Belfast Health and Social Care Trust

Reference No: SG 52/11

Title:	**Medicines Reconciliation policy**			
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Ownership:	Dr Cathy Jack, Medical Director			
Approval by:	Drugs and Therapeutics Standards and Guidelines Policy Committee Executive Team Meeting		**Approval date:**	22/01/2015 28/01/2015 04/02/2015 06/02/2015
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Date	Version	Author	Comments
01/03/2011	V0.2	Orla Daly	Pharmacist Medicines Reconciliation Implementation Group – Angela Carrington, Louise Brown, Matthew Dolan, Peter McKee
22/03/2011	V0.3	Orla Daly	BHSCT Drugs and Therapeutics &T committee
01/04/2011	V1	Orla Daly	Sample of NIECR "G.P medication form" inserted in Appendix 3
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
Jan 2014	V1.1	As Above	S+G put into new template
01/08/2014	V1.2	Leeanne Stewart	Review

1.0 INTRODUCTION

Every time a patient is transferred from one healthcare setting to another it is essential that 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. This process is called Medicines Reconciliation and it is one of the fundamental principles of good medicines management. This policy is applicable to any healthcare professional who has responsibility for ensuring the continuity of care for a patient with respect to medicines management.

This policy supplements the guidance "Technical patient safety solution for medicines reconciliation on admission of adults to hospital" published by the National Institute for Health and Clinical Excellence (NICE) in conjunction with the National Patient Safety Agency (NPSA) in December 2007 [(1)] which tasks health organisations to develop policies for medicines reconciliation.

The safety solution also states that

- Pharmacists should be involved in the medicines reconciliation process as soon as possible after admission.
- The responsibilities of pharmacists and other staff involved in medicines reconciliation are clearly defined.

1.2 Purpose

The aim of this policy is to provide a framework of practice to support the implementation of the NICE/NPSA "Technical patient safety solutions for Medicines reconciliation on admission of adults to hospital." for all patients admitted to BHSCT and to

- make sure the right patient gets the right drug, in the right dose and at the right time (i.e. continuity of treatment)
- reduce the risk of medication errors occurring when the care of a patient is passed from one care setting to another
- provide on-going personalised medicines management care for each patient
- reduce confusion about patients' medication regimens (for both healthcare professionals as well as for patients)
- Improve service efficiency and make the best use of staff skills and time.
- To ensure a consistent approach to the process involved in medicines reconciliation.
- To define the process for collecting and documenting information about current medications
- To identify relevant sources of information for medicines reconciliation
- To list the data to be collected
- To clarify responsibilities of clinical staff in the medicines reconciliation process.

2.0 SCOPE OF THE POLICY

This policy applies to all registered nursing, pharmacy and medical staff involved in the admission, transfer and discharge of patients within the Belfast Health and Social Care Trust (BHSCT).
This policy also refers to and is formally linked with the following supporting documents and procedures:

- BHSCT Medicines Code
- Northern Ireland Clinical Pharmacy Standards
- Guidelines on regional immediate discharge documentation for patients being discharged from secondary into primary care. GAIN June 2011 [(3)]

3.0 ROLES/RESPONSIBILITIES

Medicines reconciliation on admission

Medicines reconciliation is the responsibility of **all** staff involved in the admission, prescribing and administration of medicines, monitoring, transfer and discharge of patients requiring medicines. The responsibilities of healthcare staff on admission are summarised below.

LEVEL	DESCRIPTION	PATIENT GROUP	RESPONSIBLE STAFF
1	Verifying the medication history i.e. confirming and documenting an accurate list of medicines and detailing a treatment plan which includes changes to prescribed medicines.	All patients within 24 hrs of admissions as per NICE guidelines[(1)]	Admitting doctor should detail a list of current medications together with a treatment plan which may include changes to medication as appropriate. These should then be prescribed on a medicines kardex. This responsibility lies with the admitting doctor.
2	Builds on stage 1 of the process and involves comparing the verified medication history to the patient's medicine kardex and treatment plan to: a. Identify and resolve unintentional discrepancies b. Consider pharmaceutical aspects of treatment and ensure medicines optimisation	All patients within 48 hours of admission	It is the responsibility of medical, pharmacy and nursing staff to ensure this level of medicines reconciliation is carried out within 48 hours of admission.

3.1 Medicines reconciliation on transfer or discharge.

At the point of transfer or discharge an accurate list of "current" medication must be provided to the patient/carer, G.P and to the transfer unit/ward as appropriate. Information must be complete and relate to any medications that have been stopped, started or altered and the reasons for these. The patient and/or carers must also be fully informed of these changes.

Medicines reconciliation roles and responsibilities of staff during transfer or discharge.

	Medical Staff/Prescribers	**Pharmacy staff where available**	**Nursing Staff**
At Transfer or Discharge	Responsible for completing accurate transfer letter or immediate discharge letter and ensuring medicines have been reconciled and reasons for changes documented. (Minimum data set for inclusion in appendix 4)	Clinically check discharge or transfer letter and supply medicines as appropriate. If appropriate counsel patient/carers on medicine treatment at discharge Dispose of obsolete Patient's Own Medications (with patient/carer consent).	Check discharge Medicines against prescription and medicines kardex. Discuss medicines with patient/carer (if not already completed by pharmacy staff) Dispose of obsolete Patient's own medications (with patient/carer consent).

4.0 <u>KEY POLICY PRINCIPLES</u>

4.1 What is medicines reconciliation?

The National Prescribing Centre defines medicines reconciliation as:

- **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 and

- **Checking** or verifying this list against the current kardex/prescription chart in the hospital, ensuring any discrepancies are accounted for and actioned appropriately and finally
- **Communicating** through appropriate documentation, any changes, omissions and discrepancies.

There are two discreet levels of medicines reconciliation (Levels One and Two) and a third level that involves a full medication review [(2)]

Level one: Basic reconciliation (Medication History)

- Involves collecting and verifying a patient's current medicines list as it exists immediately prior to admission. The minimum dataset of information required to be gathered is outlined in appendix 1. The medication history must be collected using two or more information sources described within appendix 3 and documented in the patients' clinical record (Trust Medicines Reconciliation Form or NIECR "G.P medication form"). This documentation must also include any changes made to medicines as a result of the on-going treatment plan. Where level 1 has been completed by a prescriber the patient's medicine kardex must also be completed. Circumstances relating to the patients inability to communicate effectively or the completeness of clinical information accompanying the patient may make it difficult to document an accurate medication history on admission. If this is the case the admitting doctor must document this and communicate any required follow up.

Level two: Full reconciliation.

- Involves comparing the verified medication history (as gathered above) with the patient's medicines kardex to document intentional discrepancies (any changes in medicines with appropriate reasons) and to identify and rectify unintentional discrepancies. This ensures appropriate transcription of medicines has taken place and that therapies are clinically appropriate, in line with the current treatment plan. Again level 2 must be clearly documented in the patient's clinical record (Trust Medicines Reconciliation Form or NIECR "G.P medication form"). All outstanding issues must be communicated and actioned appropriately. Work pressures and human error can lead to transcription errors when documenting medicines which may cause medicines to be omitted or prescribed at the wrong dosage. It is therefore essential that whenever possible the initial level one reconciliation is backed up by level two medicines reconciliation.

Level three: Medication Review

- This involves a structured critical examination of a patient's medicine 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. A medication review can only be conducted accurately once medicines reconciliation is complete. Medication review requires additional skills to those required for medicines reconciliation and for the purposes of this policy medication review is considered outside the scope of this policy.

5.0 IMPLEMENTATION OF POLICY

HSC have asked all Trusts to ensure that all patients with highest risks (complexity; high risk medicines) have their medicines reconciled on admission and at discharge in line with NICE guidance and have asked for quarterly assurance reports for this. Medicines reconciliation has been operational within BHSCT and consistent application of this policy throughout the BHSCT will further support this objective.

NICE / NPSA recommends that pharmacists are involved in medicines reconciliation as soon as possible after admission. A 2009 ScHARR report 6 commissioned by NICE, evaluated economic modelling of several different methods of medicines reconciliation and stated, “in terms of effectiveness, the pharmacist-led reconciliation intervention is predicted to prevent the most medication errors.” Therefore effective implementation within BHSCT is resource dependent on ward based clinical pharmacy services.

5.1 Dissemination

Appropriate for all clinical staff involved in the admission, transfer and discharge of patients within and from BHSCT with respect to medicines management.

6.0 MONITORING

The guideline will be reviewed and updated on a regular basis in line with regional and local developments.

7.0 EVIDENCE BASE/REFERENCES

1.Technical patient safety solutions for medicines reconciliation on admission of adults to hospital. National Institute for Health and Clinical Excellence & National Patient Safety Agency. December 2007, available http://www.nice.org.uk/Guidance/PSG001 (Accessed September 2008)

2. Medicines reconciliation: a guide to implementation. National Prescribing Centre. 2008, available at: http://www.npc.nhs.uk/improving_safety/medicines_reconciliation/resources/reconciliation_guide.pdf

3. Guidelines on regional immediate discharge documentation for patients being discharged from secondary into primary care available at http://www.gain-ni.org/images/Uploads/Guidelines/Immediate-Discharge-secondary-into-primary.pdf

8.0 CONSULTATION PROCESS

BHSCT Drug and therapeutics Committee
BHSCT Trust Clinical Pharmacy group

9.0 APPENDICES/ATTACHMENTS

- Appendix 1 -Minimum dataset required for medicines reconciliation on admission
- Appendix 2- Procedure for Medicines Reconciliation
- Appendix 3 -Sources of Information used for Medicines Reconciliation.
- Appendix 4- Minimum dataset required for discharge
- Appendix 5- Sample of NIECR "G.P medication form" utilised for medicines reconciliation

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. ☐

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

Leeanne Stewart

_____ **Date: ____February 2015____**
Author

Cathy Jack –

_____ **Date: _____February 2015_____**
Director

Appendix 1 Minimum dataset required for medicines reconciliation on admission [2]

It is suggested that the minimum dataset of information available on admission to hospital with respect to medicines should include :

- Patient details (full name, date of birth, weight, NHS/unit/hospital number, GP, date and time of admission).
- Known allergies and nature of the reaction
- A complete list of all of the medicines currently being taken by the patient including dose, frequency, formulation and route, including those bought over the counter, where known.
- An indication of any medicines that are not intended to be continued
- The presenting condition plus co-morbidities

This information should be available to the hospital when the patient is admitted for planned admissions and within 24 hours of admissions for unplanned admissions.

Appendix 2 Procedure for Medicines Reconciliation

Obtaining a medication history

- A medication history must be obtained for all patients within 24 hours of admission.
- The medication history may be taken by a doctor, pharmacist or suitably trained nurse, pharmacy technician or pre-registration pharmacist.
- The patient must be identified and their name and other demographics recorded on documentation (if not already noted).
- The drug history should be recorded in the patient's notes e.g. on BHSCT medicine reconciliation sheets already supplied in the admissions pack, or on a printed NIECR "G.P medication form." Now that NIECR is accessible in BHSCT, clinical staff should print off the patient's NIECR "G.P medication form", to enable a standardised medicines reconciliation procedure. The form should be utilised to complete the medicines reconciliation process and supplement additional medicine notes.
- Documentation of a medication history solely on the medicines kardex is unacceptable.
- The patient and/ or carer should, where possible be interviewed to establish which medication the patient is currently taking.
- Obtain all known allergies and nature of the reaction
- For each drug the name, strength, dose and frequency must be established. If patient's own drugs are available the strength and frequency may be obtained from them. It is important to check with the patient that they take the medication as prescribed. If there are discrepancies these need to be documented and highlighted as appropriate.
- The source of information must also be documented e.g. hospital notes, GP surgery, GP referral letter, community pharmacy. At least two sources of information should be used to create an accurate drug history. Normally this would be the patient/carer and the NIECR "G.P medication form".
- Communicate any issues encountered whilst compiling history which require follow up and clarification.
- Detail medication management in patients own home (include details of specific support).
- Care must be taken to ensure all medication has been verified as certain medications may not be listed on G.P information e.g. methadone for the treatment of addiction, specialist medicines.
- Other specific medications to ask about must include inhalers, eye drops, topical preparations, once weekly medication, injections, OTC medication, herbal preparations, oral contraceptives, hormone replacement therapy, insulin, nebuliser therapy, home oxygen and any medicines supplied by hospital pharmacies. Additional information for specific drugs e.g. indication for medicines that are for short-term use only (antibiotics), day of week of administration for once weekly medication (bisphosphonates ,methotrexate)
- The medication history must be signed and dated by the person completing it.

Appendix 3 Sources of Information used for Medicines Reconciliation

When completing medicines reconciliation the clinical staff must document the sources used to compile the record. At least two sources of information should be used when compiling a list of current medicines. It is essential that the clinical staff also communicates any outstanding issues which need to be addressed in relation to medicines e.g. further clarification of current therapy.

The following sources used to compile medication histories and aid medicines reconciliation are listed below. Reliability can vary according to the situation. It is recommended to use two or more sources to facilitate comprehensive medicines reconciliation:

- Patient/carer
- Northern Ireland electronic care record (NIECR)
- Patients' own drugs (POD's)/compliance aids
- Recent hospital immediate discharge letter.
- Residential/Nursing home records
- G.P referral letter
- Community pharmacy
- Repeat prescription sheets
- Patients own medicines record sheets

For some patients it may be necessary to utilise additional sources to obtain a complete medication history. Examples of further information include:

- Anticoagulant clinics
- Community pharmacists
- Specialist nurses e.g. heart failure/asthma nurse/Diabetes specialist nurse
- Drug and alcohol service
- Renal Dialysis unit
- HIV clinic
- Clozapine clinic
- Other hospitals for clinical trials/unlicensed medicines
- Residential, Nursing home data
- Community Psychiatric nurse
- JAC pharmacy records

Appendix 4 Minimum dataset required for discharge [3]

GAIN NI has recently produced guidance on the completion of immediate discharge documentation for patients being discharged from secondary to primary care. [3] This document clearly details the responsibilities of the clinician with respect to communicating medicines reconciliation information to primary care.

With respect to medicines information a comprehensive list of current medications should be documented including

- Known allergies and the nature of the reaction(record if no known drug allergies NKDA)
- Drug name (written generically where appropriate)
- Route of administration
- Frequency
- Dose (approved units)
- Start and stop dates
- Drug started with brief reason
- Dose changed with brief reason
- Drug stopped with brief reason
- Indication if supply given to patient with appropriate documentation of quantity.

It is essential to document any follow up required in relation to monitoring the effects of medicines e.g. assessment of renal function, blood pressure, serum drug levels etc.

Appendix 5- Sample of NIECR "G.P medication form" utilised for medicines reconciliation

ECR GP Medications Form (Drugs & Allergies last received)

Patient Name	HCN	DOB	Sex

GP Name	GP Practice Code	GP practice	GP Phone

GP Allergies (This must be recorded - Please confirm with patient)		
Allergy Description	Date Recorded	Comments

OR

No Known Drug Allergies: **Confirmed / Not Confirmed** (Please delete as appropriate)

Signature / Designation: Date:

Please ensure ECR information is verified with a second source: patient / carer / PODS / other

Repeat Medications (last 6 months including discontinued)

Verified With	Drug	Formulation	Total to Dispense	Dosage Instructions	Medication Start Date	Prescription Date	Cont.	Hold	Stop

Acute Medications (last 6 months) - Medicines may not be intended for long term use. Review before prescribing

Verified With	Drug	Formulation	Total to Dispense	Dosage Instructions	Medication Start Date	Prescription Date	Cont.	Hold	Stop

Please ask about other medicines not supplied by GP e.g. specialist medicines, over the counter medicines, inhalers, creams etc.

Additional Medication not supplied by GP Records above

Verified With		Drug	Formulation	Total to Dispense	Dosage Instructions	Medication Start Date	Prescription Date	Cont.	Hold	Stop

Issues/Discrepancies or comments to follow up:

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ECR GP Medications Form (Drugs & Allergies last received)

Patient Name	HCN	DOB	Sex

Patients own drugs stored: Yes / No (please delete as appropriate)

Medicines Management	Name, Tel. No. and Fax for Community Pharmacy

GP Meds Form completed by (Please Sign and Print name)	Bleep/Ext	Designation	Date & Time

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Belfast Health and Social Care Trust
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Ownership:	Dr Cathy Jack, Medical Director		
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Date	Version	Author	Comments
Jan 2014	V1.1	As Above	S+G put into new template
01/08/2014	V1.2	Leeanne Stewart	Review
Feb 2015	V2	Leeanne Stewart	Final
01/12/2016	V2.1	Leeanne Stewart	Review. Superseding Version V2

1.0 INTRODUCTION:

Every time a patient is transferred from one healthcare setting to another it is essential that 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. This process is called Medicines Reconciliation and it is one of the fundamental principles of good medicines management. This policy is applicable to any healthcare professional who has responsibility for ensuring the continuity of care for a patient with respect to medicines management.

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The safety solution also states that

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- The responsibilities of pharmacists and other staff involved in medicines reconciliation are clearly defined.

2.0 PURPOSE OF POLICY

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- make sure the right patient gets the right drug, in the right dose and at the right time (i.e. continuity of treatment)
- reduce the risk of medication errors occurring when the care of a patient is passed from one care setting to another
- provide on-going personalised medicines management care for each patient
- reduce confusion about patients' medication regimens (for both healthcare professionals as well as for patients)
- Improve service efficiency and make the best use of staff skills and time.
- To ensure a consistent approach to the process involved in medicines reconciliation.
- To define the process for collecting and documenting information about current medications
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- To list the data to be collected
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4.0 KEY POLICY PRINCIPLES

4.1 What is medicines reconciliation?

The National Prescribing Centre defines medicines reconciliation as:

- **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 and
- **Checking** or verifying this list against the current kardex/prescription chart in the hospital, ensuring any discrepancies are accounted for and actioned appropriately and finally
- **Communicating** through appropriate documentation, any changes, omissions and discrepancies.

There are two discreet levels of medicines reconciliation (Levels One and Two) and a third level that involves a full medication review (2)

Level one: Basic reconciliation (Medication History)

- Involves collecting and verifying a patient's current medicines list as it exists immediately prior to admission. The minimum dataset of information required to be gathered is outlined in appendix 1. The medication history must be collected using two or more information sources described within appendix 3 and documented in the patients' clinical record (Trust Medicines Reconciliation Form or NIECR "G.P medication form") or patients' case notes where applicable. NIECR **must not be** used as a sole source for obtaining a patient's medication history. Vital information may not be present on NIECR and could be missed such as medication prescribed by GPs outside NI, over-the-counter medications, specialist medications and complementary therapies. Documentation for medicines reconciliation in day case/theatre units must include the timing of last doses with no ambiguity. Documentation must also include any changes made to medicines as a result of the on-going treatment plan. Where level 1 has been completed by a prescriber the patient's medicine kardex must also be completed. Circumstances relating to the patient's inability to communicate effectively or the completeness of

clinical information accompanying the patient may make it difficult to document an accurate medication history on admission. If this is the case the admitting doctor must document this and communicate any required follow up.

Level two: Full reconciliation.

- Involves comparing the verified medication history (as gathered above) with the patient's medicines kardex to document intentional discrepancies (any changes in medicines with appropriate reasons) and to identify and rectify unintentional discrepancies. This ensures appropriate transcription of medicines has taken place and that therapies are clinically appropriate, in line with the current treatment plan. Again level 2 must be clearly documented in the patient's clinical record (Trust Medicines Reconciliation Form or NIECR "G.P medication form"). All outstanding issues must be communicated and actioned appropriately. Work pressures and human error can lead to transcription errors when documenting medicines which may cause medicines to be omitted or prescribed at the wrong dosage. It is therefore essential that whenever possible the initial level one reconciliation is backed up by level two medicines reconciliation.

Level three: Medication Review

- This involves a structured critical examination of a patient's medicine 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. A medication review can only be conducted accurately once medicines reconciliation is complete. Medication review requires additional skills to those required for medicines reconciliation and for the purposes of this policy medication review is considered outside the scope of this policy.

5.0 RESPONSIBILITES OF STAFF

Medicines reconciliation on admission

Medicines reconciliation is the responsibility of **all** staff involved in the admission, prescribing and administration of medicines, monitoring, transfer and discharge of patients requiring medicines. The responsibilities of healthcare staff on admission are summarised below.

LEVEL	DESCRIPTION	PATIENT GROUP	RESPONSIBLE STAFF
1	Verifying the medication history i.e. confirming and documenting an accurate list of medicines and detailing a treatment plan which includes changes to prescribed medicines.	All patients within 24 hrs of admissions as per NICE guidelines(1)	Admitting doctor should detail a list of current medications together with a treatment plan which may include changes to medication as appropriate. These should then be prescribed on a medicines kardex. This responsibility lies with the admitting doctor.
2	Builds on stage 1 of the process and involves comparing the verified	All patients within 48 hours of	It is the responsibility of medical, pharmacy and nursing staff to ensure this level of medicines reconciliation

	medication history to the patient's medicine kardex and treatment plan to: a. Identify and resolve unintentional discrepancies b. Consider pharmaceutical aspects of treatment and ensure medicines optimisation	admission	is carried out within 48 hours of admission.

5.1 Medicines reconciliation on transfer or discharge.

At the point of transfer or discharge an accurate list of "current" medication must be provided to the patient/carer, G.P and to the transfer unit/ward as appropriate. Information must be complete and relate to any medications that have been stopped, started or altered and the reasons for these. The patient and/or carers must also be fully informed of these changes.

Medicines reconciliation roles and responsibilities of staff during transfer or discharge.

	Medical Staff/Prescribers	**Pharmacy staff where available**	**Nursing Staff**
At Transfer or Discharge	Responsible for completing accurate transfer letter or immediate discharge letter and ensuring medicines have been reconciled and reasons for changes documented. (Minimum data set for inclusion in appendix 4)	Clinically check discharge or transfer letter and supply medicines as appropriate. If appropriate counsel patient/carers on medicine treatment at discharge Dispose of obsolete Patient's Own Medications (with patient/carer consent).	Check discharge Medicines against prescription and medicines kardex. Discuss medicines with patient/carer (if not already completed by pharmacy staff) Dispose of obsolete Patient's own medications (with patient/carer consent).

