is available from the Home Office and all non-medical prescribers should obtain a copy of this

document available from the Home Office Website <u>www.homeoffice.gov.uk/drugs/licensing</u>. A list of schedules is also available in the BHSCT CD policy.

6.5.2 Pharmacists

Pharmacists can prescribe controlled drugs as supplementary prescribers when the drugs are clearly defined within the clinical management plan (Appendix 8).

Pharmacist independent prescribers can prescribe any controlled drug listed in schedules 2-5 for any medical condition within their competence except diamorphine, cocaine and dipipanone for the treatment of addiction (pharmacist independent prescribers are able to prescribe other controlled drugs for the treatment of addiction). Pharmacist independent prescribers are able to requisition controlled drugs and are authorised to supply or administer the drugs they are able to prescribe. Persons acting in accordance with the directions of a pharmacist independent prescriber are authorised to administer any schedule 2-5 drug that the pharmacist can prescribe,

Detailed advice on writing a prescription for Controlled Drugs is contained in the BNF. Non-medical prescribers who need to prescribe controlled drugs a part of their role must specify them individually on the parameters of prescribing section of the application form (Appendix 5).

BHSCT pharmacy independent prescribers must:

- Adhere to BHSCT Controlled Drug policies
- Adhere to BHSCT Dealing with discrepancies and concerns about Controlled Drugs

Schedules are highlighted in the BNF.A comprehensive list of schedules is available from the Home Office and all non-medical prescribers should obtain a copy of this document available from the Home Office Website <u>www.homeoffice.gov.uk/drugs/licensing</u>. A list of schedules is also available in the BHSCT CD policy.

6.5.3 Allied Health Professionals

Physiotherapist Independent Prescribers and Podiatrist Independent Prescribers have the authority to prescribe a limited range of controlled drugs. AHPs can only prescribe controlled drugs as supplementary prescribers when the drugs are clearly defined within the clinical management plan (Appendix 8).

The clinical management plan should clearly indicate:

- The dates all parties [IP, AHPISP, and patient] agree the Clinical Management Plan
- Name of prescriber and the category of prescriber
- Name of item prescribed, quantity, dose, frequency, and treatment duration.

In primary/community care the non-medical prescriber should agree the process for accessing medical records and recording prescriptions with the GP. If the non-

Drugs and Therapeutics Committee_Non-Medical Prescribing (NMP) of Medicines Policy_V3_August 2020 Page 11 of 21

medical prescriber is using computerised records he/she must ensure that they receive adequate and relevant training. Prescribers wishing to produce computer-generated scripts should contact the Professional Lead in the first instance.

Where there is no direct access to the GP records, the prescriber will ensure:

- Written documentation of prescription is sent to the practice manager or an agreed designated member of staff at the GP practice at time of writing (in exceptional circumstances this may be extended to 48 hours). The duplicate copy pad may be used to facilitate this process. These are available from the Professional Lead.
- This designated member of staff at the GP practice will be responsible for ensuring details of the prescription are entered on the prescribing section of the patient's electronic record.

6.5.4 Optometrists

Optometrist Independent Prescribers cannot prescribe controlled drugs.

7.0 CPD AND GOVERNANCE ARRANGEMENTS

7.1 <u>Professional Bodies</u>

Non-medical prescribers are individually accountable to their professional body for this aspect of their practice, as for any other, and must act at all times in accordance with the same. Non-medical prescribers are advised to ensure that they have sufficient professional indemnity, for instance by means of membership of a professional organisation or trade union which provides this cover. NMPs must always prescribe within their parameters of prescribing and feel comfortable with the prescribing decision they have made

7.2 Continuing professional development (CPD)

Non-medical prescribers are responsible for ensuring continuous professional development (which should address their prescribing role) and keeping up to date with evidence and best practice in the management of the conditions for which they prescribe, and in the use of relevant medicines and any legislative changes.

7.3 Annual Renewal for BHSCT Register.

<u>A Competency Framework for all Prescribers</u> July 2016 (RPS)

To support all prescribers to prescribe effectively a single prescribing competency framework was published by the National Prescribing Centre/National Institute for Health and Clinical Excellence (NICE) in 2012. Based on earlier profession specific prescribing competency frameworks this framework was developed because it became clear that a common set of competencies should underpin prescribing regardless of professional background.

The 2012 framework is now in wide use across the UK and was due for review in 2014. NICE and Health Education England approached the Royal Pharmaceutical Society (RPS) to manage the update of the framework on behalf of all the

Drugs and Therapeutics Committee_Non-Medical Prescribing (NMP) of Medicines Policy_V3_August 2020 Page 12 of 21

prescribing professions in the UK. The RPS agreed to update the competency framework in collaboration with patients and the other prescribing professions many of whose professional bodies have endorsed this updated framework.

The Royal Pharmaceutical Society has produced a competency framework for all prescribers -RPS competency framework for all prescribers 2016 - which should be used as a tool to reflect on practice and identify CPD needs. <u>https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20ac</u> <u>cess/Professional%20standards/Prescribing%20competency%20framework/p</u> <u>rescribing-competency-framework.pdf</u>

The key points to note about the scope of the prescribing framework are that:

- It is a generic framework for any prescriber (independent or supplementary) regardless of professional background. It therefore does not contain statements that relate only to specialist areas of prescribing.
- It must be contextualised to reflect different areas of practice and levels of expertise.
- It reflects the key competencies needed by all prescribers; it should not be viewed as a curriculum but rather the basis on which one can be built.
- It applies equally to independent prescribers and to supplementary prescribers but the latter should contextualise the framework to reflect the structures imposed by entering into a supplementary prescribing relationship

Non-medical prescribers will be expected to ensure continuous professional development and to keep up to date with evidence and best practice in the management of the conditions for which they prescribe, and in the use of relevant medicines and any legislative changes.

The non-medical prescriber must discuss learning needs and provide evidence of learning and development as a prescriber, as part of the annual declaration of continued competence.

Evidence of learning and development should also include any compliments or negative feed-back.

As for any professional it is critical NMPs audit their own work as a means of improving the quality of care they provide their patients and provide evidence of learning as part of the annual declaration of continued competence.

8.0 IMPLEMENTATION/ RESOURCE REQUIREMENTS

All line managers and Professional Leads must be familiar with this policy All non-medical prescribers must be familiar with this policy

9.0 MONITORING

The number of NMPs from each profession will be monitored by the trust NMP committee

Drugs and Therapeutics Committee_Non-Medical Prescribing (NMP) of Medicines Policy_V3_August 2020 Page 13 of 21

10.0 EVIDENCE BASE/ REFERENCES

Medicines Code and CD polices. DOH guidance for NMPs

11.0 CONSULTATION PROCESS

Executive Director / Co-Directors of Nursing. Associate Directors of Nursing. Head of Pharmacy and Medicines Management. Non Medical Prescribers. Prescribing advisors HSCB, Standards and Guidelines Committee. Drugs and therapeutics committee.

12.0 APPENDICES / ATTACHMENTS

| Appendix | Title |
|----------|--|
| 1 | Admission to Nurse NMP Programme |
| 2 | Admission to Pharmacist NMP Programme |
| 3 | Admission to AHP NMP Programme |
| 4 | Application for inclusion on the Belfast Health and Social Care Trust Register |
| | of Non-Medical Prescribers |
| 5. | Annual declaration of continued competence for BHSCT NMP Register |
| 6 | Clinical Management Plan |

13.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.

The outcome of the Equality screening for this policy is:

Major impact

Minor impact

No impact.

14.0 DATA PROTECTION IMPACT ASSESSMENT

New activities that involve collecting and using personal data can result in privacy risks. In line with requirements of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 the Trust has to consider the impacts on the privacy of individuals and ways to mitigate against the risks. Where relevant an initial screening exercise should be carried out to ascertain if this policy should be subject to a full impact assessment. The guidance for conducting a Data Protection Impact Assessments (DPIA) can be found via this <u>link</u>.

Drugs and Therapeutics Committee_Non-Medical Prescribing (NMP) of Medicines Policy_V3_August 2020 Page 14 of 21

The outcome of the DPIA screening for this policy is:

Not necessary – no personal data involved

A full data protection impact assessment is required

A full data protection impact assessment is not required

If a full impact assessment is required the author (Project Manager or lead person) should go ahead and begin the process. Colleagues in the Information Governance Team will provide assistance where necessary.

15.0 RURAL IMPACT ASSESSMENTS

From June 2018 the Trust has a legal responsibility to have due regard to rural needs when developing, adopting, implementing or revising policies, strategies and plans, and when designing and delivering public services. It is your responsibility as policy or service lead to consider the impact of your proposal on people in rural areas – you will need to refer to the shortened rural needs assessment template and summary guidance on the Belfast Trust Intranet. Each Directorate/Division has a Rural Needs Champion who can provide support/assistance in this regard if necessary.

16.0 REASONABLE ADJUSTMENTS ASSESSMENT

Under the Disability Discrimination Act 1995 (as amended), the Trust has a duty to make reasonable adjustments to ensure any barriers disabled people face in gaining and remaining in employment and in accessing and using goods and services are removed or reduced. It is therefore recommended the policy explicitly references "reasonable adjustments will be considered for people who are disabled - whether as service users, visitors or employees.

SIGNATORIES

Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

Grear MC Cusher

14/02/2020 Date:

05/08/2020

Author

Caroline A. Leonard

Date:

Director

Drugs and Therapeutics Committee_Non-Medical Prescribing (NMP) of Medicines Policy_V3_August 2020 Page 15 of 21

<u>Appendix 1</u> ADMISSION TO THE NURSE INDEPENDENT SUPPLEMENTARY PRESCRIBING PROGRAMME (criteria checklist)

| Applicant's details Admission criteria checklist Ref: NMC Standards | Criteria met Y/N |
|---|---------------------|
| Registered first level nurse, midwife and/or specialist community public health nurse | |
| At least three years post registration experience. The year immediately | |
| preceding application must have been in the clinical field in which the applicant intends to prescribe | |
| The nurse has been identified through individual Performance Review Appraisal, the suitability to prescribe before they apply for a training place | |
| The applicant is in a role that enables them to prescribe following completion of training and which has clear benefits for patients clients | |
| The applicant must have had a Pocva completed within 3 years of starting the course | |
| The prospective candidate must either be deemed competent in Health Assessment by his/her professional lead and has successfully undertaken a relevant module in Health Assessment* | |
| Demonstrated ability to study at degree level through: | |
| 1. <u>Undergraduate level</u> (60 credits) | |
| Successful completion of three modules (60 credits) of study at level 2 | |
| with a mark of at least 50%. This will include evidence of the skills | |
| necessary for the implementation of evidence based practice | |
| OR | |
| 2. Postgraduate level | |
| Pre-registration degree in Nursing or Midwifery | |
| Post-registration degree in Nursing, Midwifery or Health Studies/Sciences | |
| Degree in any other relevant subject area | |
| In addition written confirmation will be required from | |
| 1. The Professional Lead/Line Manager of their support for the nurse to | |
| undertake the preparation programme and facilitate ongoing CPD and | |
| supervision to support the prescribing role | |
| 2. A designated medical practitioner who meets eligibility criteria for | |
| medical supervision of nurse prescribers, and who has agreed to | |
| provide the required term of supervised practice. (A guide to help | |
| doctors prepare for and carry out the role of designated medical | |
| practitioner. Feb 2005. Available at www.npc.co.uk | |
| The Health Assessment module for prescribing will be offered concurrent | |

*The Health Assessment module for prescribing will be offered concurrently with the NISP programme for approximately the first two years of the new programme (commencing autumn 2007). After that students will be expected to have evidence of successful completion of the relevant Health Assessment module in advance of the programme.

| Checklist confirmed by | (Line Manager) Date |
|---|---|
| Applicant | Date |
| Divisional Nurse Lead Dat | te |
| Drugs and Therapeutics Committee_Non-Medical Prescribing (NMP) of | Medicines Policy_V3_August 2020 Page 16 of 21 |

<u>Appendix 2</u> ADMISSION TO THE PHARMACIST INDEPENDENT / SUPPLEMENTARY PRESCRIBING PROGRAMME (criteria Checklist)

Applicant's details.....

| Admission Criteria Checklist | Criteria met Y/N |
|--|---------------------|
| Registered pharmacist with PSNI | |
| At least two years experience practicing as a pharmacist in a clinical | |
| environment in a hospital setting, following their pre-registration year. | |
| NMP has been identified through Staff Development Appraisal as | |
| appropriate in this role | |
| The applicant is in a role that enables them to prescribe following training | |
| and which has clear benefits for patients/clients or has been identified as a | |
| potential role | |
| In addition written confirmation will be required from: | |
| 1. The Pharmacy Services Manager of their support for the pharmacist to undertake the preparation programme and facilitate ongoing CPD and supervision to support their prescribing role | |
| A designated medical practitioner who meets eligibility criteria for medical supervision of pharmacist prescribers, and who has agreed to provide the required term of supervised practice | |

| Criteria confirmed: (Line Manager) | Date |
|------------------------------------|------|
| Applicant signature | Date |
| Head of Pharmacy | Date |

Appendix 3 ADMISSION TO THE ALLIED HEALTH PROFESSIONAL INDEPENDENT SUPPLEMENTARY PRESCRIBING PROGRAMME

Applicant's details.....

| Admission Criteria Checklist | Criteria met Y/N |
|---|---------------------|
| HCPC registered radiographer, physiotherapist, paramedic, podiatrist, or dietitian | |
| At least three years post registration experience. The year immediately preceding application must have been in the clinical field in which the applicant intends to prescribe | |
| Before applying for a training place the radiographer, physiotherapist, paramedic, podiatrist, optometrist or dietitian's suitability to become a prescriber has been identified through performance review/appraisal | |
| The applicant is in a role that enables them to prescribe following completion of training and which has clear benefits for patients/clients | |
| The applicant must have had an Access NI assessment which has been completed within the previous 3 years (NB in order to prescribe a registrant is required to have an up to date Access NI Assessment) | |
| In addition written confirmation will be required from: 1. The Line Manager/Professional Lead confirming their support for the radiographer/physiotherapist/paramedic/podiatrist/optometrist/dietitian to undertake the preparation programme and facilitate ongoing CPD and support the preparation relevant to preparation. | |
| supervision to support the prescribing role A designated medical practitioner who meets eligibility criteria for medical supervision of radiographer/podiatrist/physiotherapist/paramedic/optometrist/dietitian prescribers, and who has agreed to provide the required term of supervised practice. (A guide to help doctors prepare for and carry out the role of designated medical practitioner. Feb 2005. Available at www.npc.co.uk. | |

Criteria confirmed by (Professional Lead)

Date.....

Applicant.....

Date.....

Signature of Designated Professional Head of Service or Trust AHP Lead

..... Date.....

Appendix 6 CLINICAL MANAGEMENT PLAN (CMP)

The Clinical Management Plan is the foundation stone of supplementary prescribing – it must be formally agreed by the Independent Prescriber (Doctor) before prescribing occurs. It is essential that there is an agreed CMP in place (written or electronic) relating to a named patient and to that patient's specific condition to be managed by the supplementary prescriber. This must be included in the patient's record. The CMP must include the following:

- A reference to the medicines (by individual medicine or class of medicines) that may be prescribed for the named patient by the supplementary prescriber.
- The CMP may include references to published national or local guidelines. However they must clearly identify the range of relevant medicinal products to be used in the treatment of the patient and the CMP should draw attention to the relevant part of the guideline. The guidelines must also be accessible.
- The circumstances in which the supplementary prescriber can vary the dosage, frequency and formulation of the specific medicines.
- The circumstances in which the supplementary prescriber should refer back to the independent prescriber.
- Relevant warning about any known sensitivities of the patient to particular medicines and arrangements for the notification of any adverse drug reactions.
- The date on which the supplementary prescribing arrangements commence and the date by which it should be reviewed.
- The formal agreement to the CMP of the independent and supplementary prescribers and of the patient.

TEMPLATE CMP 1 (Blank): for teams that have full co-terminus access to patient records

| Name of Patient: | | Patient medication sensitivities/allergies: | | | | |
|---|--------------|---|-------------------------------|------|-------------------------------------|--|
| Patient identification e.g. ID number, date of birth: | | | | | | |
| Independent Prescriber(| | Supplementary Prescriber(s) | | | | |
| Condition(s) to be treate | | Aim of treatment | | | | |
| Medicines that may be p | rescribed by | SP: | | | | |
| Preparation II | ndication | | Dose schedule | | c indications for back to the IP | |
| Guidelines or protocols supporting Clinical Management Plan: | | | | | | |
| Frequency of review and monitoring by: | | | | | | |
| Supplementary prescriber Supplementary prescriber and Independent prescribe | | | | | ndent prescriber | |
| Process for reporting ADRs: | | | | | | |
| Shared record to be used by IP and SP: | | | | | | |
| Agreed by independent prescriber(s) | Date | | d by supplementary iber(s) | Date | Date agreed with patient/carer | |

TEMPLATE CMP 2 (Blank): for teams where the SP does not have co-terminus access to the medical record

| Name of Patient: | | | Patient medication sensitivities/allergies: | | | |
|--|--------------|----------|---|--|---|--|
| Patient identification e.g. ID number, date of birth: | | | | | | |
| Current medication: | | | Medical history: | | | |
| Independent Prescriber(s) | | | Supplementary prescriber(s): | | | |
| Contact details: (tel/email/address) | | | Contact details: (tel/email/address) | | | |
| Conditions(s) to be treated: | | | Aim of treatment: | | | |
| Medicines that may be | e prescribed | d by SP: | | | | |
| Preparation | Indication | | Dose schedule | | ific indications for al back to the IP | |
| Guidelines or protocols supporting Clinical Management Plan: | | | | | | |
| Frequency of review and monitoring by: | | | | | | |
| Supplementary prescriber Supplem prescribe | | | nentary prescriber and Independent er | | | |
| Process for reporting ADRs: | | | | | | |
| Shared record to be used by IP and SP: | | | | | | |
| | | | | | Date agreed with patient/carer | |



Standards for medicines management

BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)

We are the nursing and midwifery regulator for England, Wales, Scotland, Northern Ireland and the Islands.