6.0 IMPLEMENTATION OF POLICY

HSC have asked all Trusts to ensure that all patients with highest risks (complexity; high risk medicines) have their medicines reconciled on admission and at discharge in line with NICE guidance and have asked for quarterly assurance reports for this. Medicines reconciliation has been operational within BHSCT and consistent application of this policy throughout the BHSCT will further support this objective.

NICE / NPSA recommends that pharmacists are involved in medicines reconciliation as soon as possible after admission. A 2009 ScHARR report 6 commissioned by NICE, evaluated economic modelling of several different methods of medicines reconciliation and stated, “in terms of effectiveness, the pharmacist-led reconciliation intervention is predicted to prevent the most medication errors.” Therefore, effective implementation within BHSCT is resource dependent on ward based clinical pharmacy services.

7.0 DISSEMINATION

Appropriate for all clinical staff involved in the admission, transfer and discharge of patients within and from BHSCT with respect to medicines management.

8.0 MONITORING

The effectiveness of this policy is monitored on an on-going basis and reviewed regularly by the medicines management group.

9.0 REFERENCES

1.Technical patient safety solutions for medicines reconciliation on admission of adults to hospital. National Institute for Health and Clinical Excellence & National Patient Safety Agency. December 2007, available http://www.nice.org.uk/Guidance/PSG001 (Accessed September 2008)

2. Medicines reconciliation: a guide to implementation. National Prescribing Centre. 2008, available at: http://www.npc.nhs.uk/improving_safety/medicines_reconciliation/resources/reconciliation_guide.pdf

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10.0 CONSULTATION PROCESS

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- Appendix 6-Safety and quality Learning Letter ‘Management of patients who are on combined anticoagulant and/or antiplatelet therapy, pre and post a procedure/surgery

12.0 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).

Leeanne Stewart

_____ **Date: ____February 2017____**
Author

Cathy Jack –

_____ **Date: ____February 2017____**
Director

Appendix 1 Minimum dataset required for medicines reconciliation on admission [2]

It is suggested that the minimum dataset of information available on admission to hospital with respect to medicines should include:

- Patient details (full name, date of birth, weight, NHS/unit/hospital number, GP, date and time of admission).
- Known allergies and nature of the reaction
- A complete list of all of the medicines currently being taken by the patient including dose, frequency, formulation and route, including those bought over the counter, where known.
- An indication of any medicines that are not intended to be continued
- The presenting condition plus co-morbidities

This information should be available to the hospital when the patient is admitted for planned admissions and within 24 hours of admissions for unplanned admissions.

Appendix 2 Procedure for Medicines Reconciliation

Obtaining a medication history

- A medication history must be obtained for all patients within 24 hours of admission.
- The medication history may be taken by a doctor, pharmacist or suitably trained nurse, pharmacy technician or pre-registration pharmacist.
- The patient must be identified and their name and other demographics recorded on documentation (if not already noted).
- The drug history should be recorded in the patient's notes e.g. on BHSCT medicine reconciliation sheets already supplied in the admissions pack, or on a printed NIECR "G.P medication form." Now that NIECR is accessible in BHSCT, clinical staff should print off the patient's NIECR "G.P medication form", to enable a standardised medicines reconciliation procedure. The form should be utilised to complete the medicines reconciliation process and supplement additional medicine notes.
- Documentation of a medication history solely on the medicines kardex is unacceptable.
- The patient and/ or carer should, where possible be interviewed to establish which medication the patient is currently taking.
- Obtain all known allergies and nature of the reaction
- For each drug the name, strength, dose and frequency must be established. If patient's own drugs are available, the strength and frequency may be obtained from them. It is important to check with the patient that they take the medication as prescribed. If there are discrepancies these need to be documented and highlighted as appropriate.
- The source of information must also be documented e.g. hospital notes, GP surgery, GP referral letter, community pharmacy. At least two sources of information should be used to create an accurate drug history. Normally this would be the patient/carer and the NIECR "G.P medication form".
- Communicate any issues encountered whilst compiling history which require follow up and clarification.
- Detail medication management in patients own home (include details of specific support).
- Care must be taken to ensure all medication has been verified as certain medications may not be listed on G.P information e.g. methadone for the treatment of addiction, specialist medicines.
- Other specific medications to ask about must include inhalers, eye drops, topical preparations, once weekly medication, injections, OTC medication, herbal preparations, oral contraceptives, hormone replacement therapy, insulin, nebuliser therapy, home oxygen and any medicines supplied by hospital pharmacies. Additional information for specific drugs e.g. indication for medicines that are for short-term use only (antibiotics), day of week of administration for once weekly medication (bisphosphonates, methotrexate)
- The medication history must be signed and dated by the person completing it.

Appendix 3 Sources of Information used for Medicines Reconciliation

When completing medicines reconciliation, the clinical staff must document the sources used to compile the record. At least two sources of information should be used when compiling a list of current medicines. It is essential that the clinical staff also communicates any outstanding issues which need to be addressed in relation to medicines e.g. further clarification of current therapy.

The following sources used to compile medication histories and aid medicines reconciliation are listed below. Reliability can vary according to the situation. It is recommended to use two or more sources to facilitate comprehensive medicines reconciliation:

- Patient/carer
- Northern Ireland electronic care record (NIECR)
- Patients' own drugs (POD's)/compliance aids
- Recent hospital immediate discharge letter.
- Residential/Nursing home records
- G.P referral letter
- Community pharmacy
- Repeat prescription sheets
- Patients own medicines record sheets

For some patients it may be necessary to utilise additional sources to obtain a complete medication history. Examples of further information include:

- Anticoagulant clinics
- Community pharmacists
- Specialist nurses e.g. heart failure/asthma nurse/Diabetes specialist nurse
- Drug and alcohol service
- Renal Dialysis unit
- HIV clinic
- Clozapine clinic
- Other hospitals for clinical trials/unlicensed medicines
- Residential, Nursing home data
- Community Psychiatric nurse
- JAC pharmacy records

Appendix 4 Minimum dataset required for discharge [3]

GAIN NI has recently produced guidance on the completion of immediate discharge documentation for patients being discharged from secondary to primary care. [3] This document clearly details the responsibilities of the clinician with respect to communicating medicines reconciliation information to primary care.

With respect to medicines information a comprehensive list of current medications should be documented including

- Known allergies and the nature of the reaction (record if no known drug allergies NKDA)
- Drug name (written generically where appropriate)
- Route of administration
- Frequency
- Dose (approved units)
- Start and stop dates
- Drug started with brief reason
- Dose changed with brief reason
- Drug stopped with brief reason
- Indication if supply given to patient with appropriate documentation of quantity.

It is essential to document any follow up required in relation to monitoring the effects of medicines e.g. assessment of renal function, blood pressure, serum drug levels etc.

Appendix 5- Sample of NIECR "G.P medication form" utilised for medicines reconciliation

ECR GP Medications Form (Drugs & Allergies last received)

Patient Name	HCN	DOB	Sex

GP Name	GP Practice Code	GP practice	GP Phone

GP Allergies (This must be recorded - Please confirm with patient)		
Allergy Description	Date Recorded	Comments

OR

No Known Drug Allergies: **Confirmed / Not Confirmed** (Please delete as appropriate)

Signature / Designation: Date:

Please ensure ECR information is verified with a second source: patient / carer / PODS / other

Repeat Medications (last 6 months including discontinued)

Verified With	Drug	Formulation	Total to Dispense	Dosage Instructions	Medication Start Date	Prescription Date	Cont.	Hold	Stop

Acute Medications (last 6 months) - Medicines may not be intended for long term use. Review before prescribing

Verified With	Drug	Formulation	Total to Dispense	Dosage Instructions	Medication Start Date	Prescription Date	Cont.	Hold	Stop

Please ask about other medicines not supplied by GP e.g. specialist medicines, over the counter medicines, inhalers, creams etc.

Additional Medication not supplied by GP Records above

Verified With		Drug	Formulation	Total to Dispense	Dosage Instructions	Medication Start Date	Prescription Date	Cont.	Hold	Stop

Issues/Discrepancies or comments to follow up:

Page 1 of 2
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- **Appendix 6-Safety and quality Learning Letter 'Management of patients who are on combined anticoagulant and/or antiplatelet therapy, pre and post a procedure/surgery**


learning letter
management of pati

Belfast Health and Social Care Trust
caring supporting improving together

Reference No: SG 52/11

Title:	**Medicines Reconciliation Policy**			
Author(s)	Gary Millar, Lead Pharmacist, Emergency Department and Admissions Aideen O'Kane, Lead Pharmacist, Controlled Drugs			
Ownership:	Cathy Jack, Medical Director			
Approval by:	Drugs and Therapeutics Committee Standards and Guidelines Committee Policy Committee Executive Team Meeting		**Approval date:**	07/09/2018 03/10/2018 04/10/2018 10/10/2018
Operational Date:	October 2018		**Next Review:**	October 2023
Version No.	4	**Supercedes**	V3	
Key words:	Medicines Reconciliation, meds rec, medication history, drug history			
Links to other policies	BHSCT Medicines Code 2017 F1 Induction Handbook V9 2017-2018			

Date	Version	Author	Comments
01/04/2011	1	Orla Daly	Sample of NIECR "G.P medication form" inserted in Appendix 3
01/08/2014	2.1	Leeanne Stewart	Superseding Version 1
01/12/2016	3	Leeanne Stewart	Superseding Version 2.1
01/03/2018	3.1	Aideen O'Kane Gary Millar	Policy review following SQB project
05/06/2018	3.2	Aideen O'Kane Gary Millar	Comments from Mark Cross Consultant CAU RVH

1.0 INTRODUCTION / PURPOSE OF POLICY

Background

Medicines reconciliation (as defined by the Institute of Health Improvement is the process of identifying an accurate list of a patient's current medicines and comparing then 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.[1]

In 2007, NICE and the National Patient Safety agency (NPSA) issued an alert on medicines reconciliation following recognition of the potential for medication errors relating to patients admission to hospital and/or a transfer between care settings. Medication errors can cause harm to patients, lead to increased mortality and morbidity and increased economic impact

The NICE/NPSA alert focused on the benefits of medicines reconciliation, which improved patient safety by reducing harm from medication errors. The original NICE guideline on medicines reconciliation has been superseded by the NICE Medicines Optimisation Guideline, within which the term medicines reconciliation is defined.

The Northern Ireland Medicines Optimisation Quality Framework states that within 24 hours of admission, or sooner if clinically necessary, patients have their medicines reconciled by a trained and competent healthcare professional, ideally by a pharmacist.[2]

Medicines reconciliation involves collecting information about current medicines, checking for omission, duplications and other discrepancies, then documenting and communicating any changes. Patients, family members or carers should be involved in this process.[2]

1.2 Purpose

The purpose of this policy is to define the process for completing medicines reconciliation with a patient by all relevant staff:

- on admission to hospital
- following transfer between wards
- on discharge from hospital

Further information may be found in the following policies:

BHSCT Medicines Code	SG09/11
BHSCT F1 Induction Handbook V9	SG44/10
BHSCT Clinical Pharmacy Standards	SG27/10

1.3 Objectives

To ensure:

- medicines reconciliation is completed following the process outlined in appendix 1
- all staff involved in medicines reconciliation are aware of their roles and responsibilities

2.0 SCOPE OF THE POLICY

2.1 This policy applies to all BHSCT staff including medical, dental, nursing and midwifery staff, allied health professionals, non-medical prescribers and pharmacy staff involved in medicines reconciliation.

2.2 This policy is primarily intended for BHSCT in-patient facilities and hospital day-case units.

3.0 ROLES/RESPONSIBILITIES

3.1 Chief Executive

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

3.2 Head of Pharmacy and Medicines Management

Head of Pharmacy and Medicines Management reports to the Chief Executive via the Medicines Optimisation Committee.

3.3 Senior staff

Senior staff including managers, consultants, ward sisters/ charge nurses are responsible for ensuring all staff, including locum and agency staff, adhere to the principles and processes of this policy.

3.4 Staff involved in medicines reconciliation

Medicines reconciliation is the responsibility of all staff involved in the admission, prescribing, monitoring, transfer and discharge of patients requiring medicines.

4.0 KEY POLICY PRINCIPLES

4.1 Definitions

Medicines reconciliation is the process of identifying an accurate list of a patient'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.[1]

Specialist Medicines are medicines often prescribed by hospital clinicians and dispensed by hospital pharmacies. Currently such medicines are not displayed in the NIECR portal so alternative sources should be used to confirm dosage regimens.
Further information can be found at: **http://www.ipnsm.hscni.net/**

NIECR: The Northern Ireland Electronic Care Record is an electronic system that draws patients' electronic healthcare information from multiple sources, including hospitals, GP practices and other healthcare systems. This is a valuable tool in medicines reconciliation as it often contains a patient's GP medication history for the previous 6 months, alongside other relevant sources of medication information.

4.2 Key Policy Principles

4.2.1 To complete medicines reconciliation, accurately document the patient's medicines (including prescribed, over the counter, complementary, specialist medicines, clinical trial medicines etc.). Perform medicines reconciliation within 24 hours, or sooner if clinically necessary, or when a patient moves from one environment to another, e.g. is admitted to hospital, transfers to another ward, or transfers to another hospital.

4.2.2 Medicines reconciliation includes collecting information about current medicines, checking for omissions, duplications and discrepancies and then **documenting and communicating** any changes.

4.2.3 Medicines reconciliation should be documented on the "GP Medicines Reconciliation Form" which should be printed from NIECR prior to commencement of medicines reconciliation.

4.2.4 Medicines reconciliation should involve patients and their family or carers where appropriate and performed by trained and competent healthcare professionals. Ideally, this should occur with the first patient contact, as this will optimise the likelihood of having all the relevant information and the sources of such.

4.2.5 Medicines reconciliation should be repeated when a patient moves from one ward to another within the hospital as per Institute for Health Improvement guidance.

4.2.6 Prior to a patient's discharge from hospital their medicines should be reconciled to ensure no medicines are omitted or continued in error; this ideally should involve a clinical pharmacist.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This policy is relevant to all groups of staff who are involved in prescribing, administering, monitoring, admission, transfer and discharge of patients requiring medicines.

The lead authors should be notified of any barriers to implementation.

5.2 Resources

The policy will be available on the intranet.
It will be disseminated via BHSCT service group leads and at induction of core groups of staff, including medical, nursing and pharmacy staff.

5.3 Exceptions

None

6.0 MONITORING

The policy will be reviewed by the authors in collaboration with the Quality Improvement Plan leads for medicines reconciliation.

7.0 EVIDENCE BASE / REFERENCES

1. Medicines Optimisation: The safe and effective use of medicines to enable the best possible outcomes. NICE NG5 2015
2. Northern Ireland Medicines Optimisation Quality Framework. DHSSPS 2016

8.0 CONSULTATION PROCESS

Quality Improvement Plan Leads reviewed the policy for medicines reconciliation.

9.0 APPENDICES / ATTACHMENTS

- Appendix 1: Medicines Reconciliation and Medication History Taking Process
- Appendix 2: Medicines Reconciliation, Sources of Information
- Appendix 3: ECR User-Guide

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. ☒

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

13/09/2018

Author **Date:**

13/09/2018

Director **Date:**

Appendix 1 Medicines reconciliation & accurate medication histories

- Utilise available sources of information to compile an accurate list of the patient's current medication history (see appendix 2 for examples of sources)

- Where possible, the patient should be utilised as a source of information to confirm their medication regime, especially to confirm medicines which may not be supplied by their GP

- Confirm patient's allergy status

- NIECR has a pre-populated template to facilitate medicines reconciliation, located under "Medications", titled "GP Meds Form". Note that this template only displays GP-prescribed medication and medicines which are supplied by hospital clinics or specialist community clinics may not be recorded here

- Print the 'GP Meds Form' for the patient's notes, or document an accurate medication list, including drug doses and strengths, in the patient's admission pack or medical notes

- Document the sources used in validating the patient's medication history (see appendix 2)

- Annotate which medicines are to be continued, held or stopped upon admission

- Document any differences between what's prescribed for the patient and what the patient is actually taking; ask the patient regarding compliance with medication regimes and consider frequency of GP supplies

- Document any compliance aids that the patient uses, e.g. blister-pack, weekly dispensing, liquid medication

- Confirm and document any complex medication regimes, e.g. warfarin doses, insulin regimes or tapering dose treatment plans

- Document and give an appropriate handover (to the appropriate healthcare professional) for any issues that need clarification, e.g. contacting GP practice, district nurse, community pharmacy

- Date, sign and print your name at the bottom of the patient's medication history

- Once the medication history is complete, consider what needs prescribed for the patient's inpatient stay, annotating on the kardex if any medications are on hold or have been stopped on admission

Appendix 2 Medicines reconciliation: Sources of information

As patients' medication regimes can be complex, staff should utilise a minimum of two sources of information to produce an accurate medication history and ensure accurate medicines reconciliation.

The sources used should be documented on the medication history and examples of these are listed below:

- Patient
- Family member or patient's carer
- Northern Ireland Electronic Care record (NIECR)
- Patients' own drugs (PODs)
- Medi-boxes/blister packs/compliance aids
- Recent hospital discharge or clinic letters
- Specialist hospital clinics for hospital only medicines
- Residential/Nursing home records
- G.P referral letters
- Community pharmacies
- Repeat prescription orders from GPs

Appendix 3

Belfast Health and Social Care Trust

ECR User-Guide, CAU Medicines reconciliation QI project

SQB: Medicines Reconciliation Project: Using ECR for Medicines Reconciliation

1. Log on to ECR – select patient – select Medications – select GP Meds Form
2. Print out ECR – select page scaling – 2 pages per sheet
3. Review allergy box and sign and date
4. Use another source to verify ECR, e.g. patient, carer, PODS, other e.g. patient clinic letter
5. Review medications – repeat medications are listed first – review date is the prescription valid?
   Tick on left hand side of page – to verify drug is correct

Repeat Medications (last 6 months including discontinued)

Verified With		Drug	Formulation	Total to Dispense	Dosage Instructions	Medication Start Date	Prescription Date	Cont.	Hold	Stop
		Longtec	M/R Tablets 10 mg	56 tablet	1 TWICE A DAY	08-Apr-2016	29-Nov-2016			

6. Endorse on right hand columns if the drug is to be
   a) Continued, b) Held, or c) Stopped
7. Acute Medicines are listed next – review dates of prescription

Acute Medications (last 6 months) - Medicines may not be intended for long term use. Review before prescribing

Verified With	Drug	Formulation	Total to Dispense	Dosage Instructions	Medication Start Date	Prescription Date	Cont.	Hold	Stop

8. Ask patients if they are prescribed any other medicines that are not on the ECR list, e.g. any medicines dispensed by hospital or community pharmacy

Please ask about other medicines not supplied by GP e.g. specialist medicines, over the counter medicines, inhalers, creams etc.

Additional Medication not supplied by GP Records above

Verified With		Drug	Formulation	Total to Dispense	Dosage Instructions	Medication Start Date	Prescription Date	Cont.	Hold	Stop

9. Complete comments box e.g. "meds confirmed with patient" or note any issues, discrepancies, or follow up, e.g. "check with pharmacy/GP in am"

Issues/Discrepancies or comments to follow up:

10. Sign and print name indicate date and time that GP Meds form has been completed

GP Meds Form completed by (Please Sign and Print name)	Bleep/Ext	Designation	Date & Time

11. Document "See ECR printout" in relevant section in admissions pack
12. Any further endorsements on the GP Meds form must be signed and printed, & dated with time

Department of Health

Safer Management of Controlled Drugs

A guide to good practice in secondary care (England)

October 2007

Royal Pharmaceutical Society of Great Britain

Safer Management of Controlled Drugs: a guide to good practice in secondary care (England)

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Clinical	Social Care / Partnership Working

Document Purpose	Best Practice Guidance		
ROCR Ref:		**Gateway Ref:**	8913
Title	Guidance on the Safe Management of Controlled Drugs in Secondary Care in England		
Author	DH/MPI		
Publication Date	October 2007		
Target Audience	NHS Trust CEs, Care Trust CEs, Foundation Trust CEs , Directors of PH, Directors of Nursing, Allied Health Professionals, Chief Pharmacists in NHS Trusts and NHS Foundation Trusts		
Circulation List			
Description	This document provides guidance which will promote the safe and effective use of controlled drugs in healthcare organisations providing secondary care in England		
Cross Ref	The Safe and Secure Handling of Medicines: A Team Approach (the revised Duthie report) March 2005		
Superseded Docs	Guidance on the Safe Management of Controlled Drugs in Secondary Care in England published May 2007		
Action Required	N/A		
Timing	**N/A**		
Contact Details	Anne Spence MPI, Department of Health Skipton House, 80 London Road London SE1 6LH 020 7972 3114		
For Recipient's Use			

Contents

1 Executive Summary

The purpose of this guidance is to promote the safe and effective use of controlled drugs in healthcare organisations providing secondary care. The new strengthened governance arrangements for controlled drugs and legislative changes that flow from the Government response to the fourth report of the Shipman Inquiry impose significant new responsibilities on healthcare organisations. This guidance sets out how these changes apply to the use and management of controlled drugs in secondary care settings and will support healthcare professionals and organisations in implementing the new arrangements. It has been developed following widespread consultation with key stakeholders chaired by the Royal Pharmaceutical Society of Great Britain on behalf of the Department of Health.

The Government's response to the Shipman Inquiry's Fourth Report was set out in *Safer Management of Controlled Drugs.* The response accepted the need for strengthening the current systems for managing controlled drugs to minimise the risks to patient safety of the inappropriate use of controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. However, as the Inquiry recognised, there have been major advances in the therapeutic use of controlled drugs in the last few years. Controlled drugs are now an essential part of modern clinical care. Strengthened controls must be implemented in a way that supports professionals and encourages good practice in the use of these important medicines when clinically required by patients.

Safer Management of Controlled Drugs set out a substantial programme of work to improve the management of controlled drugs. As a result a number of changes affecting the prescribing, record keeping and destruction of controlled drugs were introduced through amendments to the Misuse of Drugs Regulations (2001) (SI 2001 No. 3998) (MDR). The Health Act (2006) provided for Regulations to be laid relating to strengthened governance and monitoring arrangements for controlled drugs. The Health Act 2006 is primary legislation and applies to the whole of the UK. The Regulations developed under the Health Act may differ in each of the home countries. In England the Controlled Drugs (Supervision of Management and Use) Regulations 2006 **(**SI 2006 No. 3148) [*http://www.opsi.gov.uk/si/si2006/20063148.htm*] came into force in January 2007. The legislative changes, guidance from the Department of Health and new governance arrangements are described in detail in Chapter 2

This document is intended to provide guidance on good practice for the management of controlled drugs (CDs) in secondary care **in England**. It aims to set out robust systems for procuring, storing, supplying, transporting, prescribing, administering, recording, and disposing safely of CDs, whilst at the same time helping to ensure appropriate and convenient access for those patients that require them. It is not designed to provide advice on the clinical choice or use of CDs. However, individual professional organisations provide a range of advisory services to their members (see Appendix 4). Although this guidance is focussed on the safe use and management of controlled drugs in secondary care settings, patients and healthcare professionals will move and work across care sectors. The National Prescribing Centre has published a guide to good practice in the management of controlled drugs in primary care which is available on its website www.npc.co.uk

The statutory appointment of Accountable Officers (AOs) who will have responsibility for the safe use and management of CDs within their trusts provides an opportunity for organisations to review their processes and procedures to ensure that they are robust and fit for purpose. It is recognised that this will promote active discussion about local systems and processes, especially where custom and practice is out of step with Home Office Regulations. Organisations will need to review their systems, clarifying, for example, those issues which are a matter for individual clinical judgement and those which are not and discuss with their AOs in order to develop strong governance arrangements that fit with the current legal framework.

This guidance recognises developments that have taken place to modernise working practices in recent years: the changing roles of healthcare professionals, the need to ensure optimal use of skill mix and the key contribution of pharmacy technicians and other healthcare professionals, for example, Operating Department Practitioners, and seeks to clarify how these fit within the existing legal framework for controlled drugs. .

Controlled Drugs are those defined in the MDR, and within this document the emphasis is placed on those contained in Schedule 2, as these are subject to the highest levels of control. On occasions, health care organisations choose to manage non-CDs and CDs in other Schedules in the same way as Schedule 2 CDs to ensure a higher level of governance. This is a matter for local decision and does not form part of this guidance.

This guidance is intended to build on and augment the advice provided in *The Safe and secure handling of medicines: A team approach* (the Revised Duthie Report, March 2005). It is concerned specifically with CDs and readers are encouraged to refer to the Revised Duthie Report (March 2005) [http://www.rpsgb.org.uk/pdfs/safsechandmeds.pdf.] for guidance on more general aspects of medicines' management.

This guidance has been organised into chapters dealing with the legislative requirements, governance arrangements and guiding principles. Chapters that deal with the management of CDs in wards, operating theatres and pharmacies follow. A chapter on special situations has been included to accommodate a number of situations that do not obviously fit elsewhere. There is also a brief chapter on training. Separate sections have not been written for each hospital department, because the requirements for the safe management of CDs do not differ between medical and surgical wards or general wards and high-dependency wards. Although the guidance includes most of the commonly-encountered situations, inevitably, as practice continues to develop, users will on occasions find gaps or points which fit uneasily with their situation. In such cases we hope that the principles listed in Chapter 3 will provide a basis for policy formulation.

The style of the Revised Duthie Report (March 2005) has been adopted. The term "should" has been used for recommendations that relate to good practice and "must" for those governed by legal requirements. Recommendations have also been inserted that "may" be followed as matters of good practice, if they are relevant to local circumstances.

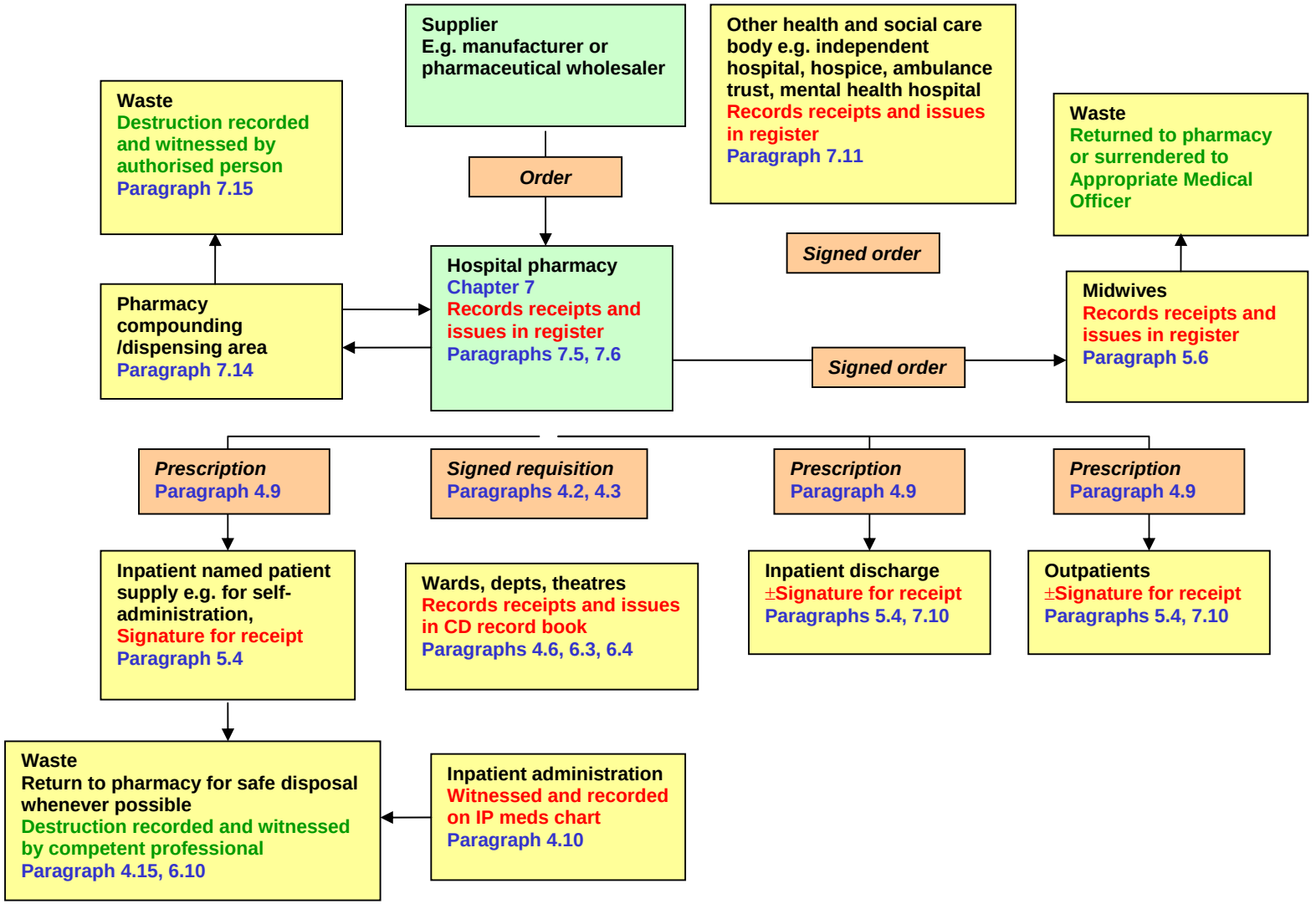
This document has been designed both for those who are involved in management of CDs in secondary care and for those who are responsible for ensuring that CDs are managed appropriately in their organisations or in their part of the organisation. It should be of value in a number of settings where CDs are used including:

- Pharmacies
- Hospital wards and departments including operating theatres
- Midwifery units
- Supply to other health and social care bodies (e.g., hospices, ambulance trusts).

This guidance should also be of value in a number of settings outside the secondary sector such as hospices, community hospitals, rehabilitation centres and other similar organisations where CDs are used and managed. It has been prepared on the basis of extensive consultation with stakeholders. A list of those who contributed to the design and content of the guidance appears at Appendix 6.

Unfortunately, the Department of Health is not in a position to answer specific individual queries relating to the management of controlled drugs. Healthcare professionals should in the first instance contact their local Medicines Information Centres. Appendix 4 lists professional organisations that provide advice for their members. The Department's website www.dh.gov.uk/controlleddrugs, the Home Office websites www.homeoffice.gov.uk and www.drugs.gov.uk/drugslaws and the Royal Pharmaceutical Society of Great Britain website www.rpsgb.org.uk should also be referred to regularly.

Figure 1 The product journey – CDs in secondary care



2 Legislation and governance arrangements

Legislation

Legislative Framework for Controlled Drugs

The management of CDs is governed by the Misuse of Drugs Act (1971) and its associated Regulations (in England, Wales and Scotland).
Additional statutory measures for the management of CDs are laid down in the Health Act (2006) and its associated Regulations.

The relevant legislation and guidance is summarised briefly in Appendix 1. Readers are encouraged to refer the relevant websites for detailed, up-to-date information.

The legal requirements pertaining to the main groups of CDs are summarised in Table 1. Schedule 1 drugs have been omitted from the table as drugs in this group have virtually no therapeutic uses.

Table 1: Summary of legal requirements that apply to controlled drugs in Schedules 2,3,4 and 5 of the Misuse of Drugs Regulations

Schedule (refers to schedules of the Misuse of Drugs Regulations)	**Schedule 2** Includes – Opioids, (e.g. diamorphine, morphine, methadone), major stimulants (eg amphetamines) ,remifentanil secobarbital,	**Schedule 3** Includes minor stimulants, temazepam, diethylpropion, buprenorphine, flunitrazepam, Barbiturates except secobarbital	**Schedule 4, pt I** Includes benzo-diazepines	**Schedule 4, pt II Includes** anabolic steroids, clenbuterol, growth hormones	**Schedule 5** Includes low strength opioids
Designation	CD	CD No Reg	CD Benz	CD Anab	CD Inv
Safe custody	Yes, except quinalbarbitone	Yes, with certain exemptions (see MEP)	No	No	No
Prescription requirements (including handwriting*) – apply to OP and discharge prescriptions	Yes	Yes, except temazepam	No	No	No
Requisitions necessary?	Yes	Yes	No	No	No
Records to be kept in CD register	Yes	No	No	No	No
Pharmacist must ascertain the identity of the person collecting CD	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbitone for epilepsy	Yes	Yes	Yes
Validity of prescription	28 days	28 days	28 days	28 days	6 mths (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	

(Table adapted from the Medicines, Ethics and Practice Guide *(http://www.rpsgb.org/pdfs/MEP30s1-2b.pdf)*

* Prescriptions for schedule 2 and 3 CDs may be typed or computer generated but must be signed by the prescriber. (SI 2005 No.2864)

Further information can be found in the Medicines, Ethics and Practice Guide (MEP) and in the British National Formulary (http://www.bnf.org/bnf/)

2.1 Supply and administration of controlled drugs

There are a number of mechanisms for the supply and administration of controlled drugs in secondary care. Controlled drugs can be

- Prescribed by a doctor or nurse independent prescriber
- Supplied and administered by a midwife
- Supplied and administered under Patient Group Directions

Certain restrictions apply to each of these routes of supply

2.2.1 Supply and /or administration of controlled drugs under Patient Group Directions

A Patient Group Direction (PGD) allows a range of specified health care professionals to supply and /or administer a medicine directly to a patient with an identified clinical condition within an identified set of circumstances without the patient first seeing a prescriber. Individual professionals who are to work within a PGD must be named on it and have signed it

Named nurses, paramedics and other specified health professionals can supply and administer certain CDs in restricted circumstances in accordance with a PGD and the additional requirements of the Misuse of Drugs (Amendment) (No 3) Regulations (SI 2003 No.2429. (www.opsi.gov.uk/si/si2003/20032429.htm) (*HO circular Home Office Circular 049 / 2003. Controlled Drugs Legislation - Nurse Prescribing And Patient Group Directions*) [http://www.knowledgenetwork.gov.uk/ho/circular.nsf/79755433dd36a66980256d4f004d1514/248786ae1bb78d6180256dab003b2948?OpenDocument]

There are currently only limited circumstances in which certain CDs may be administered or supplied under a PGD by certain named heath professionals. These are:

- Registered nurses (but no other health care practitioners) in an accident and emergency departments and coronary care units in hospitals can supply or administer diamorphine for the treatment of cardiac pain in accordance with a PGD.
- Registered nurses, pharmacists, paramedics, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists, radiographers, occupational therapists and orthotists or prosthetists can supply or administer any schedule 4 or 5 CD in accordance with a PGD, except
    - The anabolic steroids in Schedule 4, part 2
    - Injectable formulations for the purpose of treating a person who is addicted to a drug

2.2.2 Midwife's exemptions

Registered midwives may administer parenterally, a number of specified CDs in the course of their professional practice. These are:

- Diamorphine
- Morphine
- Pentazocine lactate
- Pethidine hydrochloride

(See - The Prescription Only Medicines (Human Use) Order 1997(SI 1997 No. 1830). The Misuse of Drugs Regulations 2001] (SI 2001 No. 3998))

(See also paragraph 5.8 Controlled drugs for midwives)

Governance arrangements

2.3 Accountability and responsibility

At local level, all healthcare organisations or designated bodies (see Controlled Drugs (Supervision of Management and Use) Regulations 2006; (SI 2006 No. 3148) www.opsi.gov.uk) are accountable, through the Accountable Officer (see below), for ensuring the safe management of controlled drugs. In England, the following are designated bodies:

- A primary health care trust
- An NHS trust
- An NHS foundation trust
- An independent hospital

All designated bodies, including NHS Trusts, Foundation Trusts and independent healthcare organisations, are accountable for the monitoring of all aspects of the use and management of controlled drugs by all healthcare professionals whom they employ, with whom they contract or to whom they grant practice privileges. This will be done through normal governance arrangements such as analysing baseline data and clinical governance visits (for example by clinical governance leads).

Where one organisation provides services to another, responsibility for governance arrangements should be specified in the contract (or service level agreement). Reporting should be to the Accountable Officer for the organisation that is receiving the service. (Once the CDs have been received responsibility for them passes to receiving organisation.) In setting up and reviewing these governance arrangements, the AO will want to pay particular attention to and prioritise key areas of risk which will include the interface with other health and social care providers.

2.4 The Accountable Officer

The Accountable Officer is responsible for all aspects of the safe and secure management of CDs in his or her organisation. This includes ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents related to CDs.

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations 2006; (SI 2006 No.3148) [http://www.opsi.gov.uk/si/si2006/20063148.htm] and a summary of the main provisions is provided at Appendix 2 of this document.

2.5 Standards for monitoring and inspection

Guidelines for inspection visits have been developed. A working group of representatives from the RPSGB, Healthcare Commission, Commission for Social Care Inspection (CSCI), the police and the NHS has agreed the guidelines. They set out the core activities that should be included in an inspection and cover areas such as ensuring safe storage arrangements and proper record keeping. They also suggest a frequency for visits: a minimum ten per cent random sample of designated bodies to be inspected each year. Notice should be given of routine inspections.

The guidelines can be found at: www.dh.gov.uk/controlleddrugs. A competency framework is also available for those involved in monitoring and inspection. (See - www.npc.co.uk/pdf/CDI_Competency_Framework.pdf)

2.6 Standard operating procedures

Each of the activities that relate to CDs, regardless of where in the organisation they occur, must be described in a standard operating procedure (SOP). This is particularly important if tasks are delegated to others. For example, issue and receipt of Controlled Drugs in the pharmacy may be delegated to a pharmacy technician. However, final responsibility lies with the chief pharmacist.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each one should be clearly marked with the date of issue and review date.

All staff who are involved in the prescribing, supplying, administering or disposing of controlled drugs of CDs need to be familiar with the SOPs.

There is a regulatory requirement for the Accountable Officer (AO) to ensure that there are adequate and up-to-date SOPs in place in relation to the management and use of controlled drugs within their organisation.

The standard operating procedures must, in particular, cover the following matters -

(a) who has access to the controlled drugs;

(b) where the controlled drugs are stored;

(c) security in relation to the storage and transportation of controlled drugs as

required by misuse of drugs legislation;

(d) disposal and destruction of controlled drugs;

(e) who is to be alerted if complications arise; and

(f) record keeping, including:

(i) maintaining relevant controlled drugs registers under Misuse of Drugs legislation, and

(ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2001 (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

SOPs within a health care organisation should be formally approved by the Accountable Officer for that organisation. This task may be delegated to a suitably qualified person, however, the final responsibility lies with the Accountable Officer. (See Appendix 2)

Further information about SOPs for CDs can be found in the document, *Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs* at http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=122755&Rendition=Web.

2.7 Additional Information

- A comprehensive list of drugs included within these schedules is given in the 2001 Misuse of Drug Regulations and can be accessed at www.opsi.gov.uk
- The Healthcare Commission is responsible for overseeing the management of controlled drugs by healthcare organisations in England and a section of the website is dedicated to controlled drugs www.healthcarecommission.org.uk
- Home Office www.homeoffice.gov.uk
- Medicines and Healthcare Products Regulatory Agency (MHRA) www.mhra.gov.uk
- Department of Health Controlled Drugs pages www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/Prescriptions/ControlledDrugs/fs/en
- Royal Pharmaceutical Society of Great Britain. *Medicines, Ethics and Practice: A guide for pharmacists.* http://www.rpsgb.org.uk/pdfs/MEP30s1-2a.pdf
- Royal Pharmaceutical Society of Great Britain. Patient Group Directions: A resource pack for pharmacists. http://www.rpsgb.org.uk/pdfs/pgdpack.pdf.
- Pharmaceutical Services Negotiating Committee (PSNC). *Controlled Drugs – recent changes.* http://www.psnc.org.uk/index.php?type=more_news&id=2056&k=3
- National Prescribing Centre (NPC). *A guide to good practice in the management of controlled drugs in primary care (England)*. http://www.npc.co.uk/background_for_cd.htm

- Nursing and Midwifery Council (www.nmc-uk.org). NMC Circular 25/2005 *Midwives Supply Orders*; NMC Circular 1/2005, *Medicine legislation: what it means for midwives.*

3 General principles

There are a number of overarching principles that guide the use of medicines in general and CDs in particular. They underpin and inform the decisions that are made about the safe management of CDs within the current legal framework. The following principles should apply in relation to the management of CDs.

3.1 Patients have timely access to the medicines prescribed for them

3.2 Organisations and individuals comply with the current legal requirements for CDs

3.3 Patients are partners in their treatment and share decision-making with healthcare professionals about their treatment.

3.4 Patients are adequately informed about their treatment

3.5 CDs are used and managed safely and securely

3.6 There is a clear audit trail for the movement and use of all CDs

3.7 The use of CDs is audited and action is taken if necessary

3.8 CDs are prescribed by professionals who are competent to do so and who receive regular training and support on the safe management of CDs

3.9 Local procedures and protocols are designed to be as clear and accurate in operationalisation as possible and do not impose an intolerable administrative burden

3.10 The stock levels and preparations of CDs held in wards and departments match what is routinely used in that clinical area

3.11 Health care staff have access to up-to-date information about CD legislation and official (Department of Health, Home Office and other) guidance

3.12 Health care staff in the organisation work to standard operating procedures, approved by the Accountable Officer, that are appropriate to their area of work

3.13 Health care and appropriate ancillary staff receive adequate training and are competent in the management of CDs (appropriate to their sphere of activity and level of responsibility)

3.14 Access to CDs is restricted to appropriate, designated and legally authorised personnel

4 Management of CDs in wards and departments

This chapter deals with the management of CDs in wards and departments. The management of CDs in operating theatres is covered in Chapter 6.

Contents of this chapter:

This section deals with measures concerned with the management of controlled drugs that are applicable in most wards and departments, including diagnostic departments. The requirements for pharmacy departments can be found in Chapter 7.

Where additional information can be found in other paragraphs, cross-references are also included.

4.1 Accountability and responsibility

4.1.1 Accountable individuals

The registered nurse, midwife or Operating Department Practitioner (ODP) in charge of a ward or department is responsible for the safe and appropriate management CDs in that area.

The registered nurse, midwife or ODP in charge can delegate control of access (i.e. key-holding) to the CD cupboard cabinet to another, such as a registered nurse or ODP. However, legal responsibility remains with the registered nurse, midwife or ODP in charge. Whilst the task can be delegated, the responsibility cannot.

4.1.2 Standard operating procedures

There should be standard operating procedures (SOPs) covering each of the activities concerned with CDs such as requisitioning, receipt, administration etc.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each one should be clearly marked with the date of issue and review date.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The AO remains finally accountable for all the systems for the safe management of CDs. (See Appendix 2)

4.2 Controlled Drug stocks

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 pharmacist or pharmacy technician responsible for stock control of medicines on the ward and the registered nurse, midwife or ODP in charge.

4.2.1 The list should be modified if practices change and should be subject to regular review at agreed intervals.

4.3 Requisitioning of Controlled Drugs

The registered nurse, midwife or ODP in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in that area.

4.3.1 The registered nurse, midwife or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or ODP (See Chapter 6; The management of CDs in operating theatres). However, legal responsibility remains with the registered nurse, midwife or ODP in charge.

4.3.1.1 Orders should be written on suitable stationery (e.g. a controlled drug requisition book with duplicate pages) and must be signed by an authorised signatory. (See also 4.3.5 Electronic systems)

4.3.1.2 A copy of the signature of each authorised signatory should be available in the pharmacy department for validation. Where electronic systems are in use, there should be a reliable means of validating the identity of individuals who requisition CDs.