- We exist to safeguard the health and wellbeing of the public.
- We set the standards of education, training and conduct that nurses and midwives need to deliver high quality healthcare consistently throughout their careers.
- We ensure that nurses and midwives keep their skills and knowledge up to date and uphold the standards of their professional code.
- We ensure that midwives are safe to practise by setting rules for their practice and supervision.
- We have fair processes to investigate allegations made against nurses and midwives who may not have followed the code.

Introduction

The Nursing and Midwifery Council (NMC) is the UK regulator for two professions: nursing and midwifery. The primary purpose of the NMC is protection of the public. It does this through maintaining a register of all nurses, midwives and specialist community public health nurses eligible to practise within the UK and by setting standards for their education, training and conduct. One of the most important ways of serving the public interest is through providing advice and guidance to registrants on professional issues. The purpose of this booklet is to set standards for safe practice in the management and administration of medicines by registered nurses, midwives and specialist community public health nurses.

Standards for medicine management replace the Guidelines for the administration of medicines 2004, although many of its principles remain relevant today, for example:

"The administration of medicines is an important aspect of the professional practice of persons whose names are on the Council's register. It is not solely a mechanistic task to be performed in strict compliance with the written prescription of a medical practitioner (can now also be an independent and supplementary prescriber). It requires thought and the exercise of professional judgement..."

Many government and other agencies are involved in medicines management from manufacture, licensing, prescribing and dispensing, to administration. As the administration of a medicinal product is only part of the process, these standards reflect the process from prescribing through to dispensing, storage, administration and disposal. There exists an extensive range of guidance on medicines management from a range of relevant bodies. Sources of information are listed on pages 55–58. One of the best sources of advice locally is the pharmacist.

As with all NMC standards, this booklet provides the minimum standard by which practice should be conducted and will provide the benchmark by which practice is measured. Due to the complexity, speed and extent of change in contemporary health care, it is not intended to cover every single situation that you may encounter during your career. Instead, it sets out a series of standards that will enable you to think through issues and apply your professional expertise and judgement in the best interests of your patients. It will also be necessary to develop and refer to additional local and national policies and protocols to suit local needs.

Definitions

Medicinal products

"Any substance or combination of substances presented for treating or preventing disease in human beings or in animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product." Council Directive 65/65/EEC.

Medicines management

"The clinical, cost-effective and safe use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimising potential harm." (MHRA 2004).

Blood and blood products

Blood is not classified as a medicinal product although some blood components are. Products derived from the plasma component of blood such as blood clotting factors, antibodies and albumin are licensed and classified as considered to be medicinal products. For the purpose of the administration of medicinal products registrants would be expected to apply the standards for medicines management to all medicinal products but should consider additional guidance by the National Patient Safety Agency – guidance launched on 9 November 2006; Right patient, Right blood (available at **www.npsa.nhs.uk**). A key requirement of this guidance is that all staff involved in blood transfusion undergo formal competency assessment on a three-yearly basis.

Use of the word 'patient' throughout the document

Throughout this document where the word 'patient' is used this refers to whoever the medication may be administered to, for example, patient, client, user or woman (midwifery).

Use of the word 'registrant' throughout the document

Throughout this document where the word 'registrant' is used this refers to nurses, midwives and specialist community public health nurses who are registered on the NMC register.

Summary of standards

This section provides a summary of the standards for easy reference. For further detail you should read, follow and adhere to the standards as detailed later in the document. It is essential that you read the full guidance.

Section 1

Methods of supplying and/or administration of medicines

Standard 1: Methods

Registrants must only supply and administer medicinal products in accordance with one or more of the following processes:

- Patient specific direction (PSD)
- Patient medicines administration chart (may be called medicines administration record MAR)
- Patient group direction (PGD)
- Medicines Act exemption
- Standing order
- Homely remedy protocol
- Prescription forms

Standard 2: Checking

Registrants must check any direction to administer a medicinal product.

Standard 3: Transcribing

As a registrant you may transcribe medication from one 'direction to supply or administer' to another form of 'direction to supply or administer'.

Section 2

Dispensing

Standard 4: Prescription medicines

Registrants may in exceptional circumstances label from stock and supply a clinically appropriate medicine to a patient, against a written prescription (not PGD), for self-administration or administration by another professional, and to advise on its safe and effective use.

Standard 5: Patients' own medicines

Registrants may use patients' own medicines in accordance with the guidance in this booklet *Standards for medicines management*.

Section 3

Storage and transportation

Standard 6: Storage

Registrants must ensure all medicinal products are stored in accordance with the patient information leaflet, summary of product characteristics document found in dispensed UK-licensed medication, and in accordance with any instruction on the label.

Standard 7: Transportation

Registrants may transport medication to patients including controlled drugs, where patients, their carers or representatives are unable to collect them, provided the registrant is conveying the medication to a patient for whom the medicinal product has been prescribed, (for example, from a pharmacy to the patient's home).

Section 4

Standards for practice of administration of medicines

Standard 8: Administration

As a registrant, in exercising your professional accountability in the best interests of your patients:

- you must be certain of the identity of the patient to whom the medicine is to be administered
- you must check that the patient is not allergic to the medicine before administering it
- you must know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications
- you must be aware of the patient's plan of care (care plan or pathway)
- you must check that the prescription or the label on medicine dispensed is clearly written and unambiguous
- you must check the expiry date (where it exists) of the medicine to be administered
- you must have considered the dosage, weight where appropriate, method of administration, route and timing
- you must administer or withhold in the context of the patient's condition, (for example, Digoxin not usually to be given if pulse below 60) and co-existing therapies, for example, physiotherapy

- you must contact the prescriber or another authorised prescriber without delay where contra-indications to the prescribed medicine are discovered, where the patient develops a reaction to the medicine, or where assessment of the patient indicates that the medicine is no longer suitable (see Standard 25).
- you must make a clear, accurate and immediate record of all medicine administered, intentionally withheld or refused by the patient, ensuring the signature is clear and legible. It is also your responsibility to ensure that a record is made when delegating the task of administering medicine.

In addition:

- Where medication is not given, the reason for not doing so must be recorded.
- You may administer with a single signature any prescription only medicine (POM), general sales list (GSL) or pharmacy (P) medication.

In respect of controlled drugs:

- These should be administered in line with relevant legislation and local standard operating procedures.
- It is recommended that for the administration of controlled drugs a secondary signatory is required within secondary care and similar healthcare settings.
- In a patient's home, where a registrant is administering a controlled drug that has already been prescribed and dispensed to that patient, obtaining a secondary signatory should be based on local risk assessment.
- Although normally the second signatory should be another registered health care
 professional (for example doctor, pharmacist, dentist) or student nurse or midwife,
 in the interest of patient care, where this is not possible, a second suitable person
 who has been assessed as competent may sign. It is good practice that the second
 signatory witnesses the whole administration process. For guidance, go to
 www.dh.gov.uk and search for safer management of controlled drugs: guidance on
 standard operating procedures.
- In cases of direct patient administration of oral medication from stock in a substance misuse clinic, it must be a registered nurse who administers, signed by a second signatory (assessed as competent), who is then supervised by the registrant as the patient receives and consumes the medication.
- You must clearly countersign the signature of the student when supervising a student in the administration of medicines.

Standard 9: Assessment

As a registrant, you are responsible for the initial and continued assessment of patients who are self-administering and have continuing responsibility for recognising and acting upon changes in a patient's condition with regards to safety of the patient and others.

Standard 10: Self-administration – children and young people

In the case of children, when arrangements have been made for parents or carers or patients to administer their own medicinal products prior to discharge or rehabilitation, the registrant should ascertain that the medicinal product has been taken as prescribed.

Standard 11: Remote prescription or direction to administer

In exceptional circumstances, where 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 information technology (such as fax, text message or email) may be used but must confirm any change to the original prescription.

Standard 12: Text messaging

As a registrant, you must ensure that there are protocols in place to ensure patient confidentiality and documentation of any text received including: complete text message, telephone number (it was sent from), the time sent, any response given, and the signature and date when received by the registrant.

Standard 13: Titration

Where medication has been prescribed within a range of dosages, it is acceptable for registrants to titrate dosages according to patient response and symptom control and to administer within the prescribed range.

Standard 14: Preparing medication in advance

Registrants must not prepare substances for injection in advance of their immediate use or administer medication drawn into a syringe or container by another practitioner when not in their presence.

Standard 15: Medication acquired over the internet

Registrants should never administer any medication that has not been prescribed, or that has been acquired over the internet without a valid prescription.

Standard 16: Aids to support compliance

Registrants must assess the patient's suitability and understanding of how to use an appropriate compliance aid safely.

Section 5

Delegation

Standard 17: Delegation

A registrant is responsible for the delegation of any aspects of the administration of medicinal products and they are accountable to ensure that the patient, carer or care assistant is competent to carry out the task.

Standard 18: Nursing and midwifery students

Students must never administer or supply medicinal products without direct supervision.

Standard 19: Unregistered practitioners

In delegating the administration of medicinal products to unregistered practitioners, it is the registrant who must apply the principles of administration of medicinal products as listed above. They may then delegate an unregistered practitioner to assist the patient in the ingestion or application of the medicinal product.

Standard 20: Intravenous medication

Wherever possible, two registrants should check medication to be administered intravenously, one of whom should also be the registrant who then administers the intravenous (IV) medication.

Section 6

Disposal of medicinal products

Standard 21: Disposal

A registrant must dispose of medicinal products in accordance with legislation.

Section 7

Unlicensed medicines

Standard 22: Unlicensed medicines

A registrant may administer an unlicensed medicinal product with the patient's informed consent against a patient-specific direction but NOT against a patient group direction.

Section 8

Complementary and alternative therapies

Standard 23: Complementary and alternative therapies

Registrants must have successfully undertaken training and be competent to practise the administration of complementary and alternative therapies.

Section 9

Management of adverse events (errors or incidents) in the administration of medicines

Standard 24: Management of adverse effects

As a registrant, if you make an error you must take any action to prevent any potential harm to the patient and report as soon as possible to the prescriber, your line manager or employer (according to local policy) and document your actions. Midwives should also inform their named supervisor of midwives.

Standard 25: Reporting adverse reactions

As a registrant, if a patient experiences an adverse drug reaction to a medication, you must take any action to remedy harm caused by the reaction. You must record this in the patient's notes, notify the prescriber (if you did not prescribe the drug) and notify via the Yellow Card Scheme immediately.

Section 10

Controlled drugs

Standard 26: Controlled drugs

Registrants should ensure that patients prescribed controlled drugs are administered these in a timely fashion in line with the standards for administering medication to patients. Registrants should comply with and follow the legal requirements and approved local standard operating procedures for controlled drugs that are appropriate for their area of work.

Contents

| Standards | |
|--|----|
| Section 1: Method of supplying and/or administration of medicines | |
| Standard 1: Methods | 13 |
| Standard 2: Checking | |
| Standard 3: Transcribing | |
| Section 2: Dispensing | |
| Standard 4: Prescription medicines | |
| Standard 5: Patients' own medicines | |
| Section 3: Storage and transportation | |
| Standard 6: Storage | |
| Standard 7: Transportation | |
| Section 4: Standards for practice of administration of medicines | |
| Standard 8: Administration | |
| Standard 9: Assessment | - |
| Standard 10: Self-administration – children and young people | |
| Standard 11: Remote prescription or direction to administer | |
| Standard 12: Text messaging | |
| Standard 13: Titration | |
| Standard 14: Preparing medication in advance | |
| Standard 15: Medication acquired over the internet | |
| Standard 16: Aids to support compliance | |
| Section 5: Delegation | |
| Standard 17: Delegation | |
| Standard 18: Nursing and midwifery students | |
| Standard 19: Unregistered practitioners | |
| Standard 20: Intravenous medication | |
| Section 6: Disposal of medicinal products | |
| Standard 21: Disposal | |
| Section 7: Unlicensed medicines | |
| Standard 22: Unlicensed medicines | |
| Section 8: Complementary and alternative therapies | |
| Standard 23: Complementary and alternative therapies | |
| Section 9: Management of adverse events (errors or incidents) in the | |
| administration of medicines | |
| Standard 24: Management of adverse events | |
| Standard 25: Reporting adverse reactions | |
| Section 10: Controlled drugs | |
| Standard 26: Controlled drugs | |

Annexes

Annexe 1 Legislation

Annexe 2 Guidance on labelling and over-labelling of medicines

Annexe 3 Suitability of patients' own medicinal products for use

Annexe 4 Exclusion criteria for self-administration medicines

Annexe 5 Administering medicinal products in research clinical trials

Annexe 6 Information and publications

Annexe 7 Glossary

Annexe 8 Contributors

The standards: Section 1

Methods of supplying and/or administration of medicines

Methods to enable nurses, midwives and specialist community public health nurses to supply and/or administer may include the following:

Standard 1: Methods

- 1 Registrants must only supply and administer medicinal products in accordance with one or more of the following processes:
 - 1.1 Patient-specific direction (PSD)
 - 1.2 Patient medicines administration chart (may be called a medicines administration record (MAR))
 - 1.3 Patient group direction (PGD)
 - 1.4 Medicines Act Exemption (where they apply to nurses)
 - 1.5 Standing order
 - 1.6 Homely remedy protocol
 - 1.7 Prescription forms
- 2 Once a medicinal product has been prescribed and dispensed to an individual, the drug is the individual's own property. To use it for someone else is theft . Registrants should refer to DH (2006) *Medicines Matters: A guide to mechanisms for the prescribing, supply and administration of medicines.*

Patient-specific direction (PSD)

- 3 A patient-specific direction (PSD) is a written instruction from a qualified and registered prescriber for a medicine including the dose, route and frequency 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 medicines administration chart. The direction would need to be specific as to the route of administration it cannot simply authorise a course of treatment to several patients. Where a PSD exists, there is no need for a patient group direction.
- 4 Each individual patient must be identified on the PSD. An example of using a PSD is in the administration of routine vaccine where a list of patients due a vaccine may be identified beforehand. In the case of controlled drugs, it is essential to comply with full prescription requirements. Go to www.dh.gov.uk and search for controlled drugs.

Patient medicines administration chart

5 The patient medicines administration chart is not a prescription but a direction to administer medication. It must be signed by a registered prescriber and authorises the delegation to administer medication on the prescriber's behalf. However, in doing so the registrant is accountable for their actions and for raising any concerns about the direction with the prescriber, for example, in respect to clarity.

Patient group direction (PGD)

- 6 Patient group directions (PGDs) are specific written instructions for the supply or administration of a licensed named medicine including vaccines to specific groups of patients who may not be individually identified before presenting for treatment. Guidance on the use of PGDs is contained within *Health Service Circular (HSC)* 2000/026.
- 7 See Home Office circular 049/2003. *Controlled Drugs Legislation Nurse Prescribing And Patient Group Directions*. Go to **www.dh.gov.uk** and search for controlled drugs.
- 8 Guidance has also been issued in Wales (WHC 2000/116), and in Scotland and Northern Ireland.
- 9 The circular also identifies the legal standing of PGDs plus additional guidance on drawing them up and operating within them. It is vital that anyone involved in the delivery of care within a PGD is aware of the legal requirements. PGDs are not a form of prescribing.
- 10 PGDs are drawn up locally by doctors, dentists, pharmacists, and other health professionals where relevant. They must be signed by a doctor or dentist and a pharmacist, both of whom should have been involved in developing the direction, and must be approved by the appropriate health care organisation. The NMC would consider it good practice that a lead practitioner from the professional group using the PGD and senior manager where possible, are also involved and sign off a PGD.
- 11 PGDs can be used by independent providers for NHS commissioned services. As medicines legislation does not apply outside the UK, a PGD would not be required for example on cruise ships. However, the NMC would consider it good practice for such bodies to develop protocols using PGD templates that are signed off by a doctor, dentist, pharmacist, other health professionals where relevant and a senior manager where possible.
- 12 PGDs should only be used once the registrant has been assessed as competent and whose name is identified within each document. The administration of drugs via a PGD may not be delegated. Students cannot supply or administer under a PGD but would be expected to understand the principles and be involved in the process. Where medication is already subject to exemption order legislation there is no requirement for a PGD.

- 13 When supplying under PGD, this should be from the manufacturer's original packs or over-labelled pre-packs so that the patient details, date and additional instructions can be written on the label at the time of supply. Registrants must not split packs. For more information on labelling see annexe 2.
- 14 See To PGD or not to PGD at: www.portal.nelm.nhs.uk/PGD/viewRecord.aspx?recordID=422
- 15 PGDs in the NHS: www.mhra.gov.uk/home/idcplg?ldcService=SS_GET_PAGE&nodeld=148
- 16 PGDs in the private sector: www.mhra.gov.uk/home/idcplg?ldcService=SS_GET_PAGE&nodeld=147

Medicines Act Exemptions

- 17 Allow certain groups of healthcare professionals including occupational health nurses under occupational health schemes and midwives to sell, supply and administer specific medicines directly to patient and clients.
 - 17.1 Provided the requirements of any conditions attached to those exemptions are met, a PGD is not required.
 - 17.2 Registrants must work to locally agreed written protocols and procedures, and maintain auditable records.
 - 17.3 Occupational health nurses that offer services, for example, open access travel clinics outside of occupational health schemes must comply with guidance from the appropriate regulator.
- 18 Registrants may only supply and administer under an exemption order where the order pertains to them. Where nurses are working as emergency care practitioners within an ambulance service they may not supply and administer under paramedic exemptions unless they are also registered as a paramedic with the Health Professions Council to do so would contravene medicine legislation and the employer's vicarious liability would not apply.
- 19 Search for NMC Circular 1/2005 *Medicine legislation: what it means for midwives* at **www.nmc.org.uk**

Standing orders

20 In the past, maternity service providers and occupational health schemes have produced local guidelines, often referred to as 'standing orders', to supplement the legislation on the medicinal products that practising midwives and occupational health nurses may supply and/or administer. These guidelines are not a prerequisite under any legislation. There is no legal definition for standing orders and this term does not exist in any medicines legislation. The NMC would consider it good practice where midwives and occupational health nurses are using standing orders for medicinal products that are not covered by Medicines Act Exemptions that these should be converted to PGDs.