4.3.1.3 Requisitions must contain the following:

- Name of hospital
- Ward / Department
- Drug name, form, strength, ampoule size if more than one available
- Total quantity
- Signature and printed name of registered nurse
- Date
- Signature of person issuing the item from the pharmacy

The person who receives the CDs on the ward should sign the duplicate copy of the requisition.

4.3.1.4 The person who accepts the CDs for transit should sign for receipt. This may be on the duplicate requisition (if space permits) or may be in a separate book kept for this purpose.

4.3.2 CD Top-up schemes

In some situations pharmacy-led CD top-up schemes for replenishing stocks of CDs on wards and departments are a practical and convenient mechanism of stock control. These are usually carried out by a pharmacy technician or senior assistant technical officer (SATO), but may also be carried out by other suitably-trained, competent members of the pharmacy staff.

4.3.2.1. When a CD top-up scheme is in operation, the responsibility for CDs in a ward or department remains with the registered nurse, midwife or ODP in charge.

4.3.2.2 In a top-up scheme a member of the pharmacy staff is responsible for checking the stock balances in the ward Controlled Drug Record Book against the levels in the agreed stock list and preparing the CD requisition forms in order to replenish the stock. These requisition forms should be signed by the registered nurse, midwife or ODP in charge.

4.3.3 Electronic systems

Where electronic systems for the requisitioning of CDs are introduced, safeguards in the software should be put in place to ensure that:

- Only individuals who are authorised to requisition CDs from the pharmacy can do so
- Safeguards should be incorporated in the software to ensure the author of each entry is identifiable

- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

4.4 Receipt of controlled drugs

When CDs are delivered to a ward or department they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of CDs). A local procedure should define the appropriate persons who are permitted to receive CDs and the way in which messengers identify them. As a matter of good practice the receiving person should not be the same person who ordered the controlled drugs.

4.4.1 As soon as possible after delivery the registered nurse, midwife or ODP in charge should:

- Check the CDs against the requisition – including the number ordered and received. If this is correct then the duplicate sheet in the controlled drug requisition book should be signed in the "received by" section. Any tamper-evident seals on packs should be left intact when they are received from pharmacy. This will simplify and speed up routine checks. A seal should only be broken when the pack is required for administration.
- If when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the nurse or ODP in charge should contact the pharmacy department.
- Appropriate records should be made in the CD Register and all necessary action taken to resolve the discrepancy.
- Place the CDs in the appropriate CD cupboard
- Enter the CDs into the controlled drug record book, update the running balance and check that the balance tallies with quantity that is physically present.

4.4.2 Depending on local circumstances, some health care organisations may wish to stipulate that receipt of CDs and updating of the register should be witnessed by a second competent professional

See also paragraph 6.4 Receipt of CDs in Theatre

4.5 Storage of controlled drugs

The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No 798) cover the safe custody of controlled drugs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store controlled drugs.

4.5.1 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, and/or there is not a 24-hour staff presence, or easy control of access. In this case a security cabinet that has been evaluated against the SOLD SECURE standard SS304 (See www.soldsecure.com) should be used.

4.5.2 All controlled drugs must 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 the registered nurse, midwife or ODP in charge, or a person working under their authority e.g. a pharmacy technician.

4.5.3 In certain circumstances, for example when CD discharge medicines (TTOs) are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. These medicines should be segregated from the ward CD stock. (See paragraph 5.4 Management of CDs that are patients' property – TTOs)

4.5.4 General measures for the storage of CDs include the following:

- Cupboards must be kept locked when not in use
- The lock must not be common to any other lock in the hospital
- Keys must only be available to authorised members of staff and at any time the key-holder should be readily identifiable
- The cupboard should be dedicated to the storage of CDs.
- No other medicines or items should normally be stored in the CD cupboard. Occasionally, in response to local circumstances health care organisations may decide to allow other drugs that are not CDs to be stored in the CD cupboard. Trusts should carry out a risk assessment and have clear guidelines and SOPs in place to cover this
- CDs must be locked away when not in use
- There must be arrangements for keeping the keys secure. This is particularly important for areas such as day surgery units and five-day wards that are not operational at all times.

4.6 Key-holding and access to CDs

4.6.1 Responsibility for CD keys

The registered nurse, midwife or ODP in charge is responsible for the CD key.

4.6.1.1 Key-holding may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the registered nurse, midwife or ODP in charge.

4.6.1.2 The controlled drug key should be returned to the nurse, midwife or ODP in charge immediately after use by another registered member of staff.

4.6.1.3 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff (e.g. the pharmacy technician responsible for stock control of medicines on the ward).

4.6.2 Missing CD keys

If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible e.g. by contacting nursing, midwifery or ODP staff who have just gone off duty.

4.6.2.1 A procedure should be in place to ensure that the senior registered nurse, midwife or matron or the duty nurse or midwife manager is informed as soon as possible and the duty pharmacist as soon as appropriate.. The procedure should specify the arrangements for preserving the security of CD stocks and for ensuring that patient care is not impeded e.g. by issuing a spare key.

4.6.2.2. If the keys cannot be found then the Accountable Officer should be informed. Depending on the circumstances, it may also be appropriate to contact the police.

4.7 Record-keeping

Each ward or department that hold stocks of CDs should keep a record of CDs received and administered in a CD record book (CDRB).

The Registered nurse, midwife or ODP in charge is responsible for keeping the CD Record book up to date and in good order.

4.7.1. Controlled drug record books

4.7.1.1 The CDRB should be bound (not loose-leaf) with sequentially numbered pages and it should have separate pages for each drug and each strength, so that a running balance can be kept easily. Entries should be made in chronological order, in ink or be otherwise indelible.

4.7.1.2 All entries should be signed by a registered nurse, midwife or ODP and should be witnessed preferably by second registered nurse, midwife or ODP. If a second registered nurse, midwife or ODP is not available, then the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant.

4.7.1.3 On reaching the end of a page in the CDRB, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. As a matter of good practice this transfer may be witnessed.

4.7.1.4 If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed by

a second registered nurse, midwife or other registered professional or by an appropriately trained healthcare assistant. The witness should also sign the correction

4.7.2 Records of receipts

A record should be kept of all Schedule 2 CDs that are received or administered.

4.7.2.1 For CDs received, the following details should be recorded on the appropriate page in the CDRB:

- Date of entry.
- Name of pharmacy making supply and the serial number of requisition
- Quantity received
- Form (name, formulation and strength) in which received
- Name/signature of nurse/authorised person making entry
- Name/signature of witness
- Balance in stock

4.7.2.2 When recording CDs received from pharmacy, the number of units received may be recorded in words not figures (e.g. ten, not 10) to reduce the chance of entries being altered.

4.7.2.3 After every administration, the stock balance of an individual preparation should be confirmed to be correct and the balance recorded in the controlled drug record book. The entry should be signed and dated.

For records of CDs administered see paragraph 4.11 Administration of CDs

4.8 Controlled drug stock checks

The stock balance of all CDs entered in the CD record book (CDRB) should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out. In addition, regular stock checks should be carried out by pharmacy staff (see paragraph 7.7.2 - Checks of CD stocks held in wards, theatres or departments).

4.8.1 The registered nurse, midwife or ODP in charge is responsible for ensuring that the regular CD stock check is carried out by staff in the ward or department

4.8.1.1 Two registered nurses, midwives or registered health professionals should perform this check. Where possible the staff undertaking this check should be rotated periodically. The check should take account of the following points:

- Checking of controlled drugs involves checking of balance in the CDRB against the contents of the CD cupboard, not the reverse, to ensure all balances are checked.
- It is not necessary to open packs with intact tamper-evident seals for stock checking purposes.
- Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks may be helpful. The balance must be confirmed to be correct on completion of a bottle.

4.8.1.2 A record indicating that this reconciliation check has been carried out and confirming the stock is correct may be kept in a separate bound record book or in the CDRB. This record should as a minimum state the date and time of the reconciliation check and include wording such as, "check of stock level" and be signed by the registered nurse, midwife or ODP and the witness.

4.8.1.3 If a discrepancy is found it should be investigated without delay. (See paragraph 5.9 Discrepancies and diversion) The local investigation and reporting procedures should be followed

4.9 Archiving of controlled drug records

Healthcare organisations must make arrangements to store CD records for a minimum period of two years. Some health care organisations may want to keep records for longer than two years. Once electronic CD registers are in common use, the Government intends a further requirement to keep secure copies for up to eleven years.

All registers and CDRBs used in the organisation should be kept for a period of at least two years from the date when the last entry was made.

All local documents designed to track and/or monitor CD usage should also be kept for two years after the last entry/date of use

See also paragraph 7.9 - Archiving of controlled drug records

4.10 Prescribing

4.10.1 Prescribing for inpatients/discharge patients

For hospital inpatients or discharge patients, CDs can be prescribed on the inpatient medicines chart or case sheet (commonly called the inpatient prescription and administration chart) or the anaesthetics card in line with local policies and procedures.

4.10.1.1 The written requirements for controlled drugs on these charts are the same as for other medicines:

- Drug name and form

- Route
- Dose
- Frequency (if prescribed “when required” e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum total quantity to be administered in 24hrs)
- Include a finish date where appropriate
- Start date
- Signature of prescriber

The patient’s name, unit number and allergy status should also be written on the chart.

4.10.2 Prescribing for discharge patients

Prescriptions for CDs for patients who are going home (discharge medicines) should be written on locally-approved TTA (to take home or to take out) prescription forms for dispensing by the pharmacy. These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a controlled drugs prescription (see section 4.10.3).

4.10.2.1 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other POM medicines) on these prescription forms for in patient use so far as this is necessary for the purposes of his employment as defined in the Medical Act 1983. Further guidance is available from the GMC http://www.gmc-uk.org/education/documents/provisional_registration_prescribing.pdf

4.10.2.2 Up to a maximum of 30 days supply should be prescribed, as a matter of good practice. There may be circumstances where there is a genuine need to prescribe for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a note of the reasons in the patient’s notes

4.10.3. Prescribing for outpatients

Prescriptions for CDs for outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations (Regulation 15). The prescription document can either be a locally-approved outpatient prescription form for the hospital pharmacy to dispense or a hospital FP10 for the a community pharmacy to dispense.

4.10.3.1 A prescription for Schedule 2 and 3 CDs (with the exception of temazepam and preparations containing it) must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated (SI 2005 No.2864) [http://www.opsi.gov.uk/SI/si2005/uksi_20052864_en.pdf]

- The patient’s full name, address and, where appropriate, age

- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to
- be supplied in both words and figures

In addition, it is good practice to include the patient's NHS number on the prescription.

4.10.3.2 The prescription must be signed by the prescriber with his/her usual signature, in his own handwriting (this must be handwritten) and dated by him/her (the date does not have to be handwritten).
Amendments to the Misuse of Drugs Regulations 2001, which came into force on 14th November 2005, removed the requirement for prescriptions for Schedule 2 and 3 CDs (except temazepam) to be written in the prescriber's own handwriting (other than their signature).
CD prescriptions may be computer-generated but **do not have** to be computer-generated. Prescribers may issue computer-generated prescriptions for all CDs. Only the signature has to be in the prescriber's own handwriting. The prescriber should sign any manuscript changes.

4.10.3.3 If the prescription is prepared by someone other than the prescriber then that person should, ideally, be a registered healthcare professional.

4.10.3.4 The use of pre-printed sticky labels on prescriptions is not recommended. Technically the new legislative requirements for computer generated prescriptions for CDs do not prevent the use of preprinted sticky labels on prescriptions. If and where they are used, such sticky labels should be tamper-evident (i.e. it is obvious if an attempt has been made to remove them). If a sticky label is used, prescribers should also sign the sticky label or at least start their signature on the sticky label. This is a further safe guard to ensure sticky labels are not tampered with or another sticky label is not placed on top of the one that the prescriber signed for.

4.10.3.5 Up to a maximum of 30 days supply should be prescribed as a matter of good practice. There may be circumstances where there is a genuine need to prescribe a supply for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe a supply for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a note of the reasons in the patient's notes.

4.10.4 Supplementary prescribers

Regulations were amended in 2005 to permit a supplementary prescriber, when acting under and in accordance with the terms of an agreed individual clinical management plan (CMP) to prescribe and administer and/or supply or direct any person to administer any CD provided that the CD is included in the CMP.

4.10.4.1 If the patient takes his prescription to a community pharmacy for dispensing, then the appropriate prescription form must be used (FP10SS). Details of the prescription forms on which CDs for outpatients

can be prescribed, are provided in the RPSGB Medicines, Ethics and Practice guide. [http://www.rpsgb.org.uk/pdfs/MEP30s1-2a.pdf]

4.10.5 Non-medical independent prescribers

Community Practitioner Nurse Prescribers
Community Practitioner Nurse Prescribers may only prescribe those products and medicines specified in the Nurse Prescribers' Formulary for Community Practitioners. No CDs are included in this formulary.

Nurse Independent Prescribers (formerly Extended Formulary Nurse Prescribers)
Following amendments to the Medicines Regulations, which came into force in January 2006, the range of drugs that Nurse Independent Prescribers were able to prescribe independently has been extended. From 1st May 2006, the Nurse Prescribers' Extended Formulary was discontinued and qualified Nurse Independent Prescribers are now able to prescribe any licensed medicine for any medical condition within their competence, including some CDs for specific conditions. The 2001 Misuse of Drugs Regulations were amended, with effect from 1st May 2006, to reflect the change in terminology relating to Nurse Independent Prescribers. The condition of tonic-clonic seizures was also added as an allowable indication for the prescribing of diazepam, lorazepam and midazolam.

Nurse Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer the following CDs solely for the medical conditions indicated. Details of the appropriate route of administration for these CDs can also be found in the table below.

Table 2: CDs that can be prescribed and administered for specified indications by Nurse Independent Prescribers

Drug	Schedule	Indication	Route of administration
Buprenorphine	3	Transdermal use in palliative care	Transdermal
Chlordiazepoxide hydrochloride	4	Treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it	Oral
Codeine phosphate	5	N/A	Oral
Co-phenotrope	5	N/A	Oral
Diamorphine hydrochloride	2	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case postoperative pain relief	Oral or parenteral
Diazepam	4	Use in palliative care, treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it, tonic-clonic seizures	Oral, parenteral or rectal
Dihydrocodeine tartrate	5	N/A	Oral
Fentanyl	2	Transdermal use in palliative care	Transdermal
Lorazepam	4	Use in palliative care, tonic-clonic seizures	Oral or parenteral
Midazolam	4	Use in palliative care, tonic-clonic seizures	Parenteral or buccal
Morphine hydrochloride	2	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief	Rectal
Morphine sulphate	2	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief	Oral, parenteral or rectal
Oxycodone hydrochloride	2	Use in palliative care	Oral or parenteral administration in palliative care

4.10.6 Pharmacist Independent Prescribers

At present Pharmacist Independent Prescribers are not able to prescribe Controlled Drugs. Readers are advised to consult the DH and HO websites for up-to-date information.

The Home Office has issued a consultation for nurse and pharmacist independent prescribers to be able to prescribe any CD provided they work within their competence. The outcome of the consultation will inform any regulatory changes required.

4.11 Administration

See also paragraph 4.7 Record keeping.

The administration of Controlled Drugs should comply with all local policies and procedures for the administration of medicines.

Nurses and midwives must follow Nursing and Midwifery Council standards and guidance.

Anyone can administer any drug specified in Schedule 2,3 or 4 provided they are acting in accordance with the directions of an appropriately qualified prescriber. (MDR 2001, Regulation 7(3)). Any person can administer to another person any drug specified in Schedule 5 – MDR 2001- Regulation 7 (1)

4.11.1 Health care organisations should carry out a risk assessment to determine whether the introduction of double checking for administration of CDs as an additional risk-reduction measure is necessary, within their organisation.

4.11.1.1 Where two practitioners are involved in the administration of CDs, one of them should be a registered nurse, midwife, doctor or ODP. (The MHRA is consulting (April 2007) on potential changes to the legislation which if approved would add pharmacists to this list.) Both practitioners should be present during the whole of the administration procedure. They should both witness:

- The preparation of the CDs to be administered.
- The CD being administered to the patient.
- The destruction of any surplus drug (e.g. part of an ampoule infusion not required).

A record should be made in the ward or department CD Record Book when a CD is removed from the CD cupboard.

4.11.1.2 For CDs administered the following details should be recorded:

- Date and time when dose administered
- Name of patient
- Quantity administered
- Form (name, formulation and strength) in which administered
- Name/signature of nurse/authorised person who administered the dose
- Name/signature of witness (where there is a second person witnessing administration)
- Balance in stock

4.11.1.3 If part of a vial is administered to the patient, the registered nurse, midwife or registered health professional should record the amount given and the

amount wasted e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted* " This should be witnessed by a second registered nurse midwife or registered health professional who should also sign the record. If a second registered nurse midwife or registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant.

4.11.1.4 Individual doses of CDs which have been prepared but not administered should be destroyed by a registered nurse midwife or registered health professional on the ward or department in the presence of a witness and the reason documented in the CD Record Book.

(For appropriate methods of destruction see paragraph 4.16 Disposal and destruction of CDs).

4.12 Management of CDs when patients are admitted

See paragraph 5.4 Management of CDs that are the patient's property

4.13 Management of CDs when patients are transferred to other wards or departments

See paragraph 5.2 Transfer of CDs

There should be a local procedure which covers all aspects of the safe management of patient-controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (for example, pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the CDRB
- Arrangements for documentation when the patient is moved from theatre to wards
- Arrangements for recording administration
- Arrangements for disposal of surplus CDs

4.14 Management of CDs when patients are discharged

See paragraph 4.10.2 Prescribing for discharge patients and 7.10 Supply to outpatients and discharge patients

4.15 Returning controlled drugs to the pharmacy

4.15.1 Unused CD stock from wards or departments may be returned to the pharmacy. Such CD stock can be re-issued by the pharmacy provided it was initially issued by that pharmacy and has at all times been under the control of that hospital. The pharmacy department should carry out a risk assessment of CDs returned to pharmacy to ensure they are fit for re-use.

Controlled Drugs that are time-expired or otherwise unfit for use (e.g. opened liquids) should also be returned to the pharmacy for safe destruction and onward disposal.

Any other controlled drug that is no longer needed on the ward should be returned to pharmacy. This should be done as soon as is practicable. Local policies may define time limits.

4.15.2 Records of CDs returned

The ward or department should keep a record of drugs returned to pharmacy. This may be in the form of a returns advice note with duplicate pages so that both the pharmacy and the ward have a record of the transaction.

The following details should be recorded when CDs are returned to the pharmacy:

- Date
- Name, form, strength and quantity of drug being returned
- Reason for return
- Name and signature of the registered nurse, midwife or ODP

The top copy will be taken from the book and transported with the drugs to the pharmacy.

In addition, an entry should be made on the relevant page of the ward CDRB, showing:

- Date
- Reason for return
- Names and signatures of the registered nurse, midwife or ODP responsible and a competent witness
- Quantity removed
- Name, form and strength of drug
- Balance remaining

The drugs should be transferred to the pharmacy in a safe and secure way. (See paragraph 5.2 transfer of CDs)

4.16 Disposal of controlled drugs in wards and departments

See also paragraph 7.15 Disposal of CDs in pharmacies

In the interests of safety and containment of environmental pollution, CDs should, as far as is practicable, be returned to the pharmacy for safe denaturing and disposal.

CDs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used. Where denaturing is carried out on the wards, the methods used should be those currently recommended by the RPSGB [Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales. www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf]

Some health care organisations may wish to provide denaturing kits for use on wards to destroy CDs that have been used for patients. This may be appropriate on wards or departments where large quantities of CDs are used and where the volume of part-used vials, ampoules, syringes and infusion bags may be high. A risk assessment should be carried out before a decision is made whether denaturing kits should be available on the wards. Where denaturing kits are provided to wards or department, an SOP should be developed for this practice.

4.16.1 Disposal of small amounts of CDs

4.16.1.1 Only small amounts of CDs should be destroyed on wards, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used. Larger quantities of CDs, for example, discontinued infusions or patient-controlled analgesia (PCA) syringes, should be either be returned to the pharmacy for safe denaturing and disposal or denatured on the ward using denaturing kits.

4.16.1.2 All destruction must be documented in the appropriate section of the CD record book (see below). It should be witnessed by a second competent professional such as a registered nurse, midwife or ODP. Both persons should sign the CD record book.

4.16.2 Method of disposal

Small amounts of CDs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable by emptying into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

5 Management of CDs – general processes and specific circumstances

Contents of this chapter:

5.1 Controlled Drug stationery

All stationery which is used to order, return or distribute controlled drugs (CD stationery) should be stored securely and access to it should be restricted. These measures are important to guard against unauthorised use of the stationery to obtain CDs for inappropriate purposes.

5.1.1 Definition of CD stationery

CD stationery includes:

- Controlled drug requisition books
- Controlled drug record books
- Local CD documents such as CD returns advice notes, pharmacy distribution documents

5.1.2 Secure storage of CD stationery

CD stationery which is kept in wards, theatres or departments should be kept in a locked cupboard or drawer.

Stocks of CD stationery held in pharmacy departments should be kept in a secure area that is locked when there is no one present.

5.1.3 Supply of CD stationery

CD stationery should be issued from the pharmacy against a written requisition signed by an appropriate member of staff. The local policy should define the groups of staff who can sign requisitions for CD stationery.

5.1.3.1 A record should be kept of the supply of CD stationery. It should include:

- Date
- Ward/department
- Name of person ordering the stationery
- Type of stationery issued
- Quantity
- The serial numbers of the stationery
- Signature of the member of pharmacy staff making the supply
- Signature of member of staff receiving the stationery

5.1.3.2 Any unused stationery returned to pharmacy will be recorded as a return, with the details above, in the supply record.

5.1.3.3 Health care organisations may wish to number CD requisition books to provide an additional means of tracking.

5.1.4 Loss or theft of CD stationery

Loss or theft of any controlled stationery which may be used to order CDs should be reported immediately to the chief pharmacist and Accountable Officer.

5.1.5 Use of CD stationery

Only one CD requisition book per ward or department should normally be in use.

5.1.5.1 When a new CD Record Book is started, the balance of CDs in stock should be written into the new book promptly by ward staff. This transfer should be witnessed by a registered nurse, midwife or operating department practitioner or authorised member of staff e.g. pharmacy technician.

5.1.5.2 Completed ward requisition books and CD record books must be retained for a minimum of two years from the date of the last entry. (See paragraphs 4.9 and 7.9 Archiving of records)

5.2 Transfer of CDs within and outside the hospital

Transfer of CDs is likely to involve the following situations:

- Collection by ward staff from the pharmacy
- Collection by porters from the pharmacy
- Delivery by pharmacy staff to wards, departments, theatres
- Collection by patient or representative for outpatient items only;
- Delivery by Trust porter/driver
- Delivery by commercial courier (for example, taxi out-of-hours)
- Delivery using recorded delivery Postal Service (The use of postal services should not be routine but should be limited to exceptional situations such as when there is an urgent clinical need.)

5.2.1 Methods of transfer

Wherever possible, CDs should be transferred or conveyed in a secure, locked or sealed, tamper-evident container.

5.2.1.1 Depending on local circumstances, some health care organisations may choose to use bags with numbered seals for delivery and require a signature for receipt of the bag with the correctly numbered seal. Whatever system is used it must be fully auditable and explicit as to who has custody of the controlled drugs at any point in time.

5.2.1.2 CDs may not be transported in pneumatic tubes.

5.2.2 Records of transfer

At each point where a controlled drug moves from the authorised possession of one person to another, a signature for receipt should be obtained by the person handing over the drug and the person receiving it.

5.2.2.1 Health care organisations may wish to design local distribution/transport documentation as a means of keeping a full audit trail.

5.2.3 Messengers

The person who conveys the CD acts as a messenger, that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container.

5.2.3.1 The person acting as the messenger should:

- Ensure destination is known

- Be aware of safe storage and security, the importance of handing over the item to an authorised person and obtaining a signature for delivery on the delivery document.
- Have valid ID badge

5.2.3.2 Health care organisations may wish to stipulate that CDs should only be handed to members of staff who are wearing valid ID badges.

5.2.3.3 Where a commercial courier or taxi driver is responsible for conveying a CD he/she should be asked to show their valid company ID, as they would for any other medicine.

- Taxi drivers or commercial couriers should not be made aware that CDs are being transported as this may increase the potential for diversion or may discourage taxi drivers from carrying CDs.
- As a matter of good practice the taxi registration number may also be recorded.

5.2.3.4 Health care organisations may wish to keep a list of porters who are authorised to transfer controlled drugs. A list of their names with sample signatures may be kept in pharmacy for validation purposes.

5.2.4 Transfer from ward to ward or theatre to ward

Local procedures should define safe, secure and auditable methods to transfer CDs from ward to ward when a patient moves. The three situations in which this is most likely to arise are:

- When a patient is receiving a CD by means of syringe pump (PCA pump) or infusion
- When a patient has his/her own CDs for self-administration
- When a CD has been dispensed on a “named-patient” basis

5.2.4.1 Patients’ own Controlled Drugs should be transferred from ward to ward with the patient in line with local procedures for transferring all other medicines and properties belonging to that patient.

5.2.4.2 There should be a local procedure for all aspects of the management of patient controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (for example, pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the CDRB

- Arrangements for documentation when the patient is moved from theatre to wards
- Arrangements for recording administration
- Arrangements for disposal of surplus CDs

See also paragraph 5.4 managing CDs that are the patient's property

5.2.5 Transfer from ward to pharmacy

When CDs have to be returned to the pharmacy they should be placed in a secure container and handed to an authorised messenger. (See paragraph 4.15 Returning CDs to the pharmacy)

5.3 Clinical trials

The procedures for the use of CDs in clinical trials must comply with the MDR and with local policies governing the management of clinical trial medicines, in addition to clinical trials legislation and MHRA guidance on clinical trials.

5.3.1 Storage and records

5.3.1.1 All clinical trial CDs should be stored separately from stock CDs. They do not necessarily need to be stored in a separate CD cupboard. A separate page in the register should be used to record receipt and issues in addition to clinical trial documentation so that a running balance of trial stock can be kept.

5.3.1.2 If a discrepancy is identified then it should be reported on the internal incident reporting system in accordance with local procedures. A note to file should be stored with all the clinical trials documentation. The sponsor and investigator should be informed and also the chief pharmacist and AO. (See also paragraph 5.9 Discrepancies and diversion)

5.3.1.3 For double blind trials in which only one arm involves a CD, pharmacy staff may be unaware which packs contain CDs. In this situation, all supplies should be treated as CDs until the end of trial.

5.3.1.4 For trials that involve the use of Schedule 1 CDs, such as cannabinoids, a licence from the Home Office must be obtained before the item is received into stock or supplied. The licence should normally be held by the Chief Pharmacist and/or the AO. A copy should be kept with the trial protocol.

5.3.2. Labelling

All clinical trial CDs must be labelled and dispensed in accordance with the specific trial protocol in addition to the MDR requirements.

5.3.2 Disposal

Clinical trial CDs must be destroyed in the same way as other CDs. (See section 7. 15 Destruction of controlled drugs in pharmacies) However, this destruction may need to be carried out following the monitoring instructions with the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation (in addition to the check and reconciliation carried out by the pharmacy department) prior to any destruction.

5.3.4. Clinical trial CDs returned by patients

The pharmacy should establish secure arrangements for the storage (and destruction) of CD clinical trial medicines returned by patients. Drug accountability records should be completed promptly when a patient returns the CD clinical trial medicine and opportunities for diversion should be minimised.

5.3.5 Arrangements for research departments

If a hospital pharmacy supplies CDs to a research department, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

5.4 Management of CDs that are the patient's property

A local procedure should be in place for the management of CDs that are the patient's property.

5.4.1 Use of a patient's own controlled drugs on the ward

It may be appropriate to use a patient's own CDs (i.e. CDs brought into the hospital by the patient on admission) whilst they are in hospital, for example, if the patient is self-administering other medicines. On such occasions the drugs should be checked for suitability according to the local procedure for patients own drugs (PODs) to ensure that they are fit for purpose. (See paragraph 5.4.4 Self administration of CDs)

5.4.1.1 If patients' own CDs are not required for use in this way then one of the following procedures should be followed and all actions should be recorded:

- If the patient or the patient's agent agrees, medicines may be sent to the pharmacy for safe destruction. The pharmacist should take responsibility for destruction.
- If the patient wishes, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult. If the medicines are not safe and/or appropriate for use, then the

patient and/or patient's agent should be advised and they should be encouraged to send them to the pharmacy for safe destruction

5.4.1.2 Patients' own CDs that are not to be used for self-administration should not routinely be stored on the ward.

5.4.1.3 Temporary storage of patients' own controlled drugs on the ward may be necessary whilst they are awaiting collection and removal to the pharmacy or to the patient's home. In this situation, they should placed in the CD cupboard but should be clearly marked and kept separate from ward stock.

5.4.1.4 Patient's own controlled drugs should never be used to treat other patients.

5.4.2 Controlled drug discharge medicines (TTOs)

When CD discharge medicines (TTOs) are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. These medicines should be segregated from the ward CD stock and clearly marked and should remain in a sealed bag.

When Schedule 2 CD TTOs are collected from the pharmacy, the person collecting them (who may be the patient, his representative, a health care professional or porter) should be asked to sign for receipt as a matter of good practice.

5.4.3 Receipt of CDs by outpatients

Patients or their representatives may be asked to provide evidence of identity when collecting CDs.

From July 2006, there has been a requirement for persons asked to supply CDs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the dispenser:

- **May** request evidence of that person's identity and
- May refuse to supply the medicine if he is not satisfied as to the identity of the person

Where it a healthcare professional acting in his professional capacity on behalf of the patient, the dispenser:

- **Must** obtain the person's name and address
- **Must,** unless he is acquainted with that person, request evidence of that person's identity; but

- **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The new requirement placed on the dispenser therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if, for example, they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicines dispensed.

From 1st February 2008, it will be a requirement to record the following information in the CD register for Schedule 2 CDs supplied on prescription:

- Whether the person who collected the drug was the patient, the patient's representative or a health care professional acting on behalf of the patient
- If the person who collected the drug was a health care professional acting on behalf of the patient, that person's name and address
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

Depending on local circumstances, some health care organisations may wish to stipulate that outpatients receiving CDs sign for receipt of a specified number of doses.

5.4.4 Self-administration of CDs

A local procedure should be in place for wards or departments where patient self-administer their own medicines including their CDs.

5.4.4.1 When patients who self-administer CDs require additional supplies, these should be dispensed for discharge. Health care organisations may wish to consider whether the administration of these CDs is recorded in the CDRB or they may consider having a separate book for recording of CDs that are self-administered.

5.4.4.2 Patients receiving CDs for self-administration should sign for receipt of a specified number of doses.

5.4.4.3 Health care organisations may wish to stipulate that these CDs are entered in and out of the ward CDRB so that there is an auditable record of their arrival on the ward. A daily count of the quantity of the CDs in the patient's individual medicines cabinet may be made by the registered

nurse, midwife or other healthcare professional and recorded on the medicines chart or in the CDRB

5.4.4.4 The CDs for patients who self-administer their medicines should be kept in a locked metal receptacle immediately adjacent to their bed, or in their bedside locker. The receptacle should not be easily portable. Health care organisations may wish to consider the use of electronic patient medicines lockers accessed by means of programmable transponders. Such systems provide a high level of security and a clear record who accessed the locker and when.

5.4.4.5 Useful sources of information about controlled drugs for patients are listed at Appendix 5.

5.5 Out-of-hours supply

Under the current Regulations, a ward sister (or the registered nurse, midwife or ODP in charge) can only supply CDs to a patient on that ward, theatre or department in accordance with the written instructions of an authorised prescriber.

Every effort should be made to ensure that adequate stock levels are maintained to meet likely needs.

Local arrangements for emergency issues of CDs should be discussed with the Accountable Officer and/or chief pharmacist. Where such systems exist, an SOP should be developed.

5.6 Temporary ward closure and transfer of wards

5.6.1 Temporary ward closure

There should be a local procedure for the management of CDs during short and long term ward closures. The procedure should ensure the security of the CDs and should be auditable.

5.6.1.1 The procedure should include:

- A provision for a risk assessment to be carried out
- Arrangements for removal and temporary storage of CDs by the pharmacy, if appropriate
- Arrangements for return of CDs to the pharmacy for re-use, if appropriate
- Specification of the entries required in the CDRB
- Arrangements for secure storage of current (i.e. in use) CD stationery during closure
- Arrangements for return of stocks, including reconciliation with list of CDs removed, if appropriate
- Arrangements for restocking, if appropriate

5.6.1.2 As a matter of good practice, the list of authorised signatories for the ward that is kept in the pharmacy must be annotated by the pharmacist or pharmacy technician responsible for stock control of medicines on the ward so that the pharmacy and audit staff are aware that the ward is temporarily closed. The list will need to be reviewed by the ward pharmacist when the ward reopens, to ensure that signatures are valid and up to date.

5.6.2. Transfer of wards

When a ward moves to another location, a decision must be made as to whether its CDs and CDRBs may be transferred or, where swapping of wards occurs, left on the ward. This will depend upon the appropriateness of the stock list, the periods for which ward premises will be unoccupied and the security of the drugs during this time. (See paragraph 5.6.1 Temporary ward closures).

5.6.2.1 There should be a local procedure for the management of CDs during ward moves. This procedure should ensure the security of the CDs and should be auditable.

5.6.2.3 The procedure, which should have been agreed with the pharmacy department should include:

- A provision for a risk assessment to be carried out
- Arrangements for transfer of CDs and CDRBs, if appropriate
- Arrangements for checking and reconciliation of stocks, in particular when ward staff transfer but CDs and CDRBs are left in place
- Specification of the entries required in the CDRB, in particular when ward staff transfer but CDs and CDRBs are left in place

5.6.2.4 The pharmacist or pharmacy technician responsible for stock control of medicines on the ward should ensure that the ward signatory lists and stock lists are updated to reflect the new ward location/name/number.

5.7 Paediatrics

The management of CDs in paediatrics does not differ significantly from the management in adult care and so all the general provisions apply. There are, however, a few specific situations when the management of CDs may require a slightly different approach.

5.7.1 Part vials of controlled drugs

On many occasions in paediatrics, the dose required for the patient is smaller than that which is contained in a single vial or ampoule. When a dose is given to a child, an amount may be left, which needs to be discarded. In order to minimise the opportunities for diversion, the following steps should be taken:

- When a dose is given, the nearest suitable dose volume should be selected, so that the minimum volume has to be discarded.
- When only part of the contents of a vial or ampoule are used, the entry made in the ward CD record book (CDRB) should clearly show how much was given to the patient and how much was discarded. For example, if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, “2.5mg given and 2.5mg wasted “ This should be witnessed by a second registered nurse, midwife or registered health professional who should also sign the record. If a second registered nurse or midwife is not available, the transaction can be witnessed by another registered health professional (e.g. doctor, pharmacist, ODP, pharmacy technician)
- The CD to be discarded should be rendered irretrievable by emptying into a sharps bin. This should be witnessed by another person. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled “contains mixed pharmaceutical waste and sharps - for incineration”.
- Some health care organisations may wish to provide denaturing kits for use on wards to destroy CDs that have been used for patients. This may be appropriate where large quantities of CDs are used and where the volume of part-used vials, ampoules, syringes and infusion bags may be high. A risk assessment should be carried out before a decision is made whether denaturing kits should be available on the wards. This is particularly relevant within children’s services. Where denaturing kits are provided, an SOP should be developed for this practice.
- The person who administers the dose is responsible for making the entry and this must be done immediately or as soon as is practicable after administration.
- The destruction should be recorded in the CDRB by both the person who undertook the destruction and the witness.

5.7.2 Child protection

Parents who are substance misusers sometimes bring CDs on to hospital premises. Health care organisations may wish to consider whether, on a parent’s request, they may want to store the CD in the CD cupboard and the parent requests the nurse when a dose is required. These CDs should be clearly labelled and kept separate from other CDs.

Where there are concerns about potential diversion, staff should be alert that this may be a possibility and if appropriate, reference should be made to the appropriate child protection services

5.8 Controlled drugs for midwives

A registered midwife may possess diamorphine, morphine, pethidine and pentazocine in her own right so far as is necessary for the practice of her profession.

5.8.1 Acquisition of CDs by midwives

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.

5.8.1.1 The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate).

5.8.1.2 The order must specify the name and occupation of the midwife, the purpose for which the controlled drug is required and the total quantity to be obtained.

5.8.1.3 Supplies of pethidine, pentazocine, morphine and diamorphine may be obtained from a hospital pharmacy. The pharmacist who makes the supply must ensure that medicines are only supplied on the instruction of an authorised person.

5.8.1.4 The pharmacist must retain the midwife's supply order for two years.

5.8.2 Storage and records

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.

5.8.2.1 Once medicines are received by midwives working in the community or self-employed midwives, they become the responsibility of the midwife, and should be stored safely and securely.

5.8.2.2 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.

5.8.2.3 Administration of Controlled Drugs by midwives should be in accordance with locally agreed procedures.

5.8.2.4 A record of administration of the CDs should also be kept in the woman's records.

5.8.3 Returns and disposal

When a midwife is in possession of CDs that are no longer required they should be returned to the pharmacy from which they were obtained, another pharmacy or to an Appropriate Medical Officer, who should make arrangements for safe disposal. A record of the return should be made in the midwife's Controlled Drugs Register.

5.8.3.1 Surplus or expired CD stock held by a midwife may only be destroyed by the midwife in the presence of an authorised witness. (see paragraph 7.15.1.1) The method of disposal should be in accordance with current Home Office guidance, Waste Management Regulations and Environment Agency guidance. CDs for destruction should be denatured using an approved method (see 7.15.3) and sent for incineration; they should not be disposed of in the sewerage system. The midwife could also return surplus or expired stock to a pharmacy for safe destruction and onward disposal.

5.8.3.2 When a Schedule 2 CD has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current Regulations. Where possible a member of the family should witness the destruction. A record of the destruction should be made in the midwife's record. Some health care organisations may wish to provide denaturing kits to midwives to ensure safe destruction.

5.8.3.3 Controlled drugs that have been prescribed for a woman by her doctor for use in her home confinement are her own property and are not the midwife's responsibility. Even when no longer required they should not be removed by the midwife, but the woman should be advised to return them to the community pharmacy for destruction. Where this is not possible, the midwife should obtain the patient's agreement in writing before removing it from the patient's home and returning it to a pharmacy for safe disposal, on behalf of the woman.

5.9 Discrepancies and diversion

The balances in the Controlled Drug record books (CDRBs) should always tally with the amounts of CDs in the cupboard. If they do not, the discrepancy must be reported, investigated and resolved. It is important to remember that a discrepancy can indicate misuse.
There should be a procedure for dealing with discrepancies and this should specify the arrangements for reporting and investigation.

In the first instance the following should be carefully checked:

- All requisitions received have been entered into the correct page of the register
- All CDs administered have been entered into the CDRB
- Items have not been accidentally put into the wrong place in the cupboard
- Arithmetic to ensure that balances have been calculated correctly

If the error or omission is traced, the registered nurse, midwife or ODP in charge should make an entry in the CDRB, clearly stating the reason for the entry and the corrected balance. This entry should be witnessed by a second nurse, midwife, ODP, pharmacist, pharmacy technician or doctor. Both persons will sign the CDRB.

If no errors or omissions are detected then the discrepancy should be reported to the Chief Pharmacist and the Accountable Officer without delay and a local incident form completed in line with the health care organisation's policy or procedure for reporting incidents.

5.10 Illicit substances

The health care organisation should take advice from the local police and if necessary the Serious and Organised Crime Agency concerning appropriate procedures for dealing with patients who bring suspected illicit substances into the hospital.

6 Management of CDs in in-house operating theatres

Contents of this chapter:

This chapter describes measures for management of CDs in in-house operating theatres and departments where CDs are used primarily by anaesthetists.

6.1 Accountability and responsibility

6.1.1 Accountable individuals

The registered nurse, midwife or Operating Department Practitioner (ODP) in charge of an operating theatre or theatre suite is responsible for the safe and appropriate management of CDs.

The registered nurse, midwife or ODP in charge can delegate control of access (i.e. key-holding) to the CD cupboard to another, such as a registered nurse or an ODP. A nurse or ODP may then only remove controlled drugs from the cupboard and/or return them to the cupboard on the specific authority of either the registered nurse, midwife or ODP in charge or doctor. However, legal responsibility remains with the registered nurse, midwife or ODP in charge. Whilst the task can be delegated, the responsibility cannot. (The person to whom the task has been delegated is still professionally accountable for his/her actions)

Similar considerations apply to requisitioning and checking of CDs.

6.1.2 Standard operating procedures

The health care organisation should ensure that all the procedures for the management of CDs in in-house operating theatres and recovery wards are included in written standard operating procedures and that all staff, including anaesthetists, are aware of these procedures. It is good practice to ensure all staff who have to work in accordance with SOPs have an opportunity to comment on draft versions before the SOPs are finalised to ensure ownership. This is especially important in areas where many different staff are working perhaps for only a small part of their working week.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The AO remains accountable for the safe management of CDs

6.2 Controlled Drug stocks

There should be a list of CDs to be held in each theatre as stock items. The contents of the list should reflect current patterns of usage of CDs in the theatre and should be agreed between the pharmacy technician or pharmacist responsible for stock control of medicines in the theatre and the Operating Department manager, appropriate medical staff and the registered nurse, midwife or ODP in charge.

The list should be modified if practices change and should be subject to regular review at agreed intervals.

6.3 Requisitioning of CDs

The registered nurse, midwife or ODP in charge is responsible for the requisitioning of controlled drugs for use in the theatre. The registered nurse, midwife or ODP in charge is not permitted to requisition controlled drugs from wholesalers.

The registered nurse, midwife or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or registered ODP. However, legal responsibility remains with the registered nurse, midwife or ODP in charge.

Wherever practicable different persons should be responsible for requisitioning and receipt of Controlled Drugs.

Requisitions must comply with the requirements for suitable stationery, authorised signatories and content set out in paragraph 4.3 Requisitioning of controlled drugs

Health care organisations should consider the introduction of a pharmacy-led top-up scheme as an efficient way of maintaining adequate stock levels of CDs in theatres

6.4 Receipt of controlled drugs

When CDs are delivered to a theatre or theatre suite they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of CDs). A local procedure should define the persons who are permitted to receive CDs and the way in which messengers identify them. As a

matter of good practice the receiving person should not normally be the same person who ordered the controlled drugs.

Receipt of CDs in theatre should follow the provisions set out in section 4.4 Receipt of controlled drugs

6.5 Storage of controlled drugs

The storage arrangements for CDs in theatres should conform to the general provisions set out in section 4.5 Storage of controlled drugs

Where robotic storage cabinets are installed in theatre areas, access should be controlled by secure passcodes and the software should provide an auditable record of transactions.

It may also be necessary to install separate, secure, CD fridges for aseptically-prepared parenteral doses of CDs.

6.6 Record-keeping

The records for CDs in theatres should conform to the general provisions set out in section 4.7 Record-keeping

There should be a separate CD record book for each theatre.

In addition to the standard CD record books, some health care organisations may wish to stipulate the use of stationery that permits more detailed records of CDs issued, administered and destroyed.

6.7 Controlled drug stock checks

The stock balance of all controlled drugs entered in the CD Record Book should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out.

The registered nurse, midwife or ODP in charge is responsible for ensuring that stock checks are carried out and recorded. It may be appropriate for pharmacy staff to carry out a stock check at regular intervals but this should be at least every six months.