Homely remedy protocols

21 Homely remedy protocols cannot be used for prescription only medicines including controlled drugs. These must be supplied and administered under a PSD, a prescription or a PGD.

Guidance

- 22 Homely remedy protocols are not prescriptions but protocols to enable administration of general sales list (GSL) and pharmacy only (P) listed medicines in settings, for example, care homes, children's homes and some educational institutions. Although they have no legal standing they are required for liability purposes. Any registrant using a homely remedy protocol must ensure there is a written instruction that has been drawn up and agreed in consultation with other relevant qualified professionals. (Where possible this should be a medical practitioner or pharmacist.) The protocol should clarify what medicinal product may be administered and for what indication it may be administered, the dose, frequency and time limitation before referral to a GP. An example of a homely remedy could be paracetamol for a headache. All registrants using the protocol should be named and they should sign to confirm they are competent to administer the medicinal product, acknowledging they will be accountable for their actions.
- 23 The NMC considers it good practice that the employing organisation signs off all protocols.

Prescription forms

- 24 NHS prescription forms are classified as secure stationery. Prescription forms are serially numbered and have anticounterfeiting and anti-forgery features. Within the NHS they are purchased by primary care trusts (PCTs), hospital boards and hospitals via a secure ordering system, and distributed free. The range of prescription forms used by registered prescribers can be found in each UK country government website.
- 25 Specific controlled drug prescription forms are available from the local health care organisation, for example, PCT, LHB, for use in the private healthcare sector. Specific controlled drug prescriptions are used for treatment of addiction and for private prescriptions for controlled drugs. Only the designated prescription form should be used. Detailed guidance on how to complete prescription forms, including special requirements when prescribing controlled drugs, is available from the Department of Health (DH), Health Care Commission (HCC), Home Office, the Prescription Prices Division of the NHS Business Services Authority website and in the BNF. The Regulation and Quality Improvement Authority is equivalent to the HCC in Northern Ireland. Registrants in Northern Ireland should access their website for up-to-date information on their standards.

www.npc.co.uk/controlled_drugs/CDGuide_2ndedition_February_2007.pdf

26 For the Welsh Health circular, go to: www.wales.nhs.uk/documents/WHC_2006_018.pdf 27 Search for the Home Office Circular Controlled Drugs Legislation – Nurse Prescribing and Patient Group Directions at: www.knowledgenetwork.gov.uk/HO/circular.nsf

Who may write a prescription?

- 28 Any qualified and registered independent prescriber may prescribe all prescription only medicines for all medical conditions. In addition, nurse independent prescribers may also prescribe some controlled drugs.
- 29 Supplementary prescribers may prescribe in accordance with a clinical management plan (CMP) in a tripartite arrangement with a doctor or dentist, the patient and the supplementary prescriber. A supplementary prescriber, when acting under and in accordance with the terms of a CMP, may administer and supply or direct any person to administer controlled drugs in schedules 2, 3, 4 and 5, and can prescribe unlicensed medicinal products. Please see section 5 of this document on delegation.

Prescribing by nurses, midwives and specialist community public health nurses

30 The Medicinal Products: Prescription by Nurses Act 1992 and subsequent amendments to the pharmaceutical services regulations allow nurses and midwives, who have recorded their qualification on the NMC register, to become nurse or midwife prescribers. There are two levels of nurse and midwife prescribers:

Community practitioner nurse prescribers

30.1 These are registrants who have successfully undertaken a programme of preparation to prescribe from Community Practitioner Nurse Prescribers' Formulary. They can prescribe the majority of dressings and appliances, and a limited range of prescription only medicines. The Community Nurse Prescribers' Formulary can be found on the **British National Formulary** website. Go to: **www.bnf.org**

Independent and supplementary nurse and midwife prescribers

- 30.2 These are nurses and midwives who are trained to make a diagnosis and prescribe the appropriate treatment (independent prescribing). They may also, in cases where a doctor has made an initial diagnosis, go on to prescribe or review the medication, and change the drug, dosage, timing or frequency or route of administration of any medication as appropriate as part of a clinical management plan (supplementary prescribing).
- 31 Nurse or midwife independent prescribers can prescribe all prescription only medicines including some controlled drugs, and all medication that can be supplied by a pharmacist or bought over the counter. They must only prescribe drugs that are within their area of expertise and level of competence, and should only prescribe for children if they have the expertise and competence to do so.

- 32 Nurse, midwife and specialist community public health nurse prescribers must comply with current prescribing legislation and are accountable for their practice.
- 33 For Department of Health guidance go to **www.dh.gov.uk** and search: nurse independent prescribing.

Standard 2: Checking

- 1 Registrants (1st and 2nd level) must check any direction to administer a medicinal product.
- 2 As a registrant you are accountable for your actions and omissions. In administering any medication, or assisting or overseeing any self-administration of medication, you must exercise your professional judgement and apply your knowledge and skill in the given situation. As a registrant, before you administer a medicinal product you must always check that the prescription or other direction to administer is:
 - 2.1 not for a substance to which the patient is known to be allergic or otherwise unable to tolerate
 - 2.2 based, whenever possible, on the patient's informed consent and awareness of the purpose of the treatment
 - 2.3 clearly written, typed or computer-generated and indelible
 - 2.4 specifies the substance to be administered, using its generic or brand name where appropriate and its stated form, together with the strength, dosage, timing, frequency of administration, start and finish dates, and route of administration
 - 2.5 is signed and dated by the authorised prescriber
 - 2.6 in the case of controlled drugs, specifies the dosage and the number of dosage units or total course; and is signed and dated by the prescriber using relevant documentation as introduced, for example, patient drug record cards.
- 3 And that you have:
 - 3.1 clearly identified the patient for whom the medication is intended
 - 3.2 recorded the weight of the patient on the prescription sheet for all children, and where the dosage of medication is related to weight or surface area (for example, cytotoxics) or where clinical condition dictates recorded the patient's weight.

Standard 3: Transcribing

1 As a registrant you may transcribe medication from one 'direction to supply or administer' to another form of 'direction to supply or administer'.

Guidance

- 2 This should only be undertaken in exceptional circumstances and should not be routine practice. However, in doing so you are accountable for your actions and omissions. Any medication that you have transcribed must be signed off by a registered prescriber. In exceptional circumstances this may be done in the form of an email, text or fax before it can be administered by a registrant.
- 3 Any act by which medicinal products are written from one form of direction to administer to another is transcribing. This includes, for example, discharge letters, transfer letters, copying illegible patient administrations charts onto new charts, whether hand-written or computer-generated.
- 4 When medicine administration records in a care home are hand-written by a registrant, they may be transcribed from the details included on the label attached to the dispensed medicine. However, in doing so the registrant must ensure that the charts are checked by another registrant where possible, and where not, another competent health professional.
- 5 The registrant is accountable for what they have transcribed.
- 6 Managers and employers are responsible for ensuring there is a rigorous policy for transcribing that meets local clinical governance requirements.
- 7 As care is being increasingly provided in more 'closer to home' settings that are often nurse-led, managers and employers should undertake a risk assessment involving registrants, pharmacists and responsible independent prescribers to develop a management process to enable transcribing to be undertaken where necessary. It should not be routine practice. Any transcription must include the patient's full name, date of birth, drug, dosage, strength, timing, frequency and route of administration.
- 8 Transposing is the technical term used by pharmacists for transcribing.
- 9 Registrants are advised to read the Health Care Commission guidance for the transcribing of prescribed medicines for individuals on admission to children's hospices. The principles apply to all settings. Go to www.cqc.org.uk. Registrants in Northern Ireland should refer to the Regulation and Quality Improvement Authority website at www.rqia.org.uk

The standards: Section 2

Dispensing

Standard 4: Prescription medicines

1 Registrants may in exceptional circumstances label from stock and supply a clinically appropriate medicine to a patient, against a written prescription (not PGD), for self-administration or administration by another professional, and to advise on its safe and effective use.

Guidance

- 2 The definition of dispensing is "To label from stock and supply a clinically appropriate medicine to a patient, client or carer, usually against a written prescription, for self-administration or administration by another professional, and to advise on safe and effective use". (MHRA, 2006)
- 3 Dispensing includes such activities as checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product, labelling in accordance with legal requirements and providing information leaflets for the patient.
- 4 If under exceptional circumstances you, as a registrant, you are engaged in dispensing, this represents an extension to your professional practice. There is no legal barrier to this practice. However, this must be in the course of the business of a hospital, and in accordance with a registered prescriber's written instructions and covered by a standard operating procedure (SOP). In a dispensing doctor's practice, registrants may supply to patients under a particular doctor's care, when acting under the directions of a doctor from that practice. The patient has the legal right to expect that the dispensing will be carried out with the same reasonable skill and care that would be expected from a pharmacist.

Standard 5: Patients' own medicines

- 1 Registrants may use patients' own medicines in accordance with the guidance in this booklet *Standards for medicines management*.
- 2 The NMC welcomes and supports the self-administration of medicinal products and the administration of medication by carers wherever it is appropriate.

The use of patients' own medicinal products in any setting

- 3 Where patients have their own supply of medicinal products, whether prescribed, over the counter (from a pharmacy, supermarket or shop), complementary therapy, herbal preparation or homely remedy such as paracetamol, the registrant has a responsibility to:
 - 3.1 ask to see the medicinal products
 - 3.2 check for suitability of use

- 3.3 explain how and why they will or won't be used
- 3.4 establish if they are prescribed
- 3.5 ascertain if they meet the criteria for use.
- 4 These medicinal products including controlled drugs remain the patient's property and must not be removed from the patient without their permission and must only be used for that named individual.
- 5 The registrant has a responsibility to document in the patient's notes when a patient refuses consent:
 - 5.1 to use their own medicines
 - 5.2 to dispose of their own medicinal products no longer required
 - 5.3 to dispose of their own medicinal products not suitable for use
 - 5.4 when in the hospital or care home setting to send their own medicinal products home with a relative or carer

Storage of patients' own medicinal products

- 6 As a registrant you have the following responsibilities:
 - 6.1 to ensure that suitable facilities are provided to store patients' own medicinal products for their safe storage
 - 6.2 to assess patients on a regular basis using local polices to ensure that the individual patient is still able to self-administer
 - 6.3 to document issues relating to storage in their records
 - 6.4 that the medicines cabinet or locker is kept locked and that the master key is kept secure
 - 6.5 that if the patient is self-administering, consent is obtained from the patient to keep the individual medicines cabinet/locker locked and the key secure with the patient
 - 6.6 that if a patient moves to another bed, to another ward or room or is discharged, the patient's medicinal products are transferred with the patient
 - 6.7 In a hospital setting, best practice indicates that stock medicines should not be placed in the patient's locked cabinet or locker as they are not labelled for that individual patient.

Administering medicines using the patient's own supply in the hospital or care home setting

- 7 When administering medicines from the patient's own supply, the registrant must check the medicines in the locked cabinet or locker with the prescription chart and use only those medicines belonging to that named patient.
- 8 If a supply is not available, medicines belonging to another patient must not be used.
- 9 For further guidance on the use of patients' own medicinal products including discharge and checking medications to take home (TTOs) see annexe 3. For self-administration of medicines see standard 9 of this document Self-administration of medicines.

One-stop dispensing

10 In some hospitals a system of one-stop dispensing is in operation and local policies should be developed for this using the guidance for patients' own medicinal products as stated under standard 5 of this document.

Guidance

- 11 One-stop dispensing is a system of administering and dispensing medicinal products adopted in hospitals throughout the UK (Audit Commission Report: A Spoonful of Sugar 2002 The Right Medicine (Scottish Executive 2002). It involves using the patient's own medicinal products during their stay in hospital, either those dispensed by a community pharmacy or by the hospital pharmacy or both, providing they contain a patient information leaflet and are labelled with full instructions for use. Supplies are replenished should the supply run out whilst in hospital or when any new items are prescribed. Patients are discharged with a supply of medicinal products as agreed locally.
- 12 In one-stop dispensing, medicinal products are dispensed once only on or during admission ready for discharge. Registrants should check that the medication handed to the patient on discharge is as per the discharge prescription, as medicines may be altered or stopped during hospital admission. If a particular medicine has been stopped during admission and is not to be restarted on discharge, the patient must be informed. The ward pharmacist is a useful resource for advice.

The standards: Section 3

Storage and transportation

Standard 6: Storage

1 Registrants must ensure all medicinal products are stored in accordance with the patient information leaflet, summary of product characteristics document found in dispensed UK-licensed medication and in accordance with any instruction on the label.

Guidance

2 The patient information leaflet or summary of product characteristics document for UK-licensed medicinal products may be found at **www.emc.medicines.org.uk**. Policies should be in place to ensure all storage environments meet the required standards and it is the responsibility of the registrant to check such policies are in place and are being adhered to. This is particularly important for medicines requiring storage within a limited temperature range, for example, refrigeration of vaccines when maintenance of the cold chain has to be considered during transfer for school sessions or administration in the patient's home. Go to **www.the-shipman-inquiry.org.uk/4r_page.asp?id=3119**

Standard 7: Transportation

1 Registrants may transport medication to patients including controlled drugs (CDs), where patients, their carers or representatives are unable to collect them, provided the registrant is conveying the medication to a patient for whom the medicine has been prescribed (for example, from a pharmacy to the patient's home).

Guidance

- 2 However, it is considered good practice that registrants should not routinely transport CDs in the course of their practice. This should only be undertaken in circumstances where there is no other reasonable mechanism available. All drugs should be kept out of sight during transportation.
- When collecting CDs from a pharmacy, the registrant will be asked to sign for them and prove identity in the form of their professional identity badge or Pin (where self-employed). Midwives must be familiar with the use of midwives supply orders. Go to NMC Circular 25/2005 which you can find at www.nmc.org.uk/ standards. It is anticipated as a recommendation from the Shipman Inquiry Fourth Report that new documentary evidence will be required in the form of a patient drug record card. Registrants would be expected to be aware of and comply with any new legislation and guidance introduced.

The standards: Section 4

Standards for practice of administration of medicines

1 Having initially checked the direction to supply or administer that a medicinal product is appropriate for your patient or client (standard 2) you may then administer medication.

Standard 8: Administration

- 2 As a registrant, in exercising your professional accountability in the best interests of your patients:
 - 2.1 you must be certain of the identity of the patient to whom the medicine is to be administered
 - 2.2 you must check that the patient is not allergic to the medicine before administering it
 - 2.3 you must know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications
 - 2.4 you must be aware of the patient's plan of care (care plan or pathway)
 - 2.5 you must check that the prescription or the label on medicine dispensed is clearly written and unambiguous
 - 2.6 you must check the expiry date (where it exists) of the medicine to be administered
 - 2.7 you must have considered the dosage, weight where appropriate, method of administration, route and timing
 - 2.8 you must administer or withhold in the context of the patient's condition (for example, Digoxin not usually to be given if pulse below 60) and co-existing therapies, for example, physiotherapy
 - 2.9 you must contact the prescriber or another authorised prescriber without delay where contra-indications to the prescribed medicine are discovered, where the patient develops a reaction to the medicine, or where assessment of the patient indicates that the medicine is no longer suitable (see standard 25)
 - 2.10 you must make a clear, accurate and immediate record of all medicine administered, intentionally withheld or refused by the patient, ensuring the signature is clear and legible; it is also your responsibility to ensure that a record is made when delegating the task of administering medicine.

In addition:

- 3 Where medication is not given, the reason for not doing so must be recorded.
- 4 You may administer with a single signature any prescription only medicine, general sales list or pharmacy medication.

In respect of controlled drugs:

- 5 These should be administered in line with relevant legislation and local standard operating procedures.
- 6 It is recommended that for the administration of controlled drugs, a secondary signatory is required within secondary care and similar healthcare settings.

- 7 In a patient's home, where a registrant is administering a controlled drug that has already been prescribed and dispensed to that patient, obtaining a secondary signatory should be based on local risk assessment.
- 8 Although normally the second signatory should be another registered health care professional (for example doctor, pharmacist, dentist) or student nurse or midwife, in the interest of patient care, where this is not possible a second suitable person who has been assessed as competent may sign. It is good practice that the second signatory witnesses the whole administration process. For guidance, go to **www.dh.gov.uk** and search for *Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures*.
- 9 In cases of direct patient administration of oral medication, for example, from stock in a substance misuse clinic, it must be a registered nurse who administers, signed by a second signatory (assessed as competent), who is then supervised by the registrant as the patient receives and consumes the medication.
- 10 You must clearly countersign the signature of the student when supervising a student in the administration of medicines.
- 11 These standards apply to all medicinal products.

Guidance

Assessing competence to support a patient in taking their medication

- 12 A policy must be in place and adhered to in assessing the competence of an individual to support a patient in taking medication. A record of the individual's training and assessment should be kept, and all refresher or continuing education and training should also be routinely kept.
- 13 The registrant delegating should be satisfied that the individual has an appropriate level of education and training and has been assessed as competent. Where this is not the case, the registrant may refuse to delegate, even when requested to do so by another health professional. The registrant is accountable for her own actions including delegation.

Clarifying identity

14 Where there are difficulties in clarifying an individual's identity, for example, in some areas of learning disabilities, patients with dementia or confusional states, an up-to-date photograph should be attached to the prescription chart(s). For patients with burns where the wearing of a wristband is inappropriate and a photograph would not resemble the patient, local policies should be in place to ensure all staff are familiar with the patients and a system of identification is in place. Registrants are responsible for ensuring the photograph remains up to date.

Drug calculations

15 Some drug administrations can require complex calculations to ensure that the correct volume or quantity of medication is administered. In these situations, it is good practice for a second practitioner (a registered professional) to check the calculation independently in order to minimise the risk of error. The use of calculators to determine the volume or quantity of medication should not act as a substitute for arithmetical knowledge and skill.