Controlled drug stock checks should follow the provisions set out in paragraph 4.8 Controlled drug stock checks

6.8 Archiving of controlled drug records

The archiving of CD records in theatres should conform to the general provisions set out in paragraph 4.9 Archiving of controlled drug records

6.9 Prescribing of controlled drugs

The anaesthetist on duty is usually responsible for prescribing CDs but other prescribers may also be involved. Nurse Independent Prescribers may also be responsible for prescribing or administration of diamorphine and morphine for post-operative pain. In future - subject to the outcome of public consultation and Ministerial approval - Nurse Independent Prescribers may be able to prescribe other CDs in addition to the ones they are already able to prescribe and pharmacist independent prescribers may also be able to prescribe CDs.

Where separate charts are used e.g. epidural charts, anaesthetic charts they should be cross-referenced on the patient's main medicines chart.

Prescribing of CDs should follow the general provisions set out in paragraph 4.10 Prescribing of controlled drugs.

6.10 Administration

The practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the theatre CD record book, should be avoided. [See *Controlled Drugs in Perioperative Care. January 2006. www.aagbi.org*] An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed and witnessed. E.g. if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted* "

- The CD to be discarded should be rendered irretrievable by emptying the contents of the ampoule or vial into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "mixed pharmaceutical waste and sharps – for incineration".
- Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.
- A record of administration should be made on the appropriate chart immediately after administration by the person who administered the CD. This should include the identity of the person, the dose administered and the time of administration.

6.11 Patient-controlled analgesia

There should be a local procedure for all aspects of the management of patient controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (for example, pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the CDRB

- Arrangements for documentation when the patient is moved from theatre to wards
- Arrangements for recording administration
- Arrangements for disposal of surplus CDs

6.12 Returning controlled drugs to the pharmacy

The arrangements for return of CDs to the pharmacy should conform to the provisions set out in paragraph 4.15 Returning controlled drugs to the pharmacy

In general, time-expired or CDs that are otherwise unfit for use should be returned to pharmacy for safe disposal.

Surplus stock should be returned to the pharmacy as described in section 4.15

6.13 Disposal of controlled drugs

The disposal of CDs in theatres should conform to the general provisions set out in section 4.16 Disposal of controlled drugs in wards and departments

Unused part-doses should be destroyed promptly and witnessed by a registered nurse or registered ODP.

- The CD to be discarded should be rendered irretrievable by emptying the contents of the ampoule/vial into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled, “contains mixed pharmaceutical waste and sharps – for incineration”.
- If large quantities of part used CDs are being added to sharps bins, some health care organisations may wish to provide denaturing kits for use to theatres to destroy CDs that have been used for patients. A risk assessment should be carried out before a decision is made whether denaturing kits should be available in theatres. Where denaturing kits are provided to theatres, an SOP should be developed for this practice.

7 Management of CDs in hospital pharmacies

Contents of this chapter:

This chapter deals with the management of CDs in hospital pharmacies and between pharmacies and other departments or health and/or social care bodies.

7.1 Accountability and responsibility

The chief pharmacist is responsible for the safe and appropriate management of CDs in the pharmacy. Day-to-day management of CDs (for example, receipt into and issue from dispensary stock) in the pharmacy will normally be delegated to a suitably-trained, competent registered pharmacy technician or pharmacist. However, legal responsibility for CDs remains with the Chief Pharmacist.

7.2 Security of CDs

The pharmacy should have standard operating procedures (SOPs) covering each of the aspects of the safe management of CDs such as ordering, receipt, record-keeping etc.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each one should be clearly marked with the date of issue and review date.

SOPs should be approved by the Accountable Officer or by the person to whom he has delegated this task. The AO remains finally accountable for all the systems for the safe management of CDs. (See Appendix 2)

7.3 Ordering and receipt

Ordering of CDs from wholesalers and manufacturers and receipt of CDs should follow the principles of good procurement. Local procedures should ensure that there is a robust audit trail and that the opportunities for diversion are minimised.

7.3.1 Ordering

Routine orders to wholesalers and manufacturers for Controlled Drugs for stock are usually placed electronically. Some health care organisations may, following a risk assessment, make a decision to store paper records.

Stock levels should be determined by need and kept to a minimum, but should not be so low that there is a danger of running out at busy periods. This will normally be calculated by the pharmacy stock management system. It may be necessary to increase stock levels temporarily when it is anticipated that there may be a greater demand, for example, during long holiday breaks.

7.3.2 Receipt

There should be a local procedure for the receipt of CDs into the pharmacy department. The procedure should ensure the security of CDs and should be auditable. It should include:

- Who should sign for receipt
- How the goods should be checked (e.g. matching of the details on the delivery note to the goods) and appropriate stock control documentation completed
- Any tamper-evident seals on packs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks.
- If when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the pharmacy should contact the supplier.
- The action to be taken if the item received is incorrect
- Arrangements for storage of incorrect items for return, if appropriate
- Specifications of the entry required in the register including who should make the register entry and whether a witness is required

7.3.2.1 It is good practice to record receipt at the first opportunity, and in any event no later than 24 hours after receipt.

7.3.2.2 As a matter of good practice the balance in stock should be checked and recorded as correct by the person making the entry

7.3.2.3 The stock must be put away into the appropriate section of the Controlled Drug cabinet promptly.

7.4 Storage

Pharmacy CD cabinets must comply with the Misuse of Drugs (Safe Custody) Regulations

This is a minimum security standard and may not be sufficient for areas where there are large amounts of CDs in stock at a given time and/or there is not a 24-hour staff presence or easy control of access. . In this case a security cabinet that has been evaluated against the SOLD SECURE standard SS304 (See www.soldsecure.com) should be used.

7.5 Issuing of CDs to wards and departments

There should be a local procedure for the issuing of CDs to wards and departments. The procedure should ensure the security of the CDs and should be auditable. It should include:

- The procedure for checking that the requisition is valid (complete and signed by an authorised signatory – names should be detailed in local SOPs)
- The mechanism for correcting an incomplete or inaccurate requisition
- Specifications of the details required on labels (see below)
- Specification of entry required in the register including who should make the register entry
- Whether a witness is required. The decision as to whether a witness is required or not should be made following a risk assessment.
- Arrangements for transfer of the CDs to the ward or department

7.5.1 Electronic systems

Where electronic systems for the requisitioning of CDs are introduced, safeguards in the software should be put in place to ensure that:

- Only individuals who are authorised to requisition CDs from the pharmacy can do so
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

7.5.2 Labelling of CDs

There should be a standardised procedure for labelling CDs.

The label should state:

- Drug name, form and strength
- Quantity
- “Store in CD cupboard”
- Department / ward name or number
- Date of issue
- Expiry date if dispensed from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g., Oramorph).
- “Keep out of reach and sight of children”
- Address of pharmacy

Depending on local circumstances, some pharmacies may also wish to add

- The requisition number
- The batch number of a product that has been dispensed from bulk

Each carton, syringe or bottle must be labelled individually. In addition, labels may also be placed on outer wrappers or containers.

7.6 Record-keeping

7.6.1 CD registers

Pharmacy department are required to keep registers of receipts and supplies of Schedule 2 CDs.

7.6.1.1 Register entries must be made in consecutive, chronological order. The entry must be made on the day when the drug is received or supplied, or on the next day. Entries must be in ink or be otherwise indelible

7.6.1.2 If a mistake is made the entry should not be crossed out, deleted, obliterated or defaced; liquid paper must not be used. If an error is found, it must be bracketed and accompanied by a clearly recognised signature; the balance shown should be accurate and easily read. A footnote should be added to explain the alteration.

7.6.1.3 The following staff may complete the CD register:

- Any registered pharmacist under their own authority
- Any competent member of Pharmacy staff, ideally a regulated healthcare professional under the authority of the chief pharmacist, provided this is included in the SOP
- Any person who is being trained by a competent member of pharmacy staff, such as a trained technician or a pharmacist, under their supervision. The supervisor should countersign entry

7.6.1.4 Each drug form and strength should be on a different page in the register. The drug name, form and strength must be written at the top of the page. An index should be kept at the front of the register.

7.6.1.5 For CDs supplied, the register entry must also include:

- Date of transaction
- Name and address of person/department supplied
- Licence or authority of person/department supplied
- Amount supplied
- Form in which supplied
- Name of patient, if individually dispensed

7.6.1.6 For CDs received into stock the following details must be recorded in the CD register:

- The date on which the CD was received
- The name and address of the supplier, e.g. wholesaler, pharmacy
- The quantity received
- The name, form and strength of the CD

7.6.1.7 The stock balance in the register should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system. The frequency of such checks should be determined locally following a risk assessment.

7.6.1.8 The 2001 Regulations were amended in July 2006 to make clear that the record keeping requirements of the CD Regulations are a minimum and do not prevent any person required to keep a register from including additional relevant information.

7.6.1.9 The 2001 Regulations were further amended in 2007. The changes will come into force **from 1 February 2008**. The “Form of the Register” as specified in Schedule 6 of the 2001 Regulations will be removed and replaced with a requirement to maintain, where appropriate, a CD Register with specified headings/ titles by which to capture mandatory fields of information. Additionally in the CD Register or separate part of the CD Register used for each class of drug, separate pages (in paper) or sections for each strength and form of CD will be required. The name, strength and form of the drug must be entered at the top of each page or section and the mandatory fields of information recorded under the specified headings.

7.6.1.10 The headings/fields of information are largely unaltered from the previous requirements. Entries in respect of drugs supplied and drugs obtained may be made on the same page or separate pages within the CD Register as follows:

7.6.1.11 For CDs supplied the register entry must also include:

- Date supplied
- Name/address of person or firm supplied

- Details of authority to possess, prescriber or licence holder details
- Quantity supplied

7.6.1.12 For CDs obtained the following details must be recorded in the CD Register
- Date supply received
- Name and address from whom received
- Quantity received

7.6.1.13 The Misuse of Drugs And Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 can be found at http://www.opsi.gov.uk/si/si2007/20072154.htm and Home Office guidance is available at http://www.knowledgenetwork.gov.uk/HO/circular.nsf/79755433dd36a66980256d4f004d1514/457714a5c1da7f8480257338003f2479?OpenDocument

7.6.2 Liquid preparations

Discrepancies can arise with liquids CDs as a result of manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations should be recorded and the running balance adjusted. Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle. It may be appropriate to carry out volume checks at regular intervals. When spillages occur, every effort should be made to find another person who can verify that the spillage has occurred and this should be recorded and initialed by both the person making the spillage and the second person, if there is one.

7.6.3 Computerised registers

The definition of a CD Register in the 2001 Regulations was amended in November 2005 to allow (not require) the register to be held on a computerised system. The Regulations require that entries in computerised registers must be attributable and auditable.

If the CD register is held in computerised form, the following should be put in place:

- Safeguards should be incorporated in the software to ensure the author of each entry is identifiable
- Entries cannot be altered at a later date
- All entries are attributable to an individual making the entry
- A log of all data entered is kept and can be recalled for audit purposes
- Adequate backups are made
- Systems are in place to minimize the risk of unauthorized access to the data

For further details see The Misuse of Drugs and the Misuse of Drugs (Supply to Addicts) (Amendment) Regulations 2005. (SI 2864) www.opsi.gov.uk/si/si2005/20052864.htm.

7.7 Checks of CD stocks performed by pharmacy staff

7.7.1 Checks of CD stocks held in the pharmacy

All controlled drugs in the pharmacy should be checked periodically e.g. every three months. The frequency of such checks should be determined, following a risk assessment, by the pharmacist with operational responsibility for managing CDs and this should be included in an SOP.

7.7.1.1 This check may be undertaken by any competent person approved by the pharmacist with operational responsibility for CDs, the store supervisor, or by a trainee working under their direct supervision and this should be included in an SOP.

7.7.1.2 The check should be recorded in the register by means of signature, date and an appropriate entry, for example, "*Stock checked. Balance correct*".

7.71.3 Some health care organisations may also wish to stipulate periodic checks of CDs by pharmacy managers who do not routinely work in the dispensary.

7.7.2 Checks of CD stocks held in wards, theatres or departments

All stocks of CDs held in wards and departments should be checked by a pharmacist or pharmacy technician at least every three-six months and at other times when requested by the ward or department manager.

7.7.2.1 The stock check procedure should cover the following:

- A check that the levels of drugs in stock tally with the balances recorded in the CDRB.
- A check of a sample of CD requisition copies to ensure that they have been entered correctly in the CDRB
- A review of the security and quality of record keeping
- Checking and updating (if required) of the list of authorised signatories for CD requisitions
- A check for exceptional usage of CDs
- A check of the physical security arrangement for the storage of CDs, CD stationery and the key-holding policy.

7.7.2.2 The procedure may also include a check of patients' own CDS held on the ward at the time

7.7.2.3 A record of the stock check should be made clearly in ink in the CD Record Book. The entry should be signed and dated by the person who carried it out.

7.7.2.4 Local documentation may be designed to record all aspects of the CD stock-check procedure (e.g. ward CD inspection report forms) for audit purposes.

7.8 Discrepancies

The balance recorded in the hardcopy register and/or, where relevant, the electronic register/pharmacy stock control system, should be reconciled against the stock of every product in the CD cupboard. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate misuse. The discrepancy should be reported to a senior pharmacist within one working day.

There should be a careful check of transactions in the register and in the stock control system to trace an error or omission.

If an error is traced then a register entry should be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and the witness.

If no error or omission can be traced the Chief Pharmacist and Accountable Officer should be informed. They should decide on what action to take.

7.9 Archiving of controlled drug records

Every requisition, order or private prescription on which a Controlled Drug is supplied must be preserved by the Pharmacy department for a minimum period of two years from the date on which the last delivery under it was made. Although the mandatory period for keeping requisitions is two years, health care organisations may wish to store them for longer periods, as cases often come to court at a much later date.

The time periods for archiving CD documentation are:

Requisitions	2 years
Registers and CDRBs	2 years from last entry
Extemporaneous preparation worksheets	13 years
Aseptic worksheets (adult)	13 years
Aseptic worksheets (paediatric)	26 years
External orders and delivery notes	2 years
Prescriptions (inpatients)	2 years
Prescriptions (outpatients)	2 years
Clinical trials	5 years minimum (may be longer for some trials)
Destruction of CDs	7 years

Future Regulations may increase the period of time for the storage of records. Readers are advised to refer to Department of Health and RPSGB websites for up-to-date information

7.10 Supply to outpatients and discharge patients

For outpatient prescriptions being given directly to the patient or their representative:

Patients or their representatives may be asked to provide evidence of identity when collecting CDs.

From July 2006, there has been a requirement for persons asked to supply CDs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the dispenser:

- May request evidence of that person's identity and
- May refuse to supply the medicine if he is not satisfied as to the identity of the person

Where it a healthcare professional acting in his professional capacity on behalf of the patient, the dispenser:

- Must obtain the person's name and address
- Must, unless he is acquainted wit that person, request evidence of that person's identity; but
- May supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The new requirement placed on the dispenser therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.

From 1st February 2008, it will be a requirement to record the following information in the CD register for Schedule 2 CDs supplied on prescription:

- Whether the person who collected the drug was the patient, the patient's representative or a health care professional acting on behalf of the patient
- If the person who collected the drug was a health care professional acting on behalf of the patient, that person's name and address
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory).

And whether evidence of identity was provided by the person collecting the drug.

The patient's date of birth may be used as a second check if necessary.

Depending on local circumstances, some health care organisations may wish to stipulate that outpatients and discharge patients should not just sign for receipt of a dispensed item but also for receipt of a specific number of doses.

7.11 Supply to external units or other health and social care bodies

A hospital pharmacy can only supply to an external organisation if it is registered with the Society or holds a wholesale dealers licence.

Before making a supply to an external unit or other health and social care body, the hospital should satisfy itself that the recipient may lawfully possess controlled drugs. A private hospital that is not maintained by voluntary funds or by a registered charity needs a Home Office Licence to hold CD stocks. The supplier should only make supply if such a licence is held. (For further information see the Home Office see Drug Laws and Licensing pages: www.drugs.gov.uk/drugs-laws/licensing/)

Where the external unit or body is a designated body as defined in the Regulations it will have an Accountable Officer and the AO must ensure that his designated body has up-to-date SOPs for the use and management of CDs.

Where a service level agreement (SLA) is drawn up for a service to supply CDs to an external body or unit, the SLA should specify the SOPs that are to be followed (i.e. those of the provider or purchaser).

If the external unit/body does not have an AO then the SLA should specify that the SOPs of the provider organisation should be followed in relation to CDs.

7.11.1 Supply to external units (i.e. other health and social care bodies)

Other health and social care bodies include community hospitals, hospices, prisons or ambulance trusts.

The other health and social care body must comply with the legislation for controlled drugs and should also follow the guidance in this document.

7.11.2 Written agreement (service level agreement)

When the hospital pharmacy is providing services to another health and social care body the details should be specified in a written agreement or contract (service level agreement).

In relation to controlled drugs the following points should be included in the written agreement (service level agreement):

- What is to be supplied; stock controlled drugs and /or patients' own controlled drugs (e.g., for external units where patients are encouraged to self-administer their own medicines including CDs).
- An outline of the ordering and supplying processes and the documentation used.

- The arrangements for obtaining supplies of CDs in emergencies and out of hours. (These should comply with DH guidance, guidance "Securing proper access to medicines in the out of hours period" and ensure that there is a complete, documented and coherent audit trail from stock room to patient. (See – www.out-of-hours.info/downloads/ short_medicines_guidance.pdf)
- Specification of responsibilities and accountability in relation to controlled drugs medicines management including governance arrangements.
- A statement that the pharmacy department and receiving unit produce SOPs for the ordering and issuing processes including transit at their respective facilities. This should include the different ordering processes for stock controlled drugs and patient-specific controlled drugs (see below).
- It is good practice for the other health and social care body to ensure that its SOPs have been reviewed and agreed by a pharmacist. (Note that not all external organisations employ a pharmacist).
- That both parties review each others' SOPs to ensure a consistent, safe and auditable management process for CDs.
- If two different Accountable Officers cover the issuing and receiving units then each the Accountable Officer should take responsibility for the SOPs relating to his organisation.
- That the representatives from the issuing pharmacy and the other health and social care body meet on a regular basis to discuss any problems and agree any remedial action to resolve these and review services.
- That the issuing pharmacy and receiving unit conduct audits across the interface to ensure that process and procedures follow the SOPs and that any gaps in the systems, processes and procedures are identified and rectified. It is good practice to provide the Accountable Officer(s) with the audit reports and action plans.

Further information about the content of service level agreements can be found at http://www.nelm.nhs.uk/Record%20Viewing/viewRecord.aspx?id=573380

7.11.3 Ordering of stock controlled drugs by another health and social care body

Ordering of controlled drugs must comply with the current Misuse of Drugs Regulations.

Where a pharmacist is employed, the purchase of controlled drugs must be under his or her direct supervision and this includes authorising orders to suppliers. Where no pharmacist is employed a registered medical practitioner must countersign orders for controlled drugs raised by the senior registered nurse on duty.

All stock controlled drugs should be ordered as stock items only and contain no patient names.

7.11.3.1. Arrangements when the hospital pharmacy provides a supply service only

An authorised registered nurse who must be the person or acting person in charge of a hospital or nursing home can complete the controlled drugs requisition book and sign this order. The stock controlled drugs order must contain:

- Name, address and ward or department name from the other health and social care body,
- Name, formulation, strength and quantity (whole pack sizes) of the CD
- Date the order was made.
- Purpose for use
- Signature of the authorised registered nurse
- Countersignature of a doctor (or dentist) who is employed or engaged at the other health and social care body

The medical doctor will sign the order as an independent verification that the controlled drugs ordered are to be used within the requesting ward or department within the other health and social care body. The medical doctor who countersigns the CD order form is not responsible for management and accountability for the controlled drugs within the ward or department of the other health and social care body. This responsibility falls within the remit of the registered nurse or midwife in charge.

There are other corporate bodies where a medical doctor is requesting controlled drugs and is also responsible for the management of the controlled drugs within the department of other corporate body.

7.11.4 Requisitioning patients' own controlled drugs for patients by other health and social care body

7.11.4.1 Requisitioning from a hospital pharmacy

Patients' own controlled drugs can be ordered for either use within an inpatient unit (e.g. as part of self-administration scheme) or as discharge medication.

Where a hospital pharmacy dispenses CDs prescribed on FP10s for patients in an external facility, the same principles for maintaining an audit trail as for other controlled drugs should be followed e.g. from dispatch, during transport and on receipt at the external unit.

Note: In order to be able to dispense FP10s, a hospital pharmacy would first need to be registered with the Royal Pharmaceutical Society of Great Britain

It is acceptable for the other health and social care body to use locally designed and approved discharge (TTO, TTA) prescription forms for prescribing a patient's discharge medication. The hospital pharmacy should manage these TTA prescription forms in the same way as they would internal TTA prescription forms.

A full audit trail should be maintained when transferring the dispensed CDs to the other health and social care body.

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

7.11.4.2 Requisitioning from a community pharmacy

A similar arrangement of using locally designed and approved prescription forms can be used when a community pharmacy is supplying patient-specific controlled drugs under a written agreement to an inpatient unit (or prison) such as a community hospital, prison or hospice.
(It should be noted that these prescriptions are not private prescriptions but part of a system for supplying patients/prisoners with appropriate dispensed and labelled medicines including controlled drugs on discharge from that unit or as part of a patient self-administration scheme).

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug

7.12 Transfer of CDs

At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties.

Wherever possible, the drug must be transported in a secure, lockable container and a suitable delivery document completed to provide a full audit trail.

See paragraph 5.2 - Transfer of controlled drugs

7.13 Controlled drugs returned from wards

There should be a local procedure for the management of CDs returned from wards.

See also paragraph 4.17 – Returns to Pharmacy

7.14 Production and Quality Control

Where pharmacy production units are preparing products the contain CDs, then the same governance arrangements for safe use should apply as for elsewhere in the

organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

7.15 Disposal/destruction

See also section 4.16 disposal of controlled drugs in wards and departments

Unwanted CDs should be denatured and disposed of in a pharmacy.