Standard 9: Assessment

- 1 As a registrant you are responsible for the initial and continued assessment of patients who are selfadministering, and have continuing responsibility for recognising and acting upon changes in a patient's condition with regards to safety of the patient and others.
- 2 The NMC welcomes and supports the self-administration of medicinal products and the administration of medication by carers wherever it is appropriate. Registrants may assess the patients as suitable to self-administer medicinal products both in the hospital and primary care settings.

Guidance

Duty of care relating to using patients' own medicinal products

- 3 At all times the registrant jointly with other health care professionals has a duty of care to the patient to ensure that only medicinal products which are prescribed and meet the required criteria are used by the patient.
- 4 Where self-administration of medicinal products is taking place, you should ensure that records are maintained appropriate to the environment in which the patient is being cared for. The Mental Capacity Act 2005 requires all those working with potentially incapacitated people to assess the individual's capacity at a particular moment about a particular decision or issue. All patients should be assessed on a regular basis using local policies to ensure that the individual patient is still able to self-administer and this should be documented in their records.
- 5 Patients can be assessed for suitability at the following levels:

Level 1

5.1 The registrant is responsible for the safe storage of the medicinal products and the supervision of the administration process ensuring the patient understands the medicinal product being administered.

Level 2

5.2 The registrant is responsible for the safe storage of the medicinal products. At administration time, the patient will ask the registrant to open the cabinet or locker. The patient will then self-administer the medication under the supervision of the registrant.

Level 3

- 5.3 The patient accepts full responsibility for the storage and administration of the medicinal products. The registrant checks the patient's suitability and compliance verbally.
- 6 The level should be documented in the patient's notes.

Guidance

- 7 Where patients consent to self-administration of their medicines the following points should be considered:
 - 7.1 Patients share the responsibility for their actions relating to self-administration of their medicines.
 - 7.2 Patients can withdraw consent at any time.
 - 7.3 The pharmacy will supply medicines fully labelled, with directions for use, to every patient who is involved in self-administration.
- 8 Information given and supervision should be tailored to individual patient need.
- 9 The following information should be provided to a patient before commencing self-administration:
 - 9.1 the name of the medicine
 - 9.2 why they are taking it
 - 9.3 dose and frequency
 - 9.4 common side-effects and what to do if they occur
 - 9.5 any special instructions
 - 9.6 duration of the course or how to obtain further supplies.
- 10 The registrant must ensure that the patient is able to open the medicine containers or is offered assistance, for example, compliance aid.
- 11 Whilst the registrant has a duty of care towards all patients, the registrant is not liable if a patient makes a mistake self-administering as long as the assessment was completed as the local policy describes and appropriate actions were taken to prevent re-occurrence of the incident.
- 12 Guidance on exclusion criteria for self-administration of medicines can be found in annexe 4.

Standard 10: Self-administration – children and young people

1 In the case of children, when arrangements have been made for parents, carers or patients to administer their own medicines prior to discharge or rehabilitation, the registrant should ascertain that the medicinal products have been taken as prescribed.

Guidance

- 2 This should preferably be done by direct observation but when appropriate also by questioning the patient, parent or carer. The administration record should be initialled and 'patient self-administration' documented.
- 3 The administration of medicinal products by parents or carers to their children must be carefully controlled. There is the potential for inadvertent omission of doses or administration of extra doses unless there is clear communication and documentation.
- 4 Parents or carers can be encouraged to administer to their children in whatever setting when this is appropriate to the clinical condition of the child and when the registrant has assessed that the parent or carer is competent to do so. In a hospital setting the registrant should provide the medicinal product from the appropriate storage and supervise administration.

Unsupervised administration to children

- 5 Some parents and carers may administer to their children unsupervised if this has been agreed with the registrant in charge and if the medicinal products are stored in an appropriate secure locker. Responsibilities of the registrant and parent or carer must be specifically agreed and approved by the registrant in charge and agreed under local policies. Arrangements must be made for holding keys to the locker and for ensuring their return on discharge, and that any medicinal products remaining are supplied for discharge (if appropriately labelled and checked) or returned to the pharmacy.
- 6 The employing organisation should ensure appropriate clinical governance structures are in place.

Standard 11: Remote prescription or direction to administer

1 In exceptional circumstances, where medication (not including controlled drugs) 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 information technology (such as fax, text message or email) may be used but must confirm any change to the original prescription.

Guidance

- 2 A verbal order is not acceptable on its own. The fax or email prescription or direction to administer must be stapled to the patient's existing medication chart. This should be followed up by a new prescription signed by the prescriber who sent the fax or email confirming the changes within normally a maximum of 24 hours (72 hours maximum bank holidays and weekends). In any event, the changes must have been authorised (via text, email or fax) by a registered prescriber before the new dosage is administered. The registered nurse should request the prescriber to confirm and sign changes on the patient's individual medicines administration record (MAR) chart or care plan.
- 3 Where a medication has not been prescribed before, a nurse or midwife independent prescriber may not prescribe remotely if they have not assessed the patient, except in life-threatening situations. See standard 20 of the *Standards of Proficiency for Nurse and Midwife Prescribers* which you can find at www.nmc.org.uk/standards
- In exceptional circumstances, a medical practitioner may need to prescribe remotely for a previously unprescribed medicine, for example, in palliative care or remote and rural areas the use of information technology (such as fax, text message or email) must confirm the prescription before it is administered. This should be followed up by a new prescription signed by the prescriber who sent the fax/email confirming the changes within normally a maximum of 24 hours (72 hours maximum – bank holidays and weekends). The registrant is accountable for ensuring all relevant information has been communicated to the prescriber and s/he may refuse to accept a remote prescription if it compromises care to the patient. In this instance she should document accurately the communication that has taken place. Registrants should note that remote prescribing cannot be undertaken in a care home because they do not have access to a stock of medicines.
- 5 A prescription is required when the drug is to be both supplied and administered. For administration only, a direction to administer is sufficient.
- 6 It may be helpful to refer to the GMC *Good Medical Practice Guide* for further information available on the GMC website.

Standard 12: Text messaging

1 As a registrant, you must ensure that there are protocols in place to ensure patient confidentiality and documentation of any text received include: complete text message, telephone number (it was sent from), the time sent, any response given, and the signature and date when received by the registrant.

Guidance

- 2 An order to administer medication by text messaging is an increasing possibility. A second signature – normally another registrant but where this is not possible another person – should sign to confirm the documentation agrees with the text message. It must be regarded as a patient contact and all documentation should be in keeping with section 10 of *The Code: Professional standards of practice and behaviour for nurses and midwives* (NMC, 2015). All received messages should be deleted from the receiving handset after documentation to maintain high standards of confidentiality. Further guidance may be helpful including RCN – Use of text messaging services; *Guidance for nurses working with children and young people* (March 2006).
- 3 Wherever possible local policies should ensure the use of web-based products for texting that are secure and provide a robust audit trail. Clinical governance procedures should be in place to support such practice.

Standard 13: Titration

1 Where medication has been prescribed within a range of dosages it is acceptable for registrants to titrate dosages according to patient response and symptom control, and to administer within the prescribed range.

Guidance

2 A registrant must be competent to interpret test results, for example, blood results (heparin or glucose levels (insulin)), and assess, for example, withdrawal symptoms or signs of intoxication in the management of drug or alcohol withdrawal.

Standard 14: Preparing medication in advance

1 Registrants must not prepare substances for injection in advance of their immediate use or administer medication drawn into a syringe or container by another practitioner when not in their presence.

Guidance

2 An exception to this is an already established infusion, which has been instigated by another practitioner following the principles set out above, or medication prepared under the direction of a pharmacist from a central intravenous additive service and clearly labelled for that patient. Where the specific summary of product characteristic or patient information leaflet indicate it should be prepared in advance, for example, some chemotherapy treatments, it is acceptable to do so.

- Where a registrant has delegated to a named individual for a named patient's medication, this may be drawn up in advance to enable the healthcare assistant (HCA) or family to administer the medication. The registrant is accountable for the delegation, and a full risk assessment should be documented in the patient's records ensuring the registrant is aware of the risks before agreeing to delegate. The person to whom they are delegating the task is a 'named individual' who has been assessed and documented as competent.
- 4 Where you may be required to prepare substances for injection by a doctor, for example, in an emergency situation, you should ensure that the person administering the drug has undertaken the appropriate checks as indicated above.

Standard 15: Medication acquired over the internet

1 Registrants should never administer any medication that has not been prescribed, or that has been acquired over the internet without a valid prescription.

Guidance

- 2 Medication over the internet may not have been stored appropriately, the quality and safety of the medication cannot be verified, and there is often no batch number and so no redress from the manufacturer should adverse reactions occur.
- 3 Registered pharmacy premises can operate and provide internet pharmacy services. Where medicines are supplied via the internet from a registered pharmacy, the same standards are expected as would be received in a face-to-face situation.

Patients' own medication that has been purchased abroad and does not have a UK product licence

- 4 In this situation, a registrant must seek to identify the source of the original prescription to confirm its authenticity. Where this is not possible, the registrant should ascertain whether or not the patient would be prepared to have prescribed for them a drug with similar properties that is licensed in the UK. If the patient is in agreement, the registrant should request a prescription from a registered prescriber.
- 5 In a life-threatening situation or where the patient refuses to take anything but the 'unlicensed product' and they are unable to administer the medication themselves, the registrant may administer the medication in conjunction with locally agreed policies. In all circumstances a clear, accurate and contemporaneous record of all communication and administration of medication should be maintained.

Standard 16: Aids to support compliance

1 Registrants must assess the patient's suitability and understanding of how to use an appropriate compliance aid safely.

Guidance

- 2 Before considering the use of compliance aids the registrant should explore with the patient other possible solutions, for example reminder charts, large print labels, non-childproof tops. Self-administration from the dispensed containers may not always be possible for some patients. If an aid to compliance is considered necessary, careful attention should be given to the assessment of the patient's suitability and understanding of how to use an appropriate aid safely. Ideally a locally recognised assessment tool should be used. However, all patients will need to be regularly assessed for continued appropriateness of the aid. Ideally, any compliance aid, such as a monitored dose container or a daily or weekly dosing aid, should be dispensed, labelled and sealed by a pharmacist. The sealed compliance aids are generally referred to as monitored dosage systems.
- 3 Where it is not possible to get a compliance aid filled by a pharmacist, you should ensure that you are able to account for its use. The patient has a right to expect that the same standard of skill and care will be applied by you in dispensing into a compliance aid as would be applied if the patient were receiving the medication from a pharmacist. This includes the same standard of labelling and record keeping. Compliance aids, which can be purchased by patients for their own use, are aids that are filled from containers of dispensed medicines. If you choose to repackage dispensed medicinal products into compliance aids, you should be aware that their use carries a risk of error. You should also be aware the properties of the drug might also change when repackaged and so may not be covered by their product licence. Your employer needs to be aware of this activity and it should be covered by a standard operating procedure (SOP). The NMC would recommend that you confirm the appropriateness of re-packaging dispensed medicinal products with the community pharmacist who dispensed the medicines. You also need to consider how the patient will cope with medicines that cannot be included in compliance aids.

Crushing medication

4 The mechanics of crushing medicines may alter their therapeutic properties rendering them ineffective and are not covered by their product licence. Medicinal products should not routinely be crushed unless a pharmacist advises that the medication is not compromised by crushing, and crushing has been determined to be within the patient's best interest.

Disguising medication

5 As a general principle, by disguising medication in food or drink, the patient or client is being led to believe they are not receiving medication, when in fact they are. The NMC would not consider this to be good practice. The registrant would need to be sure what they are doing is in the best interests of the patient, and that they are accountable for this decision.

The standards: Section 5

Delegation

Standard 17: Delegation

1 A registrant is responsible for the delegation of any aspects of the administration of medicinal products and they are accountable to ensure that the patient, carer or care assistant is competent to carry out the task.

Guidance

- 2 This will require education, training and assessment of the patient, carer or care assistant and further support if necessary. The competence of the person to whom the task has been delegated should be assessed and reviewed periodically. Records of the training received and outcome of any assessment should be clearly made and be available.
- 3 See the guidance section 4, standard 8.

Standard 18: Nursing and midwifery students

1 Students must never administer or supply medicinal products without direct supervision.

Guidance

In order to achieve the outcomes and standards required for registration, students must be given opportunities to participate in the administration of medication but this must always be under direct supervision. Where this is done, both the student and registrant must sign the patient or woman's medication chart or document in the notes. The registrant is responsible for delegating to a student, and where it is considered the student is not yet ready to undertake administration in whatever form, this should be delayed until such time that the student is ready. Equally a student may decline to undertake a task if they do not feel confident enough to do so. The relationship between the registrant and the student is a partnership and the registrant should support the student in gaining competence in order to prepare for registration. As students progress through their training, their supervision may become increasingly indirect to reflect their competence level.

Standard 19: Unregistered practitioners

1 In delegating the administration of medicinal products to unregistered practitioners, it is the registrant who must apply the principles of administration of medicinal products as listed above. They may then delegate an unregistered practitioner to assist the patient in the ingestion or application of the medicinal product.

Guidance

- 2 Registrants may only delegate the ingestion or application of a controlled drug where the unregistered practitioner remains under the direct supervision of the registrant whether that is in a primary care, secondary care or independent sector setting. In care homes (personal care), health care assistants, support workers and care workers will not be skilled in giving medicines by invasive techniques and appropriate delegation is essential.
- 3 In the care of children with complex needs where an individual care plan has been written and signed off by a registrant, and the unregistered practitioner has been assessed by a registrant as competent to undertake the specific administration of medicinal products to a specific named patient, this may be undertaken, for example, children with complex health needs in community settings, palliative care.

Standard 20: Intravenous medication

1 Wherever possible two registrants should check medication to be administered intravenously, one of whom should also be the registrant who then administers the intravenous (IV) medication.

Guidance

- 2 In the exceptional circumstance where this is not possible, IVs should be checked by one registrant with another competent person who knows the patient. This could be a parent, carer or the patient themself. At a minimum, any dose calculation must be independently checked.
- 3 Registrants should be aware of the risks identified in the NPSA fourth report from the Patient Safety Observatory *Safety in doses: medication safety incidents in the NHS* (2007 and 2009). Search for this report at **www.npsa.nhs.uk**
- 4 In relation to the administration of intravenous medication, throughout the duration of intravenous medication therapy the registered nurse or midwife has a duty of care to the patient to monitor the patient and their response. View the standards for administration of IV therapy on the RCN website at **www.rcn.org.uk**
- 5 Registrants should also be familiar with the *UK Injectable Medicines Guide* currently under development at **www.ukmi.nhs.uk**

The standards: Section 6

Disposal of medicinal products

Standard 21: Disposal

1 A registrant must dispose of medicinal products in accordance with legislation.

Guidance

- 2 A patient or their representative (who may be a registered nurse or midwife) should return unwanted prescribed medicinal products to a pharmacy for destruction. In primary care, unwanted medication should be returned to a community pharmacy where it can be consigned as medicinal waste - classified as household waste. The definition of household waste is taken from the Controlled Waste Regulations 1992 and includes waste medicines from a patient's own home and waste medicines from a residential care home. The definition does not extend to stock medicines from other healthcare professionals, for example, midwives, nurses or doctors. There should be local procedures in hospital for the disposal of medicinal waste often overseen by the pharmacy department. If medication is taken to another health care environment it then becomes clinical waste and must be disposed of in accordance with clinical waste regulations. A community pharmacy cannot legally accept prescription medicines for disposal from care homes registered to provide nursing care, or from care homes that provide both residential and nursing care.
- 3 In this situation the care home (nursing) has to make its own arrangements for disposing of medication with a licensed waste management company. When a midwife is in possession of controlled drugs (CD) that are no longer required, they should be returned to the pharmacist from whom they were obtained, or to an appropriate medical officer. A record of the return should be made in the midwife's controlled drugs register. When a schedule 2 CD has been prepared or drawn up but is no longer required or no longer usable, it should be destroyed by the midwife, in accordance with current regulations.

The standards: Section 7

Unlicensed medicines

Standard 22: Unlicensed medicines

1 A registrant may administer an unlicensed medicinal product with the patient's informed consent against a patient-specific direction but not against a patient group direction.

Guidance

2 An unlicensed medicine is the term used to refer to a medicine that has no marketing authorisation. If an unlicensed medicine is administered to a patient, the manufacturer may not have liability for any harm that ensues. The person who prescribes and dispenses or supplies the medicine carries the liability. This may have implications for you in obtaining informed consent.

Medicinal products used outside their licence

- 3 Medication which is licensed but used outside its licensed indications (commonly known as 'off-label') may be administered under a patient group direction only where such use is exceptional, justified by best practice, and the status of the product is clearly described.
- 4 As a registrant, you should be satisfied that you have sufficient information to administer a medicine prescribed off-label safely and, wherever possible, that there is acceptable published evidence for the use of that product for the intended indication.
- 5 As a registrant, you should be satisfied that you have sufficient information to administer an unlicensed or off-label drug safely and, wherever possible, that there is acceptable published evidence for the use of that product for the intended indication. Liability for prescribing an off-label product sits with the prescriber and the dispenser or supplier.
- 6 The British National Formulary for children provides useful information for the administration of off-label medication for children. More information on unlicensed and off-label drugs can be found in the NMC publication *Standards of proficiency for nurse and midwife prescribers* which you can find at **www.nmc.org.uk/standards**

The standards: Section 8

Complementary and alternative therapies

Standard 23: Complementary and alternative therapies

1 Registrants must have successfully undertaken training and be competent to practise the administration of complementary and alternative therapies.

Guidance

- 2 Registrants are accountable for their practice and must be competent in this area (please refer to *The Code: Professional standards of practice and behaviour for nurses and midwives* (NMC, 2015)). You must have considered the appropriateness of the therapy to both the condition of the patient and any co-existing treatments. It is essential that the patient is aware of the therapy and gives informed consent.
- 3 Complementary and alternative therapies may interact with other types of medicinal products and laboratory tests. All complementary and alternative medicines should be recorded alongside other medicinal products and prescribed on inpatient prescription charts. You need to ensure that your employer has accepted vicarious liability for any complementary or alternative therapy you may undertake, or that you have indemnity insurance to cover your practice.