CDs should be disposed of in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used again.

There should be a local policy for disposal of CDs and this policy must be in accordance with current Home Office guidance, Waste Management Regulations and Environment Agency guidance. The methods used for denaturing should be in accordance with RPSGB guidance.

(See - RPSGB guidance [Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales. *www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf*)

The Environment Agency (EA), which covers England and Wales, has decided that it is not in the public interest to expect pharmacies to obtain a waste management license for denaturing CDs as this is seen by the EA as a 'low risk' activity. The EA emphasises, however, that it may amend or revoke its position at any time and will continue enforcement in all circumstances where activity has or is likely to cause pollution or harm to health. It is therefore essential that local policies and procedures for destruction of CDs not only ensure effective destruction but also protect the environment and workers and others within the pharmacy.

7.15.1 Destruction of stock controlled drugs

Any pharmacy held stock of obsolete, expired or unwanted Schedule 2 CDs not returned by patients, that requires destruction can only be destroyed in the presence of an authorised person authorised by the Secretary of State for Health in England and Wales and the Secretary of State for Scotland.

7.15.1.1 Authorised witnesses in England, Scotland and Wales currently include inspectors of the Royal Pharmaceutical Society, and police constables.

Other people authorised to witness the destruction of controlled drugs in England are:

- Chief Dental Officer of the Department of Health or a Senior Dental Officer to whom authority has been delegated;
- Supervisors of Midwives appointed by the Local Supervising Authority;
- Senior officers in an NHS Trust who report directly to the Trust Chief Executive and who have responsibility for health and safety, security or risk management matters in the Trust;

- Chief Executives of NHS Trusts;
- A Primary Care Trust Chief Pharmacist or Pharmaceutical/Prescribing Adviser who reports directly to the Chief Executive or to a Director of the Primary Care Trust;
- A Registered Medical Practitioner who has been appointed to the Primary Care Trust Professional Executive Committee or equivalent;
- The Primary Care Trust Board Executive member with responsibility for Clinical Governance or Risk Management;
- Medical Director of a Primary Care Trust;

In addition, any officer of the healthcare organisation who, for this purpose, is directly accountable to an executive officer of the organisation to witness the destruction of CDs. This could include Strategic Health Authority pharmacy leads, Medical Directors, and clinical governance leads. However, these individuals must be independent of the routine supply and administration of controlled drugs.

An amendment to The Misuse of Drugs Regulation 2001 which came into force on 16 August 2007, permits the Accountable Officer to authorise people or groups of people, within their own organisations, to witness the destruction of controlled drugs in compliance with these regulations.

Accountable Officers should not be authorised to witness destruction as one of the criteria for Accountable Officers is their independence from day-to-day management of controlled drugs.

Further guidance can be found at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_078034

7.15.1.2 Until they can be destroyed, obsolete, expired and unwanted stock CDs requiring safe custody, according to arrangements appropriate to their schedule, must be kept segregated from other CDs in the CD cupboard. Stock CDs awaiting destruction should be clearly marked in order to minimise the risk of errors and inadvertent supply.

7.15.1.3 When stock Schedule 2 CDs are destroyed, the following details must be entered into the CD register:

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed
- Date of destruction
- Signature of the authorised person in whose presence the drug was destroyed

7.15.1.4 It is good practice for the person carrying out the destruction to also sign against this record.

7.15.2 Destruction of controlled drugs returned by patients

These are CDs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used by the patient or their representative to the pharmacy.

Controlled Drugs that have been returned by patients do not form part of the pharmacy stock and can be destroyed without the presence of an Authorised Person.

7.15.2.1 Although recording of patient-returned CDs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2001, as amended, The Controlled Drugs (Supervision of Management and Use) Regulations 2006 require Standard Operating Procedures to be in place for maintaining a record of the CDs specified in Schedule 2 that have been returned by patients These Regulations came into force 1st January 2007 in England.

7.15.2.2 A record of CDs returned by patients should be kept and a record of destruction should be made. As a matter of good practice, destruction should be witnessed, preferably by a pharmacist or pharmacy technician.

7.15.2.3 The record of destruction should be made somewhere other than the CD register – for example in a separate book designated for that purpose. It is recommended that the following details are recorded:

- Date of return of the CDs
- Name, quantity, strength and form of the CDs
- Role of the person who returned the CDs (if known)
- Name and signature of the person who received the CDs
- Patient's name and address (if known)
- Names, positions and signatures of the person destroying the CDs and the witness
- Date of destruction
- Comments, for example, expiry date, name of patient and ward

A suggested recording form is available at http://www.rpsgb.org.uk/pdfs/restooldestrcd.pdf

7.15.2.4 Controlled drugs requiring safe custody awaiting destruction should be stored in the controlled drug cabinet separately from pharmacy stock controlled drugs.

7.15.2.5 Destruction of controlled drugs should occur with sufficient frequency (for example, monthly) to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment.

7.15.3 Methods of disposal for CDs

CDs for destruction should be placed in suitable waste containers which are then sent for incineration and should not be disposed of in the sewerage system. The containers containing waste should be labelled, " *contains pharmaceutical waste – for incineration*".

All CDs in Schedule 2 and those CDs in Schedule 3 that are subject to safe custody requirements (temazepam, diethylpropion, buprenorphine and flunitrazepam) must rendered irretrievable (e.g. by denaturing) before being placed into waste containers

7.15.3.1 Wherever practicable, CD denaturing kits should be used to denature CDs. Where this is not possible or practical other methods of denaturing may be used.

7.15.3.2 Details of suitable methods for destruction of CDs in different dosage forms can be found in, *Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales*. (*www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf*) and it is strongly recommended that these methods are used. The low risk position provided by the Environment Agency is based on the use of appropriate and safe methods, which do not pose risks to the environment or human health.

7.15.3.3 Small amounts of CDs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable by emptying the contents into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

The other option would be to use denaturing kits following a risk assessment. Where denaturing kits are used, their use should be included in an SOP.

This type of situation is most likely to arise when products are prepared extemporaneously. In these circumstances, the CD has already been issued to the extemporaneous preparation area or aseptic preparation area and is no longer part of the pharmacy CD stock. A full audit trail should be maintained. The worksheet should show the amount used and the amount wasted, for example: "2.5ml used 0.5ml wasted".

As a matter of good practice, the emptying of the part dose into the sharps bin should be witnessed and recorded on the worksheet. Both people should sign the worksheet.

8 Staff training for management of CDs

The Accountable Officer is responsible for ensuring that members of staff who are involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training to enable them carry out their duties.

Staff should receive appropriate training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs and then regularly thereafter. The frequency of training should be determined locally..

Staff should be informed and, if necessary receive additional training when SOPs are revised or amended and when new CD products or systems are introduced.

Glossary of terms

Accountable Officer	Officer in a health care organisation who is responsible for the safe and effective use of and management of controlled drugs. Appointment required by Controlled Drugs (Supervision and Management of Use) Regulations 2006.
Administer	To give a medicine either by introduction into the body, whether by direct contact with the body or not, (eg orally or by injection) or by external application (eg application of an impregnated dressing). There are specific definitions in meds legislation as follows: “external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations; "parenteral administration" means administration by breach of the skin or mucous membrane;
Controlled Drugs (CDs)	The drugs listed in schedules 1-5 of the Misuse of Drugs Regulations 2001 (as amended). Drugs listed in different schedules are subject to differing levels of control but all are Controlled Drugs.
CD record book (CDRB)	Bound book in which records are made of CDs received and administered in wards, theatres and departments.
CD register	A “register” as specified in the Misuse of Drugs Regulations 2001 (as amended) means either a bound book, which does not include any form of loose leaf register or card index, or a computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.
Designated body/bodies	Health care organisations e.g. hospital trusts defined in the Controlled Drugs (Supervision and Management of Use) Regulations 2006.
Discrepancy	Difference between the amount shown in the register or record book and the amount that is physically present.
Dispense, dispensing	Dispensing of Controlled Drugs Preparation (including compounding, dissolving, diluting, packing and labelling) and giving out of medicines for individual patients
Diversion	Removal of CDs for unauthorised use; theft
Duty Pharmacist	Senior pharmacist on duty for the time being
Health care organisations	Organisations responsible for the delivery of healthcare.

	Includes NHS Trust hospitals and independent hospitals.
Local Intelligence Network	A network established by the Accountable Officer of a Primary Care Trust for sharing information regarding the management and use of controlled drugs
"May"	Used in this document in connection with recommendations concerned with good practice if they are relevant to local circumstances
MDR	Misuse of Drugs Regulations – Regulations made under the Misuse of Drugs Act (1971)
"Must"	Used in this document in connection with legal requirements e.g. "records of schedule 2 CDs received and supplied by a pharmacy must be kept in a CD register."
Order	To order Controlled Drugs To make a formal order for Controlled Drugs. Can only be done by some one who is entitled to be in possession of CDs (as defined in current MDR). Must be addressed to a suitable pharmaceutical supplier.
Patient Group Directions (PGD).	Written directions from a senior doctor (or dentist) and a senior pharmacist and a representative of the appropriate organisation giving registered nurses, pharmacists and other specified health professionals a general authority to supply and administer specified medicines to patients, who are not individually identifiable, in specified clinical situations.
PCA	Patient-controlled analgesia
PODs	Patient's own drugs. In this context - CDs brought into the hospital by the patient on admission
Prescribe	Prescribing is the ordering of a medicine for an individual patient. In medicines legislation, certain medicines may be supplied only in accordance with a prescription by a doctor, dentist or other appropriate practitioner, and which meets the conditions specified in the Prescription Only Medicines (Human Use) Order 1997. The term has however become commonly used to describe authorising - by means of an NHS prescription - the supply of any medicine (Prescription Only Medicine, Pharmacy or General Sales List medicine) at public expense to a named patient;
Registered nurse, midwife or ODP in charge	The registered nurse, registered midwife or registered operating department practitioner (ODP) who is in charge for the time being (senior registered nurse, midwife or ODP on duty) and is therefore responsible for management of Controlled Drugs
Registered operating department practitioner	Operating Department Practitioner whose name is on the register of the Health Professions Council and should be a member of the College of Operating Department Practitioners
Registered pharmacist	Person registered in the register of pharmacists maintained by the Royal Pharmaceutical Society of Great Britain
Registered pharmacy technician	Pharmacy technician whose name is on the register held by the Royal Pharmaceutical Society of Great

	Britain
Relevant persons	People who • are directly or indirectly concerned with the provision of health care and/or • carry on activities that involve or may involve the supply or administration of controlled drugs • work for a designated body
Requisition	To requisition Controlled Drugs To make a formal, written request for a supply of a Controlled Drug for use in a ward or department. The requisition must be signed by an authorised signatory. Requisitions are usually made in stationery designed specifically for that purpose. These books are sometimes called “Controlled Drug Order books”
Responsible body	Bodies listed in regulation 22 of the Controlled Drugs (Supervision f Management and Use) Regulations 2006. Includes: PCT, NHS Trust, NHS Foundation rust, Strategic Health Authority, Healthcare Commission, Commission for Social Care Inspection.
Senior Assistant Technical Officer	In this context, a member of the pharmacy staff who has received in-house training for specific duties. Not a pharmacy technician.
Service Level Agreement (SLA)	Written agreement between two parties that specifies the service to be provided
“Should”	Used in this document in connection with recommendations concerned with good practice
Standard Operating Procedure (SOP)	A standard operating procedure specifies in writing what should be done, when, where and by whom in order to manage safely and accountably any set of processes, in this case around the total management of CDs.
Supervisor of midwives	A person appointed by the local supervising authority to exercise supervision over midwives in its area in accordance with rule 11(1) of the Nursing and Midwifery Council (Midwives) Rules 2004 (SI 2004/1764) www.hmso.gov.uk
Supply	Supply of Controlled Drugs Making a supply against a signed order or a prescription. In medicines legislation, “supply” is described as “retail sale or supply in circumstances corresponding to retail sale”.
Transcribe	To copy the details of one document on to another
TTOs (TTAs)	“To take outs” (also known as TTAs, “To take aways”). Medicines that patients take with them at the time of discharge

Appendix 1: Legislation for the management of CDs

Misuse of Drugs Act 1971

The Misuse of Drugs Act (MDA) 1971 and its Regulations provide the statutory framework for the control and regulation of controlled drugs. The primary purpose of the MDA is to prevent misuse of 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 to the Act.

Misuse of Drugs Regulations 2001 (MDR)

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 the website for the Office of Public Information (www.opsi.gov.uk)

Schedule 1 (CD Licence)

Schedule 1 drugs include hallucinogenic drugs such as coca leaf, lysergide and mescaline. Production, possession and supply of drugs in this Schedule are limited, in the public interest, to research or other special purposes. Only certain persons can be licensed by the Home Office to possess them for research purposes. Practitioners (e.g. doctors, dentists and veterinary surgeons) and pharmacists may not lawfully possess Schedule 1 drugs except under licence from the Home Office.
The drugs listed in Schedule 1 have no recognised medicinal use although Sativex© (a cannabis based product) 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**.**

Schedule 2 CDs may be manufactured or compounded by a licence holder, a practitioner, a pharmacist or a person lawfully conducting a retail pharmacy business acting in their capacity as such.

A pharmacist may supply schedule 2 CDs to a patient only on the authority of a prescription in the required form issued by an appropriate clinician.

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 (DN - not all prescribers can prescribe Schedule 2 CDs).

Nurse Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer some CDs for specific conditions and routes of administration

Record-keeping
There is a statutory requirement for pharmacy departments to keep a register for Schedule 2 CDs and this register must comply with the requirements of the Misuse of Drugs Regulations 2001.
As a matter of good practice wards and departments should also keep a register for Schedule 2 CDs
Midwives must keep register for the Schedule 2 CDs that they are allowed to carry.

A licence is required to import or export drugs in Schedule 2.

Destruction
The destruction of Schedule 2 CD stock must only take place in the presence of an appropriately authorised person. (For further information on appropriately authorised persons)

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 and can be stored on the open dispensary shelf. Exceptions are flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

Record keeping
There is no legal requirement to record transactions involving Schedule 3 CDs in a CD register.
Invoices must be retained for a minimum of two years.
Schedule 3 CDs are subject to full import and export control.

Destruction
The requirements for destruction do not apply unless the CDs are manufactured by the individual.

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.

Drugs in Part 1 (CD Benzodiazepines) are subject to full import and export control and a Home Office licence is also required for the importation and exportation of substances in Part 2 (CD Anabolic steroids) unless the substance is in the form of a medicinal product and is for administration by a person to themselves.

All substances in Schedule 4 are exempt from safe custody requirements, with destruction requirements only applying to importers, exporters and manufacturers.

Prescription-writing requirements for these CDs do not apply, except those requirements laid out in the Medicines Act 1968. CD registers do not need to be kept for Schedule 4 drugs, although records should be kept if such CDs are compounded, or if a licensed person imports or exports such drugs (see Regulation 22 of the Misuse of Drugs Regulations 2001).

Schedule 5 (CD Invoice)

Schedule 5 contains preparations of certain CDs (e.g. codeine, pholcodine, morphine), which are exempt from full control when present in medicinal products of low strengths, as their risk of misuse is reduced.

There is no restriction on the import, export, possession, administration or destruction of these preparations and safe custody Regulations do not apply.
Preparations containing not more than 0.1% cocaine are no longer exempt from prohibitions on import, export and possession.
A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any CD in Schedule 5.
Invoices must be retained for a minimum of two years.

Misuse of Drugs (Safe Custody) Regulations 1973

The Safe Custody Regulations 1973 impose controls on the storage of controlled drugs. The degree of control depends on the premises within which the drugs are being stored.

All schedule 2 and some schedule 3 CDs should be stored securely in accordance with the Misuse of Drugs (Safe Custody) Regulations. 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

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.

Medicines Act 1968

This Act, and Regulations made under the Act, sets out the requirements for the legal sale, supply and administration of medicines. It also allows certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, enable midwives to supply and/or administer diamorphine, morphine, pethidine or pentazocine. A number of health care professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups, but not all, are permitted to possess, supply or administer CDs in accordance with a PGD under Misuse of Drugs legislation

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 1st January 2007.

These set out the requirements for certain NHS bodies and independent hospitals 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 co-operate with each other, including with regard to sharing of information, about concerns about the use and management of controlled drugs, and set out arrangements relating to powers of entry and inspection.

Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007

This Regulation amends the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Safe Custody) Regulations to:

Give authority to Accountable Officers, within their organisation, to nominate persons or groups of persons to witness the destruction of CDs.

Allow ODPs to order, possess and supply CDs.

Remove the requirement to maintain a Controlled Drugs Register in a prescribed format.

Change the record keeping requirements for CDs.

Reschedule Midazolam from Schedule 4 to Schedule 3 of the 2001 Regulations.

Appendix 2: The Accountable Officer

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision and Management of Use) Regulations 2006; www.opsi.gov.uk. (hyperlink to www.opsi.gov.uk/si/si2006/uksi_20063148_en.pdf). Further detail is also given in, Safer Management of Controlled Drugs: Guidance on Strengthened Governance Arrangements. January 2007 (www.dh.gov.uk) [http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4141666&chk=AtnhRu]

The following paragraphs provide a summary of the main provisions.

Persons who may be appointed as Accountable Officers

Each healthcare organisation must appoint an Accountable Officer. This should be a senior executive officer of the organisation (i.e. an Executive Director or someone who reports directly to an Executive Director).

The Accountable Officer should not be personally involved in the routine prescribing, supply, administration or disposal of controlled drugs. An organisation can have an Accountable Officer who has occasional need to handle CDs (for example, in emergencies), but if this is the case, their use of CDs should be open to the scrutiny of another senior member of the organisation or Accountable Officer of another trust. Individuals such as Chief Nurses, Medical Directors and Chief Pharmacists can be appointed as Accountable Officers if they meet these criteria. Accountable Officers should call on other Accountable Officers if a conflict of interest arises.

The organisation's controlled drugs policy should specify the person whom staff should approach if they have concerns about the practice of their Accountable Officer.

The Accountable Officer for the secondary care should liaise with the PCT Accountable Officer (or an Accountable Officer on behalf of a cluster of PCTs) who will act as the hub of the network and assist with setting up and managing the network.

Responsibilities of the Accountable Officer

In discharging his responsibilities, an Accountable Officer must have regard to best practice in relation to the management and use of controlled drugs.

The Accountable Officer must:

- Secure the safe and effective use and management of controlled drugs within local organisations subject to his/her oversight (i.e. the organisation and those with which it contracts).

- Appropriate systems for the safe management of controlled drugs must be established, operated and reviewed periodically.
- All arrangements must comply with relevant statutory requirements
- Adequate ands up-to-date standard operating procedures must be in place for the management and use of controlled drugs
- Ensure that adequate destruction and disposal arrangements are made for controlled drugs
- Appropriate arrangements for securing the safe destruction and disposal of controlled drugs must be established and operated
- Ensure monitoring and auditing of the management and use of controlled drugs within the organisation and take action where necessary. The following must be in place:
    - Systems to alert the Accountable Officer to complaints or concerns involving the management of controlled drugs
    - An incident reporting system to capture untoward incidents involving the management or use of controlled drugs
- Arrangements for analysing and responding to untoward incidents involving the management or use of controlled drugs
- Ensure that individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training. Arrangements must be in place for relevant individuals:
    - to receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs
    - to be informed when any local standard operating procedures for controlled drugs are subsequently reviewed or amended
- Monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance. The Accountable Officer must, where appropriate, provide for the following
    - Recording concerns raised in relation to the management or use of controlled drugs by a relevant individual
    - Assessing and investigating concerns raised regarding the management or use of controlled drugs by a relevant individual
    - Determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers should be shared with a responsible body.

The Accountable Officer should be aware that unusually high usage of some CDs or unusually high numbers of breakages could indicate misuse.

The Accountable Officer in Acute care should also monitor prescriptions that are written in hospital but dispensed in the community.

- Maintain a record of concerns regarding relevant individuals. Such records may be paper-based or electronic. The Accountable officer must:
    - Establish and operate appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a relevant individual. This must include a system to ensure that access to such records is limited to the Accountable Officer, his staff and others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.
    - Ensure that adequate records are compiled, which must include (but not be limited to), as appropriate:
        - the date on which the concern was made known to the accountable officer;
        - dates on which the matters that led to the concern took place;
        - details regarding the nature of the concern;
        - details of the relevant individual in relation to whom the concern was expressed;
        - details of the person who, or body which, made known the concern;
        - details of any action taken by the designated body in relation to the concern;
        - the assessment of whether information in relation to the concern should be disclosed to another responsible body
        - if information regarding the concern is disclosed to another responsible body, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.

- Assess and investigate concerns
    - Establish and operate appropriate arrangements for assessing and investigating concerns about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual
    - Take appropriate action if there are well-founded concerns
    - Establish and operate appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards designated body, a relevant individual, appear to be well-founded.
- Establish arrangements for sharing information
    - Establish and operate appropriate arrangements for ensuring the proper sharing of information, by his designated body with other

responsible bodies regarding the management and use of controlled drugs
    - Provide a quarterly report to the PCT Accountable Officer lead for the Local Intelligence Network
    - Cooperate with other organisations including the Healthcare Commission, the Commission for Social Care Inspection, the NHS Business Service Authority and the police as circumstances require.

- Participate in the Local Intelligence Network

Appendix 3: Accountable Officer (acute care) - sample job description

Job Title: Controlled Drugs Accountable Officer

Reports to: The chief executive or an executive director (for NHS trusts) or for independent hospitals reporting to the registered manager.

Accountable for: Management of the safe and effective use and management of controlled drugs within the organisation

Key Working Relationships

- Members of the Local Intelligence Network
- Accountable officers of other organisations
- Performance management departments
- Information managers
- Chief Pharmacists and medical directors
- Local representative committees
- Organisations with statutory roles of inspection
- The Media or media officers within the organisation

Job Purpose

Statement of Job Purpose:

To safeguard patient safety by monitoring the use of controlled drugs within their organisation and take action where necessary.