The standards: Section 9

Management of adverse events (errors or incidents) in the administration of medicines

Standard 24: Management of adverse events

1 As a registrant, if you make an error you must take any action to prevent any potential harm to the patient and report as soon as possible to the prescriber, your line manager or employer (according to local policy) and document your actions. Midwives should also inform their named supervisor of midwives.

Guidance

- 2 The NMC supports the use of a thorough, open and multi-disciplinary approach to investigating adverse events, where improvements to local practice in the administration of medicinal products can be discussed, identified and disseminated.
- 3 It is important that an open culture exists in order to encourage the immediate reporting of errors or incidents in the administration of medicines.
- 4 The NMC believes that all errors and incidents require a thorough and careful investigation at a local level, taking full account of the context and circumstances, and the position of the practitioner involved. Such incidents require sensitive management and a comprehensive assessment of all the circumstances before a professional and managerial decision is reached on the appropriate way to proceed. If a practising midwife makes or identifies a drug error or incident, she should also inform her supervisor of midwives as soon as possible aft er the event. In the NHS, all errors (patient safety incidents) and near-misses should be reported through local risk management systems. In England and Wales you should then report the incident to the National Patient Safety Agency (NPSA) through the National Reporting and Learning System (NRLS), whereas in Northern Ireland you should report to the Northern Ireland Adverse Incident Centre, and in Scotland through the NHS Quality Improvement Scotland (NHSQIS).
- 5 When considering allegations of misconduct arising from errors in the administration of medicines, the NMC takes great care to distinguish between those cases where the error was the result of reckless or incompetent practice and/or was concealed, and those that resulted from other causes, such as serious pressure of work, and where there was immediate, honest disclosure in the patient's interest. The NMC recognises the prerogative of managers to take local disciplinary action where it is considered to be necessary but urges that they also consider each incident in its particular context and similarly discriminate between the two categories described above. Registrants and their managers may find the NPSA's Incident Decision Tree Tool and Being Open Tool (details on **www.npsa.nhs.uk** and/or **www.saferhealthcare.org.u**K) useful. Allegations related to midwives would also be investigated by a supervisor of midwives as set out in the NMC's *Midwives rules and standards*, rule 5.

Standard 25: Reporting adverse reactions

1 As a registrant, if a patient experiences an adverse drug reaction to a medication you must take any action to remedy harm caused by the reaction. You must record this in the patient's notes, notify the prescriber (if you did not prescribe the drug) and notify via the Yellow Card Scheme immediately.

Guidance

2 Yellow cards are found in the back of the **British National Formulary** and online on **www.yellowcard.gov.uk**. In addition you should report any near misses or adverse events to the NPSA. For further information read the BNF or access the Medicines and Healthcare Products Regulatory Agency website **www.mhra.gov.uk**. Adverse drug reactions and patient safety incidents involving medicines, where a side effect (adverse drug reaction) from a medicine was preventable and still occurred, should be reported as a patient safety incident (error) through local risk management systems to the NPSA NRLS.

The standards: Section 10

Controlled drugs

Standard 26: Controlled drugs

1 Registrants should ensure that patients prescribed controlled drugs (CDs) are administered these in a timely fashion in line with the standards for administering medication to patients. Registrants should comply with and follow the legal requirements and approved local standard operating procedures for controlled drugs that are appropriate for their area of work.

Guidance

Medicines management for controlled drugs

- 2 Standards for medicines management apply to controlled drugs. However, following the government response to the fourth report of the Shipman Inquiry, there has been legislative change and new governance arrangements for controlled drugs (CDs), which impact on registrants. Registrants should be familiar with the DH guide *Safer Management of Controlled Drugs 2006* and the DH document *Guidance on the Management of Safe Use and Management of Controlled Drugs in Secondary Care in England Controlled Drugs in Acute Care 2007*.
- 3 Go to **www.dh.gov.uk** and search: controlled drugs.
- 4 Changes affecting the prescribing, record keeping and destruction of controlled drugs were introduced as a result of amendments to the Misuse of Drugs Regulations (MDR, 2001), Misuse of Drugs regulations (Northern Ireland), 2002, thereafter referred to as Misuse of Drugs Regulations (MDR), and the Health Act (2006), provided for regulations to be laid relating to governance and monitoring of controlled drugs.

38

- 5 The Health Act 2006 is primary legislation and applies to the whole of the UK although the regulations may differ in each of the devolved administrations. In England, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 came into force on 1 January 2007 and in Scotland on 1 March 2007.
- 6 Go to **www.dh.gov.uk** and search: The Controlled Drugs (Supervision of Management and Use) Regulations 2006.
- 7 Within the provisions of the Act, Wales and Northern Ireland will make their own regulations in relation to controlled drugs. These will be equivalent to the Controlled Drugs (Supervision of Management and use of) Regulations 2006.
- 8 Controlled drugs are those defined in the MDR (2001) and MDR Regulations, 2002 (NI). See annexe 1. However, on occasions, health care organisations choose to handle non-CDs in the same way as CDs to ensure a higher level of governance. This is a local decision and does not form part of this guidance, although registrants are reminded they should adhere to local policies where they exist.
- 9 At local level, all healthcare organisations are accountable, through the accountable officer, (not applicable to Wales or Northern Ireland until legislation comes into effect until at least 2008) for ensuring the safe management of controlled drugs.
- 10 The regulatory requirements for accountable officers are set out in full in the Controlled Drugs (Supervision and Management of Use) Regulations 2006; **www.legislation.gov.uk/** and a summary of the main provisions is provided at Appendix 2 of the DH Guidance on the *Management of Controlled Drugs in Acute Care 2007*.

Standard operating procedures

11 Each of the activities concerned with CDs, regardless of where in an organisation they occur, must be described in a standard operating procedure (SOP). Registrants should be aware of all SOPs within their organisation.

Requisitioning of controlled drugs

- 12 All stationery which is used to order, return or distribute controlled drugs (CD stationery) must be stored securely, and access to it should be restricted.
- 13 CD stationery should be kept in a locked cupboard or drawer.
- 14 There should be a list of the CDs to be held in each ward or department as stock items. The contents of the list should reflect current patterns of usage of CDs in the ward or department, and should be agreed between the senior pharmacist, appropriate medical staff and the registrant in charge.
- 15 Only the CDs listed in the stock list may be routinely requisitioned or topped-up.

- 16 The registrant in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in that area.
- 17 The registrant in charge can delegate control of access (that is key-holding) to the controlled drugs cabinet to another, such as a registered nurse or operating department practitioner. However, legal responsibility remains with the registrant in charge. (In Northern Ireland, it is not possible to delegate key holding to another but they may allow access via the keys which are then returned to the registrant in charge).
- 18 Orders must be written on suitable stationery (for example, a controlled drug requisition book) and must be signed by an authorised signatory.
- 19 A copy of the signature of each authorised signatory should be available in the pharmacy department for validation.
- 20 Requisitions must contain the:
 - 20.1 hospital
 - 20.2 ward or department
 - 20.3 drug name, form, strength, ampoule size if more than one available
 - 20.4 quantity
 - 20.5 signature and printed name of nurse
 - 20.6 date
 - 20.7 signature to receive goods for transit
 - 20.8 signature for receipt at ward or department.

Receipt of controlled drugs

- 21 When CDs are delivered to a ward or department they should be handed to a designated person. On no account should they be left unattended. A local procedure should define the persons who are permitted to receive CDs and the way in which messengers identify them.
- 22 As soon as possible after delivery the registrant in charge should:
 - 22.1 check the CDs against the requisition including the number ordered and received. If this is correct then the relevant (usually pink) sheet in the controlled drug requisition book should be signed in the 'received by' section
 - 22.2 place the CDs in the CD cupboard
 - 22.3 enter the CDs into the ward controlled drug record book, update the running balance and check that the balance tallies with the quantity that is physically present.

Storage

- 23 The Misuse of Drugs (Safe Custody) Regulations 1973 cover the safe custody of controlled drugs in certain specified premises. The regulations also set down certain standards for safes and cabinets used to store controlled drugs.
- 24 Ward CD cupboards should conform to the British Standard reference BS2881 or be otherwise approved by the pharmacy department. 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, 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.
- 25 All controlled drugs should be stored in a locked receptacle which can only be opened by a person who can lawfully be in possession, such as a pharmacist or registrant in charge, or a person working under their authority.
- 26 General guidance for the storage of controlled drugs should include the following:
 - 26.1 cupboards must be kept locked when not in use
 - 26.2 the lock must not be common to any other lock in the hospital
 - 26.3 keys must only be available to authorised members of staff
 - 26.4 the cupboard must be dedicated to the storage of controlled drugs. No other medicines or items may be stored in the controlled drug cupboard. Controlled drugs must be locked away when not in use.

Key-holding and access to CDs

- 27 The registrant in charge is responsible for the CD key and should know its whereabouts at all times.
 - 27.1 Key-holding may be delegated to other suitably trained members of staff but the legal responsibility rests with the registrant in charge
 - 27.2 The controlled drug key should be returned to the registrant in charge immediately after use by another registered member of staff
 - 27.3 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff.
- 28 Northern Ireland registrants: see paragraph 17 on requisitioning of controlled drugs above.

Missing CD keys

29 If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible, for example, by contacting nursing or midwifery staff who have just gone off duty.

30 A procedure should be in place to ensure that the registrant in charge or duty nurse manager 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.

Record keeping – controlled drug record books

- 31 Each ward or department that hold stocks of CDs should keep a record of CDs received and issued in a CD record book. In primary care, the relevant patient drug record card (where used) or CD record card for the administration of controlled drugs should be used. The registrant in charge is responsible for keeping the CD record book up to date and in good order.
- 32 The CD record book (acute care) should be bound (not loose-leaf), and it should have separate pages for each preparation. Entries should be made in chronological order, in ink. If a mistake is made, it should be crossed out with a single line or bracketed in such a way that the original entry is still clearly legible. This should be signed and dated, and witnessed by a second registered nurse or midwife who should also sign the change.
- 33 A record should be kept of all (schedule 2) controlled drugs that are received or issued.
- 34 All entries must be signed by two registrants, or one registrant and one student nurse or midwife (for administration only). Exceptionally, the second signature can be by another practitioner (for example, doctor or pharmacist) provided that they have witnessed the administration of the drug.
- 35 For CDs received, the following details should be recorded:
 - 35.1 date on which received
 - 35.2 name of pharmacist making supply/serial number of requisition
 - 35.3 amount received
 - 35.4 form in which received
 - 35.5 balance in stock
- 36 For CDs issued the following details should be recorded:
 - 36.1 date on which issue was made
 - 36.2 name of patient
 - 36.3 amount issued
 - 36.4 form in which issued
 - 36.5 name/signature of nurse/authorised person making the issue

36.6 name/signature of witness

36.7 balance in stock

- 37 If part of a vial is given to the patient, then the registrant should record the amount given and the amount wasted, for example, if the patient is prescribed a diamorphine 2.5mg and only a 5mg preparation is available, the record should show, '2.5mg given and 2.5mg wasted'.
- 38 After every administration, the stock balance of an individual preparation **must** be confirmed to be correct and the balance recorded in the controlled drug register.
- 39 In the community where there may not be two registrants available, a second competent person (which may be the carer) may witness the administration and balance of a controlled drug.
- 40 When recording controlled drugs received from pharmacy, the number of units received should be recorded in words not figures (for example, ten, not 10) to reduce the chance of entries being altered. On reaching the end of a page in the CD record book, the balance must be transferred to another page. The new page number must be added to the bottom of the finished page and the index updated.

Stock checks

- 41 The registrant in charge is responsible for ensuring that regular (locally determined protocol) CD stock checks are carried out.
- 42 Two registered nurses or midwives, should perform this check (a student nurse or midwife may be the second checker provided they have the necessary knowledge to carry this out).
- 43 Checking of controlled drugs involves checking of entries in the register against the contents of the controlled drug cupboard, not the reverse, to ensure all entries are checked. It is not necessary to open packs with intact tamper-evident seals for stock checking purposes.
- 44 A record indicating this check has been carried out and confirming the stock is correct may be kept in a separate record book or sheet or in the controlled drug register.
- 45 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. Any discrepancy should be reported to the registrant in charge who should inform the pharmacist.

Midwives and controlled drugs

46 A registered midwife may possess diamorphine, morphine, pethidine and pentazocine in her own right so far as is necessary for the practice of her profession. See the Misuse of Drugs Regulations 2001 at: www.legislation.gov.uk/uksi/2001/3998/contents/made

- 47 Supplies of diamorphine, morphine, pethidine and pentazocine may only be made to her 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.
- 48 The supervisor of midwives or other appropriate medical officer should be satisfied that locally agreed procedure is being followed before signing the supply order (for example, that the amount being requested is appropriate etc).
- 49 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. Supplies of pethidine, pentazocine, morphine and diamorphine may be obtained from a hospital pharmacy. However, this is only when classed as within the course of the business of the hospital the midwife works in, or it is a registered hospital pharmacy, or it holds a wholesale dealer's licence. The pharmacist who makes the supply should ensure that medicines are only supplied on the instruction of an authorised person. The pharmacist must retain the midwife's supply order for two years.
- 50 Midwives should 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.
- 51 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.
- 52 Where it is necessary for midwives to keep medicines in their homes, the medicines should be placed in a secure, locked receptacle. If necessary, this should be provided by the employing body.
- 53 Administration of controlled drugs by midwives should be in accordance with locally agreed procedures. A record of administration of the controlled drugs should also be kept in the patient's records.

Returns and disposal

- 54 When a midwife is in possession of CDs that are no longer required they should be returned to the pharmacist from whom they were obtained, or to an appropriate medical officer. A record of the return should be made in the midwife's controlled drugs register.
- 55 When a schedule 2 controlled drug has been prepared or drawn up but is no longer required or no longer usable, it should be destroyed by the midwife, in accordance with current regulations. A record of the destruction should be made.
- 56 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.

Returns to pharmacy (all registrants)

- 57 The following details should be recorded when controlled drugs are returned to the pharmacy:
 - 57.1 date
 - 57.2 name, form, strength and quantity of drug being returned
 - 57.3 reason for return
 - 57.4 name and signature of pharmacist removing the drugs
 - 57.5 name and signature of nurse witnessing the removal of drugs from the ward
- 58 The top copy will be taken from the book and transported with the drugs to pharmacy.
- 59 In addition, an entry must be made on the relevant page of the ward controlled drug record book, showing:
 - 59.1 date
 - 59.2 reason for return
 - 59.3 names and signatures of both nurse and pharmacist
 - 59.4 quantity removed
 - 59.5 balance remaining.
- 60 The drugs must be transported to pharmacy in a safe and secure way.

Transport of CDs

- 61 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.
- 62 Wherever possible, CDs must be transported in a secure, lockable or sealed, tamper-evident container.
- 63 Registrants working in the community may transport CDs, however, they should present their identity badge to the pharmacist and sign for them on receipt, and should ensure they are transported securely to the patient's home. Once in the patient's home, the registrant should sign the patient drug record card and it should be witnessed that the CD has been received by the patient. Where a second registrant is not available another competent person may witness receipt (this could be a carer).

Disposal and destruction

- 64 Destruction on ward may take place at the same time as a pharmacy stock check.
- 65 CDs should be destroyed in such a way that the drug is denatured or destroyed so that it cannot be retrieved, reconstituted or used.
- 66 Destruction must occur in a timely fashion, so that excessive quantities are not stored awaiting destruction.
- 67 All destruction must be documented in the appropriate section of the register.
- 68 It must be witnessed by a second competent professional authorised under Regulation 27 of the MDR. Both persons must sign the register.
- 69 For more detail on the methods of destruction for CDs, registrants are advised to access table 2 of the *Guidance on Controlled Drugs in Acute Care* (2007), which summarises where CDs may be destroyed and who should carry out the destruction.
- 70 For guidance, go to **www.dh.gov.uk** and search for Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures.

9188 of 10305

Annexe 1

Legislation

There are a number of pieces of legislation that relate to the prescribing, supply, storage and administration of medicines. It is essential that you comply with them. The following is a summary of those that are of particular relevance.

Medicines Act 1968

This was the first comprehensive legislation on medicines in the UK. The combination of this primary legislation and the various statutory instruments (secondary legislation) on medicines produced since 1968 provides the legal framework for the manufacture, licensing, prescribing, supply and administration of medicines. Among recent statutory instruments of particular relevance to registered nurses, midwives and specialist community public health nurses is The Prescription Only Medicines (Human Use) Order 1997, SI No1830. This consolidates all previous secondary legislation on prescription only medicines and lists all of the medicines in this category. It also sets out who may prescribe them. The sections on exemptions are of particular relevance to midwives, including those in independent practice, and to nurses working in occupational health settings. The Medicines Act 1968 classifies medicines into the following categories:

Prescription only medicines (POMs)

These are medicinal products that may only be sold or supplied to a patient on the instruction of an appropriate practitioner. An appropriate practitioner is a doctor, dentist, supplementary prescriber, or nurse or pharmacist independent prescriber. For more information on the appropriate use of medicines and the relevant legislation, it is advisable to consult with a pharmacist. The Royal Pharmaceutical Society of Great Britain (RPSGB) can also provide more detailed information on medicines legislation.

Pharmacy only medicines (Ps)

These can only be purchased from a registered pharmacy. The sale must be by or under the supervision of a pharmacist.

General sales list medicines (GSLs)

These need neither a prescription nor the supervision of a pharmacist and can be obtained from retail outlets.

Controlled drugs (CDs)

The management of controlled drugs is governed by the Misuse of Drugs Act 1971 and its associated regulations.

Misuse of Drugs Act 1971

The Misuse of Drugs Act (MDA) 1971 and its associated regulations provide the statutory framework for the control and regulation of controlled drugs. The primary purpose of the MDA is to prevent misuse of CDs. 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 of the Act.

Additional statutory measures for the management of controlled drugs are laid down in the Health Act 2006 and its associated regulations.

Misuse of Drugs Regulations 2001 (MDR) and Misuse of Drugs Regulations Northern Ireland (NI) 2002

The use of CDs 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 CDs are subject to the highest level of control, whereas schedule 5 CDs are subject to a much lower level of control.

For practical purposes, health care staff need to be aware of the current regulations.

The MDR are periodically amended and revised. The MDR currently in force and its amendments can be found at **www.legislation.gov.uk/uksi/2001/3998/contents/made**

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. Only certain persons can be licensed by the Home Office to possess them for research purposes. Practitioners (for example, doctors, dentists and veterinary surgeons) and pharmacists may not lawfully possess schedule 1 drugs except under licence from the Home Office.

The drugs listed in schedule 1 have no recognised medicinal use although Sativex[®] (a cannabis-based product) is exempt from the requirements for a specific licence to be held by the pharmacist or prescriber, and 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 CDs (except secobarbital) are subject to safe custody requirements (under the Misuse of Drugs Safe Custody 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 CD or a person authorised by them.

A licence is required to import or export drugs in schedule 2.

Schedule 2 CDs 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 CDs.

Nurse independent prescribers are currently permitted to prescribe, administer, or direct anyone to administer some CDs for specific conditions and routes of administration (under review).

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 – schedule 3 CDs are exempt from safe custody requirements. Exceptions are flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

Schedule 4 (CD benzodiazepines and CD anabolic steroids)

Schedule 4 is split into two parts.

Part 1 (CD benzodiazepines) contains most of the benzodiazepines, plus eight other substances including zolpidem, fencamfamin and mesocarb.

Part 2 (CD anabolic steroids) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoreceptor stimulant) and growth hormones (5 polypeptide hormones).

There is no restriction on the possession of a schedule 4 part 2 (CD anabolic steroids) drug when it is part of a medicinal product. However, possession of a drug from schedule 4 part 1 (CD benzodiazepines) is an offence without the authority of a prescription in the required form. Possession by practitioners and pharmacists acting in their professional capacities is authorised.

Schedule 5 (CD invoice)

Schedule 5 contains preparations of certain CDs (for example, 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.

Invoices must be retained for a minimum of two years.

Misuse of Drugs (Safe Custody) Regulations 1973 Misuse of Drugs (Safe Custody) Regulations Northern Ireland 1973

The Safe Custody Regulations 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 some schedule 3 CDs should be stored securely in accordance with the MDR. These regulations state that such CDs 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 (Supply to Addicts) Regulations 1997 and Misuse of Drugs (Notification 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 Home Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

Prescription Only Medicines (Human Use) Order 1997

This order sets out the requirements for a valid prescription. It also allows midwives to possess and administer diamorphine, morphine, pethidine or pentazocine in the course of their professional practice.

A number of health care professionals are permitted to supply or administer medicines generally in accordance with a patient group direction (PGD) under Medicines Act legislation.

Registered nurses are permitted to supply or administer some CDs in accordance with a PGD under Misuse of Drugs legislation. **www.legislation.gov.uk/uksi/2001/3998/ contents/made**

Health Act 2006

The key provisions of the act are:

- all designated bodies such as healthcare organisations and independent hospitals are required to appoint an accountable officer
- a duty of collaboration placed on responsible bodies, healthcare organisations and other local and national agencies including professional regulatory bodies, police forces, the Healthcare Commission and the Commission for Social Care inspection to share intelligence on controlled drug issues
- a power of entry and inspection for the police and other nominated people to enter premises to inspect stocks and records of controlled drugs.

Controlled Drugs (Supervision of Management and Use)

Regulations 2006

The Controlled Drug (Supervision of Management and Use) Regulations 2006 came into effect in England on the 1 January 2007. These regulations set out the requirements for certain NHS bodies and independent healthcare bodies to appoint an accountable officer, and describe the duties and responsibilities of accountable officers to improve the management and use of controlled drugs.

The regulations also require specified bodies to cooperate with each other, including with regard to sharing of information, concerns about the use and management of controlled drugs, and the setting out arrangements relating to powers of entry and inspection.

Annexe 2

Guidance on labelling and over-labelling of medicines

There may be occasions when registrants are required to dispense medicinal products and it is important that they understand the requirements for labelling correctly.

General sale list medicines are sold over the counter in containers showing the product in the box. Each medicinal product includes patient information either as a leaflet or on the packet or both.

Medicines dispensed to a patient-specific prescription must be labelled with all the required information.

The standard labelling requirements for all dispensed items are:

- the name of the person to whom the medicine is to be administered
- the name and address of the person who sells or supplies the medicinal product
- the date of dispensing
- directions for use
- the words 'Keep out of the reach of children' or words of direction bearing a similar meaning (for example, 'Keep out of the reach and sight of children').

Medicines supplied for use under a patient group direction are already labelled. These labels include all the standard labelling requirements apart from the patient's name and date of supply. On supplying these medicines to the patient, the patient's name and date of supply must be completed. This is sometimes known as over-labelling.

Registrants are advised to access the Medicines Ethics and Practice Guide at **www.rpsgb.org.uk/informationresources/downloadsocietypublications**

Annexe 3

Suitability of patients' own medicinal products for use

Additional guidance to Standard 5 of this document

The registrant must check that the medicinal products are suitable for use by ensuring:

- correct packaging and labelling
- dispensing date
- expiry date
- instructions for use
- dose
- the medicinal product matches what is on the label
- the patient information leaflet is enclosed
- correct patient name and ownership.

If the registrant is in any doubt as to the suitability of any of the medicinal products they must discuss this with their line manager or the pharmacy department. The registrant must seek consent to dispose of any unwanted medicinal product or they must be returned to the patient. Every effort must be made to ensure the patient understands the correct use of medications and the consequences of taking unprescribed medicines.

Where the prescription is changed the registrant has a responsibility to ensure that the medicinal products are re-dispensed as soon as possible.

Where a medicinal product is discontinued, it must be removed and with the patient's permission disposed of in the appropriate manner.

Administering medicines using the patient's own supply in the hospital or care home setting

When administering medicines from the patient's own supply the registrant must check the medicines in the locked cabinet or locker with the prescription chart and use only those medicines belonging to that named patient.

If a supply is not available medicines belonging to another patient must not be used.

Discharge of patients from hospital who have used their own supply or when checking medications to take home (TTOs/TTAs)

On discharge, the registrant is responsible for ensuring:

- the medicinal products have been clinically checked by the pharmacist
- the medicinal products are over-labelled for the patient
- the patient has the correct medicines, prescription or discharge summary and the supply is checked by a pharmacist, registered nurse or by two registrants if out of hours or according to local policy
- the patient has had sufficient medicinal products prescribed, dispensed and supplied to cover a period of time to enable them to access further supplies from their usual practitioner
- the patient is aware of any changes to their medication, that is, new medicine, dose, brand, route
- the patient has been educated and given patient information leaflets relating to all medication whether current or new
- the patient takes all their medicinal products home with them or has given permission to dispose of the medicines no longer prescribed
- where the patient wishes to retain their discontinued medicines the risk of confusion and possible under or overdose needs to be pointed out to them
- in the hospital setting, if the patient has been self-administering the key is returned to the registrant in charge of the ward or unit before the patient is discharged or care transferred
- if the bedside cabinet or locker key is lost, the appropriate hospital policy must be followed.

Annexe 4

Exclusion criteria for self-administration of medicines

When assessing a patient's suitability for self-administration of medicines, if the assessing registrant, in his or her professional judgement, is at all unhappy to let the patient self-administer, then the patient should be excluded and reassessed at another point.

If the patient does not give consent to self-administer and other arrangements are made, information about their medicines and what to do aft er discharge must still be given.

Patients who may be confused must not be given custody of their medicines but may administer on levels one and two only (see Standard 9 of this document).

In the hospital setting, this includes patients who are 'nil by mouth', immediately post-op and under the influence of anaesthetic agents, acutely ill patients or confused patients. The assessment should be carried out at an appropriate time in the course of the patient's admission to determine if they should be able to self-administer at a later stage, that is, when the anaesthetic agents have worn off or the acute stage of their illness is over.

Patients with a past history of drug or alcohol abuse do not have to be excluded from self-administration of their medicines but the need for extra supervision and reinforcement of education should be highlighted and documented. These patients should spend more time on levels one and two to ensure they receive adequate supervision and education. These patients may never get to administer at level 3 but they can still be educated at levels 1 and 2.

Any change in the patient's condition would necessitate a review of their selfadministration status.

Local policies should be developed for this using the guidance for self-administration of medicinal products stated under Standard 9 of this document.

Registrants should be aware that the Mental Capacity Act 2005 requires all those working with potentially incapacitated people to assess the individual's capacity at a particular moment about a particular decision or issue. This would be predominantly older people and people with learning difficulties.

Annexe 5

Administering medicinal products in research clinical trials

Registrants involved in the supply or administration of a treatment or a placebo as part of a clinical trial would not need to consent to the trial itself, however, patients are required to do so. They would, however, need to know that the trial was taking place, and be willing to take part to the extent that they would be supplying or administering the medicine or placebo. The registrant's employer would need to discuss the trial with the registrant, and provide an information sheet in order to ensure that they had all the information available and confirmation that ethical approval had been sought and approved.

The purpose of the trial would be to establish whether the treatment is effective. Therefore, patients taking the placebo are not being deprived of a medicine that is known to be effective. There should be no reason for a registrant to object to taking part in that they are not depriving a patient of effective treatment but rather contributing to the evidence base for effective treatment in the future.

Also see *Midwives rules and standards* rule 8 on clinical trials which you can find at **www.nmc.org.uk/standards**

Annexe 6

Information, advice and publications

Royal Pharmaceutical Society of Great Britain 1 Lambeth High Street London SE1 7JN Telephone 020 7735 9141 www.rpsgb.org.uk

The Pharmaceutical Society of Northern Ireland 73 University Street Belfast BT7 1HL Telephone 028 90 326 927 www.psni.org.uk

Scottish Pharmaceutical General Council 42 Queen Street Edinburgh EH2 3NH Telephone 0131 467 7766 www.communitypharmacyscotland.org.uk

Office of the Chief Pharmacist Department of Health Richmond House 79 Whitehall London SW1A 2NS Telephone 020 7210 5761 www.dh.gov.uk

Home Office 50 Queen Anne's Gate London SW1H 9AP Telephone 020 7273 3474 www.homeoffice.gov.uk

Medicines and Healthcare Products Regulatory Agency Market Towers 1 Nine Elms Lane London SW8 5NQ Telephone 020 7084 2000 www.mhra.gov.uk

The Association of the British Pharmaceutical Industry 12 Whitehall London SW1A 2DY 0870 8904333 www.abpi.org.uk

The Association of the British Pharmaceutical Industry (Scotland) Third Floor East Crichton House 4 Crichton's Close Canongate Edinburgh EH8 8DT www.abpi.org.uk/Scotland/scot_intro.asp

European Council for Classical Homeopathy at www.homeopathy-ecch.org

Prince of Wales Foundation for Integrated Health at www.fih.org.uk

Publications

Royal Pharmaceutical Society of Great Britain. *Medicines, Ethics and Practice: A guide for pharmacists* is published annually and is available from **www.rpsgb.org.uk**

National Prescribing Centre (NPC). (2004) A guide to good practice in the management of Controlled Drugs in primary care (England). www.npc.co.uk

The British National Formulary and the British National Formulary for Children are published jointly by the British Medical Association and the Royal Pharmaceutical Society of Great Britain. Copies are available from the Pharmaceutical Press, PO Box 151, Wallingford, Oxfordshire OX10 8QU.

The *Monthly Index of Medical Specialities* (MIMS) is available from MIMS Subscriptions, PO Box 43, Ruislip, Middlesex HA4 0YT, telephone 020 8845 8545 or fax 020 8845 7696.

The Review of Prescribing, Supply and Administration of Medicines: A Report on the Supply and Administration of Medicines under Group Protocols, (Crown I) (Department of Health, London, April 1998) was published under cover of Health Service Circular (HSC) 1998/051 in England; Management Executive letter (MEL) (98)29 in Scotland; Welsh Health Circular (WHC) (98)27 in Wales, and by each Chief Professional Officer to their respective professional groups in Northern Ireland. Copies are available from the NHS response line on 0541 555 455. The *Review of Prescribing, Supply and Administration of Medicines: Final Report* (Crown II) (Department of Health, London 1999) is available from the same source.

Non medical prescribing in Wales: a guide for implementation, July 2007, Welsh Assembly Government

Drug Information at **www.druginfozone.nhs.uk** and includes a centrally maintained archive of approved PGDs.

Medicines for Older People: Implementing medicines-related aspects of the NSF for Older People. DH March 2001 Can be searched for, and downloaded at, **www.dh.gov. uk**

Medicines Partnership Programme at www.npc.co.uk/med_partnership

National Electronic Library of Medicines www.nelm.nhs.uk

National Health Service Quality Improvement www.nhshealthquality.org

National Institute for Clinical Excellence www.nice.org.uk

National Patient Safety Agency (2007 and 2009) *Safety in doses: medication safety incidents in the NHS*. Reports from the Patients' Safety Observatory

PRODIGY www.prodigy.nhs.uk

Royal Pharmaceutical Society Great Britain (March 2005) *The Safe and Secure handling of medicines: a team approach*. A revision of the Duthie Report (1988)

National Health Services Act 1977

Misuse of Drugs Act 1971

Misuse of Drugs Regulations 2001 SI2001 No 3998

Misuse of Drugs (Safe Custody) Regulations 1973 SI1973 No 798

Medicines Act 1968 (as amended)

POM Order 1983 (as amended)

Prescription by Nurses etc. Act 1992

NHS Executive (2000) The Prescriptions Only Medicines (Human Use) Amendment (No2) Order 2000 SI No 22899 The Stationery Office, London

NHS Executive HSC 2000/026 Patient group directions (England only) (2000)

Royal Pharmaceutical Society of Great Britain (2004) Factsheet on patient group directions **www.rpsgb.org.uk/pdfs/factsheet10.pd**f

MHRA Patient Group Directions in the NHS. Search for at www.mhra.gov.uk

MHRA Patient Group Directions in the Private Sector. Search for at **www.mhra.gov.uk** EC 92/27 Labelling and Leaflet Directive

Self-administration of medicines by hospital inpatients **www.audit-commission.gov.uk/ itc/doc/selfadmin.doc**

Care Standards Act 2000

The Regulation of Care (Scotland) Act 2001

The Health and Social Care (Community Health and Standards) Act 2003

The Private and Voluntary Health Care (England) Regulations 2001

Department of Health National Minimum Standards for social care services www.csci.org.uk/choose_and_find_care/your_rights/national_minimum_ standards.aspx

Royal Pharmaceutical Society of Great Britain (2003) *Administration and control of medicines in care homes and children's services* **www.rpsgb.org.uk**

MDA/2004/001 – Reporting adverse incidents and disseminating medical device alerts

Medicines and Healthcare Products Regulatory Agency www.mhra.gov.uk/home/ idcplg?ldcService=SS_GET_PAGE&nodeld=5

National Patient Safety Agency (2003) *National Reporting and Learning System service datasets*. Go to **www.npsa.nhs.uk**

Nursing and Midwifery Council circular – *Medicines legislation: what it means for midwives*, London: NMC 1/2005

Nursing and Midwifery Council circular – *Midwives Supplies Orders*, London: NMC 25/2005

Nursing and Midwifery Council – *Midwives rules and standards*, London: NMC 2004

Nursing and Midwifery Council – *Standards of proficiency for nurse and midwife prescribers*, London: NMC 2006

Royal College of Midwives, *Midwives and medicines legislation: An Information Paper*, London 2006

Royal Pharmaceutical Society of Great Britain (2005) *Medicines, Ethics and Practice: A Guide for pharmacists*: 29th edition Pharmaceutical Press.

The British National Formulary online www.bnf.org

For a list of current NMC publications go to www.nmc.org.uk/standards

Annexe 7

Glossary clinical governance Quality assurance activities which ensure that pre-determined clinical standards that have been set, are seen to be maintained by practitioners, and are evident within health care settings. clinical The CMP is the foundation stone of supplementary prescribing. management plan Before supplementary prescribing can take place, it is obligatory (CMP) for an agreed CMP to be in place (written or electronic) relating to a named patient or client and to that patient or client's specific condition(s) to be managed by the supplementary prescriber. The CMP is required to include details of the illness or conditions that may be treated, the class or description of medical products that can be prescribed or administered, and the circumstances in which the supplementary prescriber should refer to, or seek advice from, the doctor or dentist. Supplementary prescribers must have access to the same patient or client health records as the doctor or dentist. Since April 2005, nurse supplementary prescribers can prescribe controlled drugs, provided the doctor or dentist has agreed to this within the clinical management plan. competence Relates to the need for the student to demonstrate their 'capability' in certain skill areas to a required standard at a point in time. competencies Component skills which contribute to being competent and achieving the standards of proficiency for registration. Competencies might include skills arising from learning outcomes or other requirements. dispensing To label from stock and supply a clinically appropriate medicine to a patient, client or carer, usually against a written prescription, for self-administration or administration by another professional, and to advise on safe and effective use. Health Care The health watchdog in England. It has a statutory duty to Commission assess performance of health care organisations, award annual performance ratings for NHS and coordinate the review of health care by others. (The Care Quality Commission has since taken over the role of the Health Care Commission - see www.cqc.orq.uk).

| independent prescriber | A prescriber who is legally permitted and qualified to prescribe and takes the responsibility for the clinical assessment of the patient or client, establishing a diagnosis and the clinical management required, as well as the responsibility for prescribing, and the appropriateness of any prescribing. |
|--|--|
| licensed medication | The Medicines and Healthcare products Regulatory Agency (MHRA) operates a system of licensing before medicines are marketed (see marketing authorisation). However, the Medicines Act allows certain exemptions from licensing which include: |
| | the manufacture and supply of unlicensed relevant medicinal products for individual patients or clients (commonly known as 'specials') |
| | the importation and supply of unlicensed relevant medicinal products for individual patients or clients |
| | herbal remedies exemption. |
| marketing authorisation | Previously known as a 'product licence'. This normally has to be granted by the MHRA before a medicine can be prescribed or sold. This authorisation, which confirms that medicines have met standards for safety, quality and efficacy, considers all of the activities associated with marketing medicinal products. |
| Medicines Act exemptions | Allow certain groups of healthcare professionals including occupational health schemes and midwives to sell, supply and administer particular medicines directly to patients or clients. Provided the requirements of any conditions attached to those exemptions are met, a patient group direction is not required. |
| medicines administration record | Also known as patient administration chart, the record by which medicinal products administered to a patient are recorded. |
| Medicines Healthcare Products Regulatory Agency (MHRA) | The government agency responsible for ensuring that medicines and medical devices work and are acceptably safe. |
| National Patient Safety Agency (NPSA) | A special health authority created to coordinate all the eff orts of all those involved in health care to learn from patient safety incidents occurring in the NHS. |

| nurse independent prescribers | Nurses and midwives who are on the relevant parts of the NMC register may train to prescribe any medicine for any medical condition within their competence with the exception of controlled drugs. |
|--|---|
| Nurse Prescribers Formulary for Community Practitioners (CPF) | The formulary from which nurses who have successfully completed the integrated prescribing component of the SPQ/ SCPHN programme may prescribe independently. |
| one-stop dispensing | One-stop dispensing is a system of administering and dispensing medicinal products. It involves using the patient's own medicinal products during their stay in hospital, either those dispensed by a community pharmacy or by the hospital pharmacy or both, providing they contain a patient information leaflet and are labelled with full instructions for use. |
| parts of the register | The NMC register, which opened on 1 August 2004, has three parts: nurses, midwives and specialist community public health nurses. A record of prescriber qualifications on the register identifies the registrant as competent to prescribe as community practitioner nurse prescriber or a nurse independent and supplementary prescriber. |
| patient group direction (PGD) | Written instructions for the supply or administration of named medicines to specific groups of patients who may not be individually identified before presenting for treatment. Guidance on the use of PGDs is contained within <i>Health Service Circular (HSC) 2000/026</i> . (Note: In Wales WHC 2000/116. Separate guidance has also been issued in Scotland and NI.) The circular also identifies the legal standing of PGDs plus additional guidance on drawing them up and operating within them. It is vital that anyone involved in the delivery of care within a PGD is aware of the legal requirements. It is not a form of prescribing. See also guidance at www.npc.co.uk |
| patient information leaflet | Data sheets found in all dispensed medicinal products which should be brought to the patient's attention on administering the medicinal product. |
| patient specific direction | Written instructions from a doctor, dentist or nurse prescriber for a medicine to be supplied or administered to a named person. This could be demonstrated by a simple request in the patient or client's notes or an entry on the patient or client's drug chart. |

| prescription pricing division (PPD) registrants | Is a division of the NHS Business Services Authority in England responsible for processing all prescription items. Nurses, midwives and specialist community public health nurses currently entered in the NMC register. |
|--|---|
| repeat prescribing | A partnership between patient or client and prescriber that allows the prescriber to authorise a prescription so it can be repeatedly issued at agreed intervals, without the patient or client having to consult the prescriber at each issue. |
| Regulation and Quality Improvement Authority (RQIA) | Is an independent health and social care regulatory body for Northern Ireland which encourages continued improvement in quality of services through a programme of inspections and reviews. |
| rules | Rules are established through legislation and they provide the legal strategic framework from which the NMC develops standards, for example, Education, Registration and Registration Appeals Rules 2004 (SI 2004/1767). 'Standards' support the rules. Standards are mandatory and gain their authority from the legislation, in this case the order and the rules. |
| specialist community public health nurse | A nurse who aims to reduce health inequalities by working with individuals, families and communities, promoting health, preventing ill health and in the protection of health. The emphasis is on partnership working that cuts across disciplinary, professional and organisational boundaries that impact on organised social and political policy to influence the determinants of health and promote the health of whole populations. |
| stakeholders | Those who have a major interest in ensuring an effective programme outcome, including programme providers, placement providers, students, mentors, practice teachers, external examiners, external agencies, service users and carers. |
| standards | The NMC is required by the Nursing and Midwifery Order 2001 (the order) to establish standards of proficiency to be met by applicants to different parts of the register. The standards are considered to be necessary for safe and effective practice [Article $5(2)(a)$]. These are set out within the Standards of proficiency for each of the three parts of the register, and for the recorded qualification of nurse or midwife prescriber. |

summary of productInformation on medicinal products dispensed may be found at the **characteristics** Electronic Medicines Compendium.

- supplementary
prescribingA voluntary partnership between an independent prescriber
(doctor or dentist) and a supplementary prescriber, to implement
an agreed patient or client-specific clinical management plan with
the patient or client's agreement.
- **transcribing** (transposing) Any act by which medicinal products are written from one form of direction to administer to another is 'transcribing'. Including discharge letters, transfer letters, copying illegible patient administrations chart onto new charts (whether handwritten or computer-generated).
- unlicensedThis term refers to medicines that are not licensed for anymedicinesindication or age group. Reasons why a drug may not be licensedinclude:
 - the drug is undergoing a clinical trial, has been imported, has been prepared extemporaneously or prepared under a special manufacturing licence
 - the product is not a medicine but is being used to treat a rare condition.
- unregisteredPractitioners providing care who are neither registered or licensedpractitionersby a regulatory body and have no legally defined scope of
practice.
- Yellow Card Scheme If a patient or client experiences an adverse drug reaction to a medication the nurse or midwife should record this in the patient or client's notes, notify the prescriber (if they did not prescribe the drug) and notify via the Yellow Card Scheme immediately. Yellow cards are found in the back of the British National Formulary and online on www.yellowcard.gov.uk For further information read the BNF or access the MHRA website www.mhra.gov.uk

9205 of 10305

Annexe 8

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PB-STMM-A5-0410



Medicines Management

An overview for nursing

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BT Mod 3 Witness Stmt 20 Mar 2023 PART 5 OF 9 Exhibit Bundle (4 of 8) (T07-T08) (pp8370-10305 of 20966) (this part 1936 pages)



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Publication

This is an RCN practice guidance. Practice guidance are evidence-based consensus documents, used to guide decisions about appropriate care of an individual, family or population in a specific context.

Description

This publication provides an overview to direct nurses to the most appropriate information to support specific needs. It can be used by education and learning facilitators in practice to support robust training and competence development in medicines management. **Publication date: January 2020 Review date: January 2022**

The Nine Quality Standards

This publication has met the nine quality standards of the quality framework for RCN professional publications. For more information, or to request further details on how the nine quality standards have been met in relation to this particular professional publication, please contact **publicationsfeedback@rcn.org.uk**

Evaluation

The authors would value any feedback you have about this publication. Please contact publicationsfeedback@rcn.org.uk clearly stating which publication you are commenting on.

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Contents

| Background and context | 4 |
|---|----|
| Who is the resource for? | 4 |
| What is medicines management? | 5 |
| The right medicine for the right patient and the right time | 5 |
| Becoming an independent prescriber | 6 |
| Competencies and maintaining competence | 6 |
| Specialist prescribing | 6 |
| Delegation | 7 |
| Unregistered staff and social care | 7 |
| Administration | 7 |
| Prescribing and administration | 8 |
| Transcribing | 8 |
| Nursing associates and medicines management | 9 |
| Summary of available guidance | 10 |

Background and context

Whether or not you are a prescriber, medicines management and the administration of medicines is a key part of the nurse's role.

Following the announcement of the withdrawal of the Nursing and Midwifery Council (NMC) *Standards for Medicines Management* (2007), the Royal College of Nursing (RCN) has been working closely with the NMC and other organisations, including the Royal Pharmaceutical Society (RPS) and other colleges, to review currently available documents and we have developed new multi-professional guidelines. A web resource has been developed to provide guidance and clinical support for nurses and other health care professionals on all medicines matters including prescribing. This is available at: rcn.org. uk/clinical-topics/medicines-management. It has an extensive professional resources section, which looks at new and existing guidance to support nursing staff in a variety of settings as well as the wider health care team.

This publication provides an overview to direct nurses to the most appropriate information to support specific needs and it can be used by education and learning facilitators in practice to support robust training and competence development in medicines management.

Who is the resource for?

This resource is intended for any registered nurse working with medicines as part of their role. The principles of medicines management however, apply across all health care settings and for non-registered staff.

The RCN website provides information and resources to support nurses and other health care practitioners in their medicines management. This includes the administration of medicines, a joint publication between the RCN and RPS, safe and secure handling of medicines, along with details of other RCN, RPS, NICE and NMC publications. Further details can be found at: rcn.org.uk/clinical-topics/medicinesmanagement

What is medicines management?

Medicines management, also referred to as medicines optimisation, has been defined by the Medicines and Healthcare Products Regulatory Agency 2004 as:

"The clinical, cost effective and safe use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimising potential harm."

This is reiterated by the Department of Health, Northern Ireland, which state that:

"The goal of safe and effective medicines management is to optimise the benefits that treatment offers and attain the best outcome for each patient."

health-ni.gov.uk/articles/medicinesmanagement Effective medicines management places the patient as the primary focus, therefore delivering better targeted care with better informed individuals.

Medicines management seeks to address medicines-related problems and optimise the use of medicines by providing advice on prescribing, medication monitoring, management of repeat prescribing systems and education and training on prescribing and the use of medicines. Further information is available at: nice.org.uk/ Guidance/Service-delivery--organisationand-staffing/Medicines-management/ Medicines-management--general-and-other

The right medicine for the right patient at the right time

Activities which promote safe and effective medicines management occur at each stage of the medicines journey and aim to improve outcomes for the patient. The stages of the journey include:

| Stages | Definition |
|-----------------------------|--|
| Manufacturing and marketing | Ensuring that medicines are manufactured legitimately and safely, and that advertising complies with ABPI standards. |
| Procurement | Ensuring medicines are purchased from a legitimate source. |
| Selection | Making a choice about which medicines to use. |
| Prescribing | Ensuring legal processes are adhered to for medicines particularly prescription only medicines. |
| Dispensing | Ensuring that medicines are dispensed correctly. |
| Sale or supply | Medicines that are available over the counter either as over the counter medicines or in pharmacies, pharmacy only medicines. The supply of medicines is medicines that are supplied to a patient in a pre-dispensed form, for example over labelled medicines, and are given to the patient directly by the clinician. |
| Patient use | How patients engage in medicine management eg, self-administration and adherence. |
| Disposal | Safe disposal of medicines that have not been used or have been partially used. |

Becoming an independent prescriber

Nurses, AHPs and other non-medical clinicians (as stipulated in legislation) can complete additional education and training to become a non-medical prescriber. The NMC has provided guidance on the standard for prescribing programmes including the entry requirements and supervisory requirements which is available at: nmc.org.uk/globalassets/sitedocuments/ education-standards/programme-standardsprescribing.pdf Part 3 NMC. Standards for prescribing programmes. Part 3 of realising professionalism: Standards for education and training. Further information can be found at: rcn.org.uk/ clinical-topics/medicines-management/ professional-resources

Competencies and maintaining competence

The NMC requires nurses to work within their scope of practice and ensure they are up to date with relevant CPD. Revalidation is an essential requirement for nurses and reflections should include medicines management and prescribing, especially if you are a prescriber. Further details are available at: nmc.org.uk/standards/code

The RCN administration of medicines guidance advises the assessment and demonstration of competence prior to administering medicines. Assessment of competence in medicines administration should be assessed ideally by another registered nurse but failing that another registered health care practitioner who themselves are competent in medicines administration. The assessment should be carried out in the context of nursing practice and should draw upon the associated professional values. Please note - the assessment of competence in medicines administration can only be carried out by a manager or colleague if they are a registered health care professional. Non-registered care staff simply administer or consult with the registered health care professionals if they need any clarification, therefore they cannot assess a registrant who has the autonomy to make decisions such as whether to omit a medication or follow a titration guidance.

The RPS has developed a competency framework which provides a framework for all prescribers to demonstrate and maintenance competence, this is available at: **rpharms.com/resources/ frameworks/prescribers-competencyframework**

Specialist prescribing

As a registrant working in a specialty, it is your responsibility to ensure that you have the skills and competence to work within that role. You must also demonstrate a good understanding of the medications that you are prescribing, including side effects, and the possible interactions with other medications that the patient is taking.

Delegation

Registrants are accountable for their decision to delegate tasks and duties to other people. If a registrant delegates a task to a non-registrant, they must ensure that they have the appropriate skills and competence. Non-registrants should not accept a delegated task if they are not competent to carry it out.

For example, a HCSW or carer can refuse to give a patient their medicines if they have not been trained and assessed as competent to carry out that task. Registered nurses have a duty of care and a legal liability with regard to the patient. If they have delegated an activity they must ensure that it has been appropriately delegated.

For further advice and guidance on the responsibilities of delegation see: rcn.org.uk/professional-development/ accountability-and-delegation

Unregistered staff and social care

See the RCN position in relation to the role of nursing associates and health care support workers and vaccine administration at: rcn.org. uk/professional-development/publications/ pub-007565 and rcn.org.uk/professionaldevelopment/publications/pub-007441 These resources have been developed specifically for vaccine administration. The legislation supporting this however, would apply to the administration of other prescription only medicines (POMs) by unregistered staff and therefore may be useful in other contexts.

Administration

The administration of medicines in a health care setting must be done in accordance with a prescription, Patient Specific Direction, Patient Group Direction or other relevant exemption specified in the Human Medicines Regulations 2012 (Schedules 17 and 19, as amended).

Medicines that are not prescription only medicines may be administered according to locally written and agreed policies or a homely remedy protocol. This needs to be supported by organisational policy as it may vary depending on the area that you work in. Further information is available at: sps.nhs.uk/articles/rmocguidance-homely-remedies

The different legal mechanisms that are used for the prescribing, supply and administration of medicines are described in the publication *Medicines Matters*, available at: sps.nhs.uk/ articles/medicines-mattersa-guide-tomechanisms-for-the-prescribing-supply-andadministration-of-medicines-in-england The majority of medicines can be administered by a single health care professional. Although there are no defined requirements it is considered good practice, with certain higher risk medicines, for there to be a second checker; for example, intravenous medicines and medicines that require a complex drug calculation.

Organisational policy should define who can administer medicines and when a second checker is required and who can be a second checker. It should also consider that there may be situations where a second checker is not available and that the professional administering the medicines may need to second check themselves, following a defined process. This should be risk assessed and audited to ensure compliance with policy and to ensure safe practice.

A nurse administering a medicine must have an overall understanding of the medicine being administered and seek advice if necessary from a prescriber or a pharmacist.

Prescribing and administration

It is preferable for the actions of prescribing, dispensing/supply and administration to be separated and performed by different health care professionals. Where clinical circumstances make it necessary and in the interests of the patient, the same health care professional can be responsible for the prescribing and supply/ administration of medicines. Where this occurs, processes should be in place to limit errors along with an audit trail and clinical documentation.

Transcribing

Transcribing can be defined as the act of making an exact copy, usually in writing. Transcribing is the copying of previously prescribed medicines details to enable their administration.

Organisational policies and procedures for transcribing must be underpinned by risk assessment. Such policies are clear about who can transcribe, when it can be used, and the difference between transcribing and prescribing. Transcribing should not be confused with prescribing or badged as transcribing when in fact it is prescribing. Transcribing can only be used to make an exact copy of medicines that have already been prescribed, for example, patients own medicines that have been prescribed and dispensed by a pharmacy can be transcribed onto a Medicines Administration Record (MAR) chart so their administration can be recorded by the health care professional administering them.

In clinical circumstances where transcribing occurs it must be underpinned by training, risk assessment, an audit trail, and have processes in place to limit errors. Organisational safeguards should be in place to ensure that transcribed information is not inadvertently used as a prescription. Transcribing cannot include any changes to the medication, for example the timing of, or titration of dose, as this becomes prescribing.

For further information, please see the guidance on the administration of medicines in health care, available at: rcn.org.uk/clinical-topics/ medicines-management/professional-resources

Local policies that support both administration and transcribing should also be referred to.

Nursing associates and medicines management

Nursing associates need to work to the NMC Code which is available at: nmc.org.uk/ standards/code. They need to be trained and competent to administer medicines.

Please see links to both the RCN and NMC guidance on delegation: rcn.org.uk/ professional-development/accountabilityand-delegation and nmc.org.uk/globalassets/ sitedocuments/nmc-publications/delegationand-accountability-supplementaryinformation-to-the-nmc-code.pdf

Nursing associates are not able to operate under a Patient Group Direction, they will need a Patient Specific Direction or a signed medication chart in order to administer medicine. See guidance from the specialist pharmacy services at: sps.nhs.uk/articles/can-nursing-associatesand-physician-associates-operate-under-apatient-group-direction The NMC standards of proficiency for nursing associates advises that they should:

- understand the principles of safe and effective administration and optimisation of medicines in accordance with local and national policies
- demonstrate the ability to recognise the effects of medicines, allergies, drug sensitivity, side effects, contraindications and adverse reactions
- recognise the different ways by which medicines can be prescribed.

More information is available at: nmc.org.uk/ standards/standards-for-nursing-associates/ standards-of-proficiency-for-nursing-associates

Summary of available guidance

Following the withdrawal of the NMC Medicines Management Standards there are numerous resources on the RCN Medicines Management web area at: rcn.org.uk/clinical-topics/ medicines-management

Co-produced guidance

• Professional Guidance on the Administration of Medicines in Healthcare Settings (January 2019) covers the administration of medicines, verbal orders, transcribing and covert administration. This professional guidance has been co-produced by the RPS and RCN and provides principles-based guidance to ensure the safe administration of medicines by health care professionals. It is available at: **rpharms.com**

Guidance endorsed by the RCN

• Safe and Secure Handling of Medicines (SSHM) (December 2018) details the four core governance principles that underpin a framework for the safe and secure handling of medicines and can be used to develop working practices, policies and procedures.

Principle 1: Establish assurance arrangements – say what we do and why we do it.

Principle 2: Ensure capacity and capability – train people and ensure they have the necessary competencies and resources.

Principle 3: Seek assurance – do what we say and prove it.

Principle 4: Continually improve – improve what we do.

The guidance is available at: rpharms.com/ recognition/setting-professional-standards/ safe-and-secure-handling-of-medicines

• Polypharmacy. *Getting our Medicines Right* has been endorsed by the RCN and provides a summary of the scale and complexity of the issue of polypharmacy. It outlines how health care professionals, patients and carers can find solutions when polypharmacy causes problems for patients and points to useful resources that can help. This guidance is available at: rpharms.com/ recognition/setting-professional-standards/ polypharmacy-getting-our-medicines-right

Royal College of Nursing guidance

- RCN advice guide for non-medical prescribers (2018). This guide provides information on non-medical prescribing including types of nurse prescriber, keeping stocks of medication and the RCN Indemnity scheme. It also provides a list of further useful resources and is available at: rcn.org.uk/get-help/rcnadvice/non-medical-prescribers
- Medicines management subject guide link to RCN medicines management page and BNF and BNF for children, available at: rcn.org.uk/library/subject-guides/ medicines-management
- Children and young people: Medicines management subject guide, available at: rcn. org.uk/library/subject-guides/childrenand-young-people-medicines-management

Please see the RCN Immunisation page which has advice on immunisation clinics, the role of nursing associates and health care support workers administering vaccines. Available at: rcn.org.uk/ clinical-topics/public-health/immunisation

Royal Pharmaceutical Society guidance

- Practical guide for independent prescribers (2018). This guidance has been endorsed by the RCN.
- Medicines optimisation hub (2016).
- A competency framework for all prescribers (2016).
- Making the most of your medicines.
- Medicines Optimisation.
- Professional Guidance for the Procurement and Supply of Specials.
- Prescribing Specials Guidance for the prescribers of Specials.

RPS guidance is available at: rpharms.com

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Standards and Guidelines Committee

| Medicines Reconciliation Policy and Procedure For Patients on Admission to Hospital | | |
|--|--|--|
| Summary | This policy will standardise the approach to Medicines Reconciliation across sites in the Belfast Trust. | |
| Operational date | April 2011 | |
| Review date | April 2013 | |
| Version Number | V1 | |
| Director Responsible | Medical Director Dr Tony Stevens | |
| Author | Orla Daly | |
| Author, Position | Clinical Pharmacist – Belfast City Hospital | |
| Department / Service Group | Pharmacy Department | |
| Contact details | Orla Daly, Clinical Pharmacist BHSCT, BCH. Ext | |
| Additional Author(s) | Michael Jackson – Lead Cardiology Pharmacist BHSCT, RVH. | |

| Reference Number | SG 52/11 |
|------------------|----------|
| Supersedes | n/a |

Version Record

| Date | Version | Author | Comments |
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| 14/02/2011 | V0.1 | Orla Daly | BHSCT draft |
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| 22/03/2011 | V0.3 | Orla Daly | BHSCT Drugs and Therapeutics &T committee |
| 24/04/2011 | V0.4 | Orla Daly | BHSCT Medicines Reconciliation Working Group |
| 25/07/2011 | V0.5 | Orla Daly | BHSCT Paediatric Pharmacists – Anne Burns, Claire McKeown, Naomi Robinson |

Policy Record

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|--------------------------------------|----------------|------------|---------|
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| Approval Process – Clinical Standard | ds and Guideli | nes | |
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| Areas : | | | |
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Page 3 of 12

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Director: Dr A B Stevens Printed name

Date: September 2011

Author: Orla Daly Printed Name

Date: September 2011

Contents Page

| | Page |
|---|------|
| Medicines Reconciliation Policy and procedure | 5 |
| Appendix 1. Procedure for medicines reconciliation in BHSCT | 10 |
| Appendix 2. BHSCT Medicines Reconciliation form | 12 |

Full Description

| | Medicines Reconciliation Policy and Procedure For Adults on Admission | |
|----|--|--|
| 1. | Introduction: | |
| | The Institute for Healthcare Improvement has defined medicines reconciliation as a process of identifying the most accurate list of all medication a patient is taking, including name, dose frequency and routes – and using this list to provide correct medication for patients in hospital. ¹ | |
| | Reconciliation involves comparing this list against prescribing on admission, transfer or discharge with reasons for any omissions or dose changes being documented. | |
| | Medicines reconciliation is the responsibility of all staff involved in the admission, prescribing, monitoring, transfer and discharge of patients requiring medicines. All Trust staff should follow a clearly defined procedure in undertaking medicines reconciliation (Appendix 1). | |
| | NICE/NPSA in their guidance, "Technical patient safety solutions for medicines reconciliation on admission of adults to hospital" promote the process by reinforcing the need for medicines prescribed on admission to correspond to those that the patient was taking before admission. ² Regional best practice guidance recommends that medicines reconciliation should involve a pharmacist as soon as possible following the patient's admission and that they aim to ensure that their medicines are reconciled on admission by the next working day. | |
| 2. | Purpose: | |
| | The policy aims to ensure that there is a process in place to ensure that all medication a patient is taking on admission is correctly documented at the time of admission and at each transfer of care. | |
| | The aims of the policy are to: | |
| | Ensure there is a consistent approach to the process involved in medicines reconciliation Specify the standardised system for collecting and documenting information | |
| | about current medications Define the responsibilities of staff involved in medicines reconciliation Define a strategy for obtaining information from patients with communication difficulties. | |
| 3. | The Scope: | |
| | This policy and supporting operational guidance applies to all areas in the Trust where patients are admitted and to all staff employed by the trust that are involved in the reconciliation of medicines on admission. | |
| | This policy does not include medication review, which is a process requiring additional knowledge and skills to those required for medicines reconciliation and so the two processes have been separated for the purposes of this document. The | |

| | detailed processes involved in medication review are considered to be beyond the scope of this policy. | | |
|----|--|--|--|
| 4. | Objectives: To provide guidelines for staff on the medicines reconciliation process in BHSCT. To ensure there is a consistent approach to the process involved in medicines reconciliation | | |
| 5. | Roles and Responsibilities: The clerking healthcare professional's Responsibilities | | |
| | A medication history must be taken by the clerking healthcare professional and documented in the medical notes, including the drug name, dose and frequency and the patient's allergy status. Accurately transcribe the medication, if appropriate, and allergy status onto the inpatient drug chart. Document intentional changes to the patient's current medication in the patient's medical notes and on the appropriate section of the drug chart. Decisions regarding holding or stopping medicines are the responsibility of the medical team and must be recorded on the form. Where a BHSCT medicines reconciliation form (Appendix 2) is available in patient notes, this should be used. Pharmacist / Pharmacy Technician Responsibilities Within working hours a member of the Pharmacy team where available will confirm the patient's medication history in line with Northern Ireland Clinical Pharmacy Standards³ and reconcile this against the currently prescribed medication within the next available working day of the patient's admission. Confirm whether any discrepancies are intentional and document this. Pharmacists annotating the medicines reconciliation form to indicate if medicines are being held or stopped should indicate where the information has come from e.g. medical notes, ward round etc. | | |

| 6. | The definition and background of the policy: |
|----|---|
| | NICE/NPSA recommend that all healthcare organisations that admit adult inpatients should put policies in place for medicines reconciliation on admission. ² The principles of medicines reconciliation are appropriate to all patients and therefore this policy is applicable to both adult and paediatric patients. |
| | Medicines reconciliation is the process of creating the most accurate list possible of all medications a patient is taking and documenting at admission and at all transition points of care. |
| | Undertaking medicines reconciliation includes the appropriate collection , checking and communication of information at all stages of the patient's care pathway. Collection refers to the use of a variety of sources to obtain a medication history. Checking involves confirmation that the prescribed medication and doses on admission reflect the medication history and discrepancies may be identified. Communication refers to the transfer of information, both verbal and written, in relation to changes to medication and must include the reasons for them. |
| | Although the process and outcomes may be verbally discussed with other members of the healthcare team there must also be a written record in the patient's medical record and/or on the prescription chart. A BHSCT medicines reconciliation form has been developed and should be incorporated into patient admission packs. |
| 7. | Policy / Guideline description: |
| | The FULL procedure is in Appendix 1. |
| 8. | Policy statements: |
| | This policy will ensure a consistent approach to medicines reconciliation across sites in the Belfast Health and Social Care Trust. |
| | The policy further defines medicines reconciliation as referenced in the BHSCT Medicines Code ⁴ and in the BHSCT F1 Induction handbook. ⁵ |
| 9. | Implementation / Resource requirements: |
| | Medicines reconciliation was part of the BHSCT Safety Plan for 2010/2011 and it has also been include in the plan for 2011/12. A local Pharmacy Medicines Reconciliation Implementation Group has been established in order to ensure a consistent application of the policy throughout the Trust. The remit will be to monitor implementation, update the policy and address areas requiring further work. The group will provide feedback on the process and standards achieved to the Head of Pharmacy and Medicines Management and the Medical Director. |
| | NICE / NPSA recommends that pharmacists are involved in medicines reconciliation as soon as possible after admission. A 2009 ScHARR report ⁶ commissioned by NICE did economic evaluation modelling of several different methods of medicines reconciliation stated "in terms of effectiveness, the pharmacist-led reconciliation intervention is predicted to prevent the most medication errors." Effective implementation within BHSCT is therefore resource dependent on ward based clinical pharmacy services. |

| | Source(s) / Evidence Base: |
|-----|---|
| | The National Patient Safety Agency (NPSA) and National Institute for Health and Clinical Excellence (NICE) has issued guidance on the process of medicines reconciliation on admission of adults to hospital. ² Accurate medicines reconciliation has been identified as an intervention to prevent avoidable hospital readmissions. |
| 11. | References, including relevant external guidelines: 1. Institute for Healthcare Improvement (IHI) accessible at: http://www.ihi.org . 2. Technical patient safety solutions for medicines reconciliation on admission of adults to hospital. National Institute for Health and Clinical Excellence and National Patient Safety Agency. December 2007. 3. NI Clinical Pharmacy Standards accessible at : http://intranet.belfasttrust.local/Policies%20and%20Procedures/Clinical%20Pharmacy %20Standards%20for%20N.Ireland.pdf 4. BHSCT Medicines Code 2011 5. F1 induction handbook. How to prescribe medicines in the BHSCT. http://intranet.belfasttrust.local/Policies%20and%20Procedures/F1%20Induction%20h andbook%20%20How%20to%20Prescribe%20Medicines%20in%20the%20BHSCT.p df 6. Karnon J et al. Model-based cost-effectiveness analysis of interventions aimed at preventing medication error at hospital admission (medicines reconciliation). J Eval Clin Pract 2009; 15 (2): 299-306 |
| 12. | |
| 13. | Equality and Human Rights screening carried out: |
| | In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, the Belfast Trust has carried out an initial screening exercise to ascertain if this policy should be subject to a full impact assessment. Screening completed No action required. Full impact assessment to be carried out. |
| 14. | Procedures: Appendix 1: Standard operating procedure (SOP) for medicines reconciliation in BHSCT |
| 13. | adults to hospital. National Institute for Health and Clinical Excellence and National Patient Safety Agency. December 2007. 3. NI Clinical Pharmacy Standards accessible at : http://intranet.belfasttrust.local/Policies%20and%20Procedures/Clinical%20Pharma%20Standards%20for%20N.Ireland.pdf 4. BHSCT Medicines Code 2011 5. F1 induction handbook. How to prescribe medicines in the BHSCT. http://intranet.belfasttrust.local/Policies%20and%20Procedures/F1%20Induction%22andbook%20%20How%20to%20Prescribe%20Medicines%20in%20the%20BHSCT http://intranet.belfasttrust.local/Policies%20and%20Procedures/F1%20Induction%22andbook%20%20How%20to%20Prescribe%20Medicines%20in%20the%20BHSCT http://intranet.belfasttrust.local/Policies%20and%20Procedures/E1%20Induction%22andbook%20%20How%20to%20Prescribe%20Medicines%20in%20the%20BHSCT http://intranet.belfasttrust.local/Policies%20and%20Procedures/E1%20Induction%22andbook%20%20How%20to%20Prescribe%20Medicines%20in%20the%20BHSCT http://intranet.belfasttrust.local/Policies%20and%20Procedures%20in%20the%20BHSCT http://intranet.belfasttrust.local/Policies%20Medicines%20in%20the%20BHSCT http://intranet.belfasttrust.local/Policies% |

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Director: Dr A B Stevens Printed Name Date: September 2011

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Author: Orla Daly Printed Name Date: September 2011

Appendix 1

Procedure for medicines reconciliation in BHSCT

Summary

- **1.** All patient admissions should have a medicines reconciliation form completed, where available, by a suitable healthcare professional.
- **2.** The medicines reconciliation form must become integrated into the doctor's admission practice and not lead to duplication.
- **3.** On admission, refer to the patient's documented medication history, reconcile the medicines on the Kardex and circle 'no change', increased or decrease dose or 'new medicine' accordingly as documented in BHSCT Medicines Code.⁵
- **4.** At discharge the medicines reconciliation form should be referred to with the current medicine Kardex when completing the discharge prescription.
- **5.** The medicines reconciliation form must remain within the patients medication notes after discharge.

Medicines Reconciliation

Medicines reconciliation is a process designed to ensure that all medication a patient is currently taking is correctly documented on admission and at each transfer of care. It encompasses:

- Collection of the medication history from a variety of sources
- **Checking** that medicines prescribed on admission for the patient are correct. The 'checking' step involves ensuring that the medicines and doses that are now prescribed for the patient accurately reflect the sources consulted. Discrepancies may be identified at this stage and these may be intentional or unintentional.
- Communicating any changes in medicines so that they are readily available to the next person(s) caring for the patient. Communication must include reasons for the change(s) and any follow-up requirements. Although the process and outcomes may be verbally discussed with other members of the healthcare team there must also be a written record in the patient's medical record and/or on the prescription chart.

Medication review

Medication review has been defined as a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment,

optimising the impact of medicines, minimizing the number of medication-related problems and reducing waste.

A medication review can only be accurately performed once an accurate list of what the patient is currently taking, i.e. medicines reconciliation, has been completed.

Discrepancies

Part of the checking process includes the identification of any discrepancies. A discrepancy can be defined as any difference between the medicines the patient had been taking in their previous care setting and the medicines prescribed in their new care setting.

Discrepancies may be considered as intentional and unintentional.

Intentional discrepancies can be defined as any difference between the medicines the patient was taking prior to admission and the medicines prescribed in their new care setting that have been changed intentionally and agreed with the clinician(s) responsible for the patient's care.

Unintentional discrepancies (errors, omissions or unintentional additions) can be defined as any difference between the medicines the patient was taking prior to admission and the medicines prescribed in their new care setting that is not a conscious change.

Medicines reconciliation is the responsibility of all staff involved in the admission, prescribing, monitoring, transfer and discharge of patients requiring medicines.

On Admission

When a patient is admitted a medication history is taken as part of the admission profile. This information must be documented on the medicines reconciliation form located in the admission notes where available (Appendix 2). Otherwise it must be documented within the body of the patient's notes.

The source of this information must be recorded, and where possible original documents should be filed in the patient's notes in order to reassure other staff of the robustness of this information. The greater the number of sources used, the more reliable the information, usually a minimum of 2 sources. Sources for obtaining a medicine history include:

- The patient
- Patients carer, parent or guardian
- Current medicine record from general practitioner (preferably 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
- 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 patient's own drugs brought into hospital

The name, dose, frequency and if appropriate the strength of liquid and volume of each medication should be written in the appropriate section of the reconciliation form. It should be documented if the patient is taking any herbal or OTC medications.

Decisions regarding holding or stopping medicines are the responsibility of the medical team and should be recorded on the form.

If the medication history cannot be completed fully, (the patient is unsure about their medication) then this should be documented on the form. Follow up on the medication history must be sought as soon as possible from the GP practice, community pharmacy or relative as appropriate and this information added to the medicines reconciliation form.

The patient's allergy status should be documented.

The form can be completed by the admitting doctor, a nurse or pharmacist. If the nurse or pharmacist is involved in completing or adding to the medicines reconciliation form, they should sign and date the bottom of the form and make it clear what and when amendments have been made.

If staff find out about medication that was missed at admission, this should be added to the medicines reconciliation form at any time and the doctor informed in order to consider the prescribing of this medication while in hospital.

Each medicine entry on the Trust Kardex also has space to record medicines reconciliation annotations. This acts as a prompt for each medicine to record if there has been no change, there has been an increased or decreased dose and if it is a newly prescribed medicine. And they can be completed throughout the patient's stay in hospital.

Patients with communication difficulties

The medicines reconciliation policy and procedure applies to all patients that may have communication problems. For these patients there will be an increased need to rely on information from GP's, relatives or carers in this group. Thorough documentation in the communication stage of medicines reconciliation is particularly important so healthcare professionals or carers responsible for the next stage of the patients care have all the medicines information required to ensure effective medicines management. Confidentiality must be maintained.

On discharge

- At discharge, the medicines reconciliation form should be referred to with the current prescription chart when completing the discharge prescription.
- Any held or stopped medication should be reconsidered and any changes communicated to the GP via the discharge prescription.

Appendix 2

| Use addressograph-otherwise write in capitals | ``; |
|---|-----|
| Name: | |
| DOB: | |
| Hosp Number.: | |
| × | Ĵ |

Allergies including reaction

Drug Consider all meds including inhalers, nebules, insulin, patches, home oxygen, OTC, herbal History Use 2+ sources when possible Obtained from: 1) 2)_ 3)_ Medication Pharmacy use Route , Dose, Frequency Medication Plan Chart reconciled ACHANNE HOLD (for surgery) MEDICATION NAME Po 100mg MANE ~ Continue **Medication Notes**

Signatures for Drug History

Checked by:_____

Obtained by:_____

Position:_____ Position:

Date:_____ Date:_____

Vs 1.2b