Responsibilities

Ensures monitoring arrangements are in place for management and use of controlled drugs

Establishes mechanisms for the very quick sharing of intelligence and joint action in cases of urgency (where patient safety is at risk or evidence may be destroyed)

Ensures clear routes, such as the NHS complaints system, are available for any healthcare professional, patient or member of the public to raise matters of concern, within a framework of appropriate confidentiality. This includes routes for healthcare professionals to self-refer if they have concerns about their own performance.

Establishes mechanism for further investigation of causes for concern.

Determines whether a targeted inspection is required and those who should be involved (May do this as part of a decision-making group)

Determines remedial action to be taken (e.g. no action required, support to healthcare professional or organisation, referral to regulatory body, RPSGB, Healthcare Commission, CSCI, police) (May do this as part of a decision-making group)

Ensures remedial action is followed through (though police services retain responsibility for determining whether the evidence for possible criminal behaviour warrants a criminal investigation with a view to subsequent prosecution)

Plays full part in intelligence network (bearing in mind the need to separate the investigative and decision-making functions).

Encourages good practice and development in management of controlled drugs

Key Tasks

Data analysis – prescribing data, supply details etc
Analysis of organisational self-assessment

Determines remedial action to be taken

Maintains a record of remedial actions that have been instigated with expected dates of completion. Contacts people concerned to check actions are on target. Refers poor progress back into the review mechanism.
Approves all policies and procedures within the organisation covering controlled drugs to ensure compliance with legislations, centrally issued guidance and governance.

Regularly review internally reported incidents involving controlled drugs to identify any specific trends or additional requirement for control measures within the organisation.

Personnel Specification

Title of Post:	**Accountable Officer**

Category	**Essential/Desirable[2]**	**Description[1]**
Knowledge and Experience	Essential	
	Desirable	• Have previous experience in the handling of CDs. • Knowledge of controlled drugs legislation
Skills and Abilities	Essential	
	Desirable	• Be familiar with organisational processes for clinical governance and performance management
Training and Education	Essential	• Be a registered doctor, pharmacist or nurse with no restrictions placed upon them by their regulatory body with regards to controlled drugs Or • Be a senior manager with experience of clinical governance
	Desirable	
Other Requirements	Essential	
	Desirable	• Be remote from current practice involving CDs (except in emergencies) including, prescribing, administering or disposing of CDs

Appendix 4: Useful contacts

British Medical Association
BMA House
Tavistock Square
London
WC1H 9JP
Tel: 0207 387 4499
Fax: 0207 383 6400
Website: www.bma.org.uk

Commission for Social Care Inspection
33 Greycoat Street
London
SW1P 2QF
Tel: 0207 979 2000
Fax: 0207 979 2111
Website: www.csci.org.uk

Community Practitioners' and Health Visitors Association
33-37 Moreland Street
London
EC1V 8HA
Tel: 0207 505 3000
Website:
www.amicustheunion.org/cphva/

Council for Healthcare Regulatory Excellence
1st Floor, Kierran Cross
11 Strand
London
WC2N 5HR
Tel: 0207 389 8030
Fax: 0207 389 8040
Website: www.chre.org.uk

Department of Health
Richmond House
79 Whitehall
London
SW1A 2NS
Tel: 0207 210 4850
Website: www.dh.gov.uk

Dispensing Doctors' Association
Low Hagg Farm
Starfitts Lane
Kirbymoorside
North Yorkshire
YO62 7JF
Tel: 01751 430835
Fax: 01751 430836
Website: www.dispensingdoctor.org

General Medical Council
Regent's Place
350 Euston Road
London
NW1 3JN
Tel: 0845 357 3456
Website: www.gmc-uk.org

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG
Tel: 0207 448 9200
Website:
www.healthcarecommission.org.uk

Home Office Drugs Licensing Branch
2 Marsham Street
Tel: 0207 035 0483

Safer Management of Controlled Drugs: a guide to good practice in secondary care (England)

London
SW1P 4DF
Website: www.drugs.gov.uk

Home Office Drugs Legislation and Enforcement Unit
2 Marsham Street
London
SW1P 4DF
Tel: 0207 035 0464
Website: www.homeoffice.gov.uk

Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Tel: 0207 084 2000
Fax: 0207 084 2353
Website: www.mhra.gov.uk

National Clinical Assessment Service (part of the National Patient Safety Agency)
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Tel: 0207 062 1620
Fax: 0207 084 3851
Website: www.ncas.npsa.nhs.uk

National Patient Safety Agency
4-8 Maple Street
London
W1T 5HD
Tel: 0207 927 9500
Website: www.npsa.nhs.uk

National Pharmacy Association
Mallinson House
38-42 St Peter's Street
St Albans
Hertfordshire
AL1 3NP
Tel: 01727 832161
Fax: 01727 840858
Website: www.npa.co.uk

National Prescribing Centre
The Infirmary
70 Pembroke Place
Liverpool
L69 3GF
Tel: 0151 794 8134
Fax: 0151 794 8139
Website: www.npc.co.uk (Internet)
www.npc.nhs.uk (NHSNet)

National Treatment Agency
8th Floor, Hercules House
Hercules Road
London
SE1 7DU
Tel: 020 7261 8801
Fax: 020 7261 8883
Website: www.nta.nhs.uk

NHS Clinical Governance Support Team
1st Floor
St. Johns House
30 East Street
Leicester
LE1 6NB
Tel: 0116 295 2000
Fax: 0116 295 2001
Website: www.cgsupport.nhs.uk

Nursing and Midwifery Council

23 Portland Place
London
W1B 1PZ

Tel: 020 7637 7181
Fax: 020 7436 2924
Website: www.nmc-uk.org

Pharmaceutical Services Negotiating Committee

59 Buckingham Street
Aylesbury
Buckinghamshire
HP20 2PJ

Tel: 01296 432 823
Fax: 01296 438 427
Website: www.psnc.org.uk

Prescription Pricing Division

Bridge House
152 Pilgrim Street
Newcastle-upon-Tyne
NE1 6SN

Tel: 0191 232 5371
Fax: 0191 232 2480
Website: www.ppa.org.uk

Prescribing Support Unit

The Health and Social Care
Information Centre
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

Tel: 0113 254 7041
Fax: 0113 254 7097
Website**:** www.psu.nhs.uk

Appendix 5: Patient information

NHS Direct

The NHS Direct website has developed a Common Health Question about CDs specifically to inform the public. It is entitled 'What is a controlled drug (medicine)?' and is available at **www.nhsdirect.nhs.uk/articles/article.aspx?articleId=1391.** The text defines a CD in legal terms, how the Regulations apply to them and directs patients to information about requirements for traveling abroad.

Embedded in the text of this Common Health Question is a template leaflet with supporting information that has been agreed with the DH as suitable text for a leaflet available at the time of dispensing. The leaflet can be downloaded and used to prepare local practice leaflets.

If patients require further information about travel or other general health advice they can be advised to contact NHS Direct by telephone on 0845 4647 or visit the NHS Direct website at **ww.nhsdirect.nhs.uk**.

Medicines Guides

Medicine Guides provide a source of information for members of the public who are looking for information about individual medicines that is up-to-date, reliable and easy to understand. Medicine Guides are being developed as part of the Medicines Information Project which aims to provide people with information about medicines, conditions and the different treatment options available.

The Medicine Guides on CDs can be found on the www.medicines.org.uk website which is published by Datapharm Communications. There is a link to the NHS Direct Common Health Question within each Guide. Guides for the CDs that have been published to date can be accessed at http://medguides.medicines.org.uk/cd.

The current list available is:

- Cyclimorph
- Cyclizine / Morphine
- Diamorphine
- Filanarine
- Minijet morphine
- Morphgesic
- Morphine
- MST
- MXL
- Oramorph
- Sevredol
- Zomorph

Appendix 6: Contributors

The following individuals and organisations contributed to the design and content of this guidance:

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Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

Safer Management of Controlled Drugs

A guide to good practice in secondary care (Northern Ireland)

Updated August 2012 mainly in respect of Misuse of Drugs Regulations amendments (Original version published 2009)

Safer Management of Controlled Drugs
A guide to good practice in secondary care (Northern Ireland)

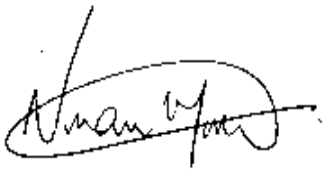
Foreword

There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care. However, as a result of the actions of Harold Shipman, and the recommendations arising from the Shipman Inquiry, significant changes have been made in both governance and legislation surrounding the use and management of controlled drugs.

In implementing better controls which support professionals and encourage good practice we must ensure that patients have appropriate and convenient access to controlled drugs to meet their clinical needs.

This document has been developed for secondary care in Northern Ireland and is designed to provide guidance on good practice for the management of controlled drugs. It seeks to take account of the important legislative changes and developments in professional practice and accountability.

In commending this guidance to secondary care organisations I wish to acknowledge the multidisciplinary input and the extent and quality of the responses to the consultative draft. The application of this guidance will, I believe, make a significant contribution to improving governance and patient safety.



Norman C Morrow

Contents

Changes to text in the August 2012 updated version include

Section 2.1: Table 1: BNF style of indication of CD schedule included
Section 2.2: Inclusion of Pharmacist Independent Prescribers
Section 2.2.1: Updating of PGD information
Section 2.2.2 and 5.8: Updating regarding Midwives
Section 4.10.5: Updating regarding Nurse Independent Prescribers; deletion of Table specifying Controlled Drugs and indications
Section 4.10.6: Updating regarding Pharmacist Independent Prescribers
Section 5 Index: Correction – omit "PGDs" include "Illicit Substances"
Section 6.1.1: Removal of word "doctor" to reflect lawful responsibility for controlled drugs in operating theatres
Section 7.9: Updating retention periods as in *Good Management Good Records*
Section 7.11: Implications of repeal of section 10(7) of the Medicines Act 1968
Glossary: Definitions -"Relevant Persons" changed; "Prescribe" updated
Appendix 1: Updating of description of legal provisions
Throughout document: Consequential page renumbering. Hyperlinks updated. Obsolete references to RPSGB removed.

1 Executive summary

The purpose of this guidance is to promote the safe and effective use of controlled drugs in healthcare organisations providing secondary care. The new strengthened governance arrangements for controlled drugs and legislative changes that flow from the Government response to the fourth report of the Shipman Inquiry impose significant new responsibilities on healthcare organisations. This guidance sets out how these changes apply to the use and management of controlled drugs in secondary care settings and will support healthcare professionals and organisations in implementing the new arrangements. It has been developed from an original document published by the Department of Health. [*Safer Management of Controlled Drugs A guide to good practice in secondary care*, 17th October 2007, www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079618]. That document emerged following widespread consultation with key stakeholders, including representation from Northern Ireland, chaired by the Royal Pharmaceutical Society of Great Britain. The work of the Royal Pharmaceutical Society is acknowledged and appreciation is expressed to the Department of Health for permission to use the original document as the basis for the Northern Ireland version. The document, as revised for Northern Ireland, has been reviewed by professionals here. A list of those who contributed to the design and content of the guidance appears at Appendix 6.

The Northern Ireland response to the Shipman Inquiry's Fourth Report was set out in *Improving Patient Safety – Building Public Confidence.* [27th Nov 2006, www.dhsspsni.gov.uk/improving_patient_safety_-_building_public_confidence.pdf] The response identified ways for strengthening the current systems for managing controlled drugs to minimise the risks to patient safety of the inappropriate use of controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. However, as the Inquiry recognised, there have been major advances in the therapeutic use of controlled drugs in the last few years. Controlled drugs are now an essential part of modern clinical care. Strengthened controls must be implemented in a way that supports professionals and encourages good practice in the use of these important medicines when clinically required by patients.

Improving Patient Safety – Building Public Confidence set out a substantial programme of work to improve the management of controlled drugs. As a result, a number of changes affecting the prescribing, record keeping and destruction of controlled drugs were introduced through amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 (SR 2002 No. 1) (MDR). The Health Act 2006 provided for regulations to be made relating to strengthened governance and monitoring arrangements for controlled drugs. The Health Act 2006 is primary legislation and applies to the whole of the UK. The Regulations developed under the Health Act differ to some extent in the different administrations. The Northern Ireland legislation, The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, came into operation on 1st October 2009.

This document is intended to provide guidance on good practice for the management of controlled drugs in secondary care in Northern Ireland. It aims to set out robust

systems for procuring, storing, supplying, transporting, prescribing, administering, recording, and disposing safely of controlled drugs, whilst at the same time helping to ensure appropriate and convenient access for those patients that require them. It is not designed to provide advice on the clinical choice or use of controlled drugs. However, individual professional organisations provide a range of advisory services to their members (see Appendix 4). Although this guidance is focussed on the safe use and management of controlled drugs in secondary care settings, patients and healthcare professionals will move and work across care sectors. The DHSSPS has published a guide to good practice in the management of controlled drugs in primary care which is available on its website.

This guidance recognises developments that have taken place to modernise working practices in recent years: the changing roles of healthcare professionals, the need to ensure optimal use of skill mix and the key contribution of pharmacy technicians and other healthcare professionals, for example, Operating Department Practitioners, and seeks to clarify how these fit within the existing legal framework for controlled drugs.

Controlled Drugs are those listed in Schedule 2 to the Misuse of Drugs Act 1971. For practical purposes they are classified in Schedules 1 to 5 to the Misuse of Drugs Regulations (Northern Ireland) 2002 according to the controls necessary for their governance. Within this document the emphasis is placed on those contained in Schedule 2 to the MDR, as these are subject to the highest levels of control. On occasions, healthcare organisations choose to manage non-controlled drugs and controlled drugs in other Schedules in the same way as Schedule 2 controlled drugs to ensure a higher level of governance. This is a matter for local decision and does not form part of this guidance.

This guidance is intended to build on and augment the advice provided in two previous documents: *Use and Control of Medicines - Guidelines for safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services* (April 2004, www.dhsspsni.gov.uk/use_control_of_medicines.pdf) and *The Safe and secure handling of medicines: A team approach* (the Revised Duthie Report), (March 2005, www.rpharms.com/support-pdfs/safsechandmeds.pdf - commended by the DHSSPS and endorsed by the Pharmaceutical Society of Northern Ireland). Neither of these documents is concerned specifically with controlled drugs and readers are also encouraged to refer to them for guidance on more general aspects of medicines management.

This guidance has been organised into chapters dealing with the legislative requirements, governance arrangements and guiding principles. Chapters that deal with the management of controlled drugs in wards, operating theatres and pharmacies follow. A chapter on special situations has been included to accommodate a number of situations that do not obviously fit elsewhere. There is also a brief chapter on training. Separate sections have not been written for each hospital department, because the requirements for the safe management of controlled drugs do not differ between medical and surgical wards or general wards and high-dependency wards. Although the guidance includes most of the commonly-encountered situations, inevitably, as practice continues to develop, users will on occasions find gaps or points which fit uneasily with their situation. In such cases it is hoped that the principles listed in Chapter 3 will provide a basis for policy formulation.

The style of the *Revised Duthie Report* (March 2005) has been adopted. The term “should” has been used for recommendations that relate to good practice and “must” for those governed by legal requirements. Recommendations have also been

inserted that "may" be followed as matters of good practice, if they are relevant to local circumstances.

This document has been designed both for those who are involved in management of controlled drugs in secondary care and for those who are responsible for ensuring that controlled drugs are managed appropriately in their organisations or in their part of the organisation. It should be of value in a number of settings where controlled drugs are used including:

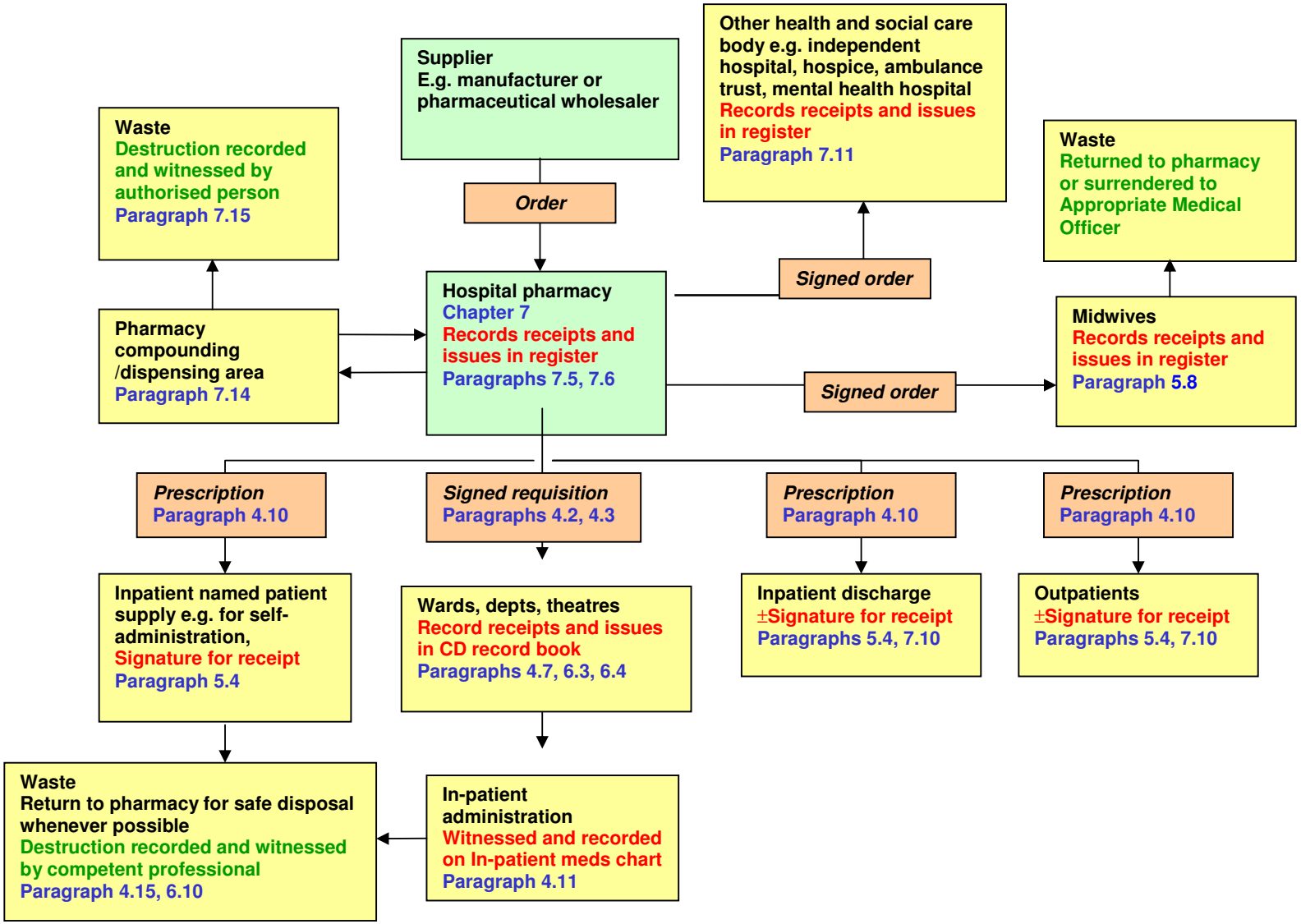
- Pharmacies
- Hospital wards and departments including operating theatres
- Midwifery units
- Other health and social care bodies

This guidance should also be of value in a number of settings outside the secondary sector such as hospices, community hospitals, rehabilitation centres and other similar organisations where controlled drugs are used and managed.

Questions relating to the management of controlled drugs may often be resolved by referring to guidance published by professional bodies. Advice may also be sought from the Pharmaceutical Advice and Services Branch of the DHSSPS. Appendix 4 includes professional organisations that provide advice for their members. Regular reference should be made to the following websites to check for up-to-date information:

The Department's website: www.dhsspsni.gov.uk
The Department of Health website: www.dh.gov.uk/controlleddrugs
The Home Office websites:
www.homeoffice.gov.uk and www.drugs.gov.uk/drugslaws
The Pharmaceutical Society of Northern Ireland website: www.psni.org.uk
The Royal Pharmaceutical Society website www.rpharms.com as available

Figure 1 The product journey – Controlled drugs in secondary care



2 Legislation and governance arrangements

Legislation

2.1 Legislative framework for controlled drugs

The management of controlled drugs is governed by the Misuse of Drugs Act (1971) and its associated Regulations.

Additional statutory measures for the management of controlled drugs are laid down in the Health Act (2006) - and its associated legislation the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

The relevant legislation and guidance is summarised briefly in Appendix 1. Readers are encouraged to refer to the relevant websites for detailed, up-to-date information.

The legal requirements pertaining to the different Schedules of controlled drugs are summarised in Table 1. Schedule 1 drugs have been omitted from the table because drugs in this group have virtually no therapeutic uses.

Table 1: Summary of legal requirements applying to controlled drugs in Schedules 2, 3, 4 & 5 of the Misuse of Drugs Regulations

Schedule (refers to schedules of the Misuse of Drugs Regulations)	**Schedule 2** Includes – Opioids, (e.g. diamorphine, morphine, methadone), major stimulants (eg amphetamines) remifentanil secobarbital	**Schedule 3** Includes minor stimulants, temazepam, buprenorphine, flunitrazepam, midazolam, barbiturates except secobarbital	**Schedule 4 pt I** Includes benzo-diazepines	**Schedule 4 pt II** Includes anabolic steroids, clenbuterol, growth hormones	**Schedule 5** Includes low strength opioids
Designation	CD or CD2 (BNF)	CD No Reg or CD3 (BNF)	CD Benz or CD4-1 (BNF)	CD Anab or CD4-2 (BNF)	CD Inv
Safe custody	Yes, except secobarbital	Yes, with certain exemptions (see MEP, details below)	No	No	No
Prescription requirements – apply to OP and discharge prescriptions	Yes	Yes, except temazepam	No	No	No
CD Requisitions necessary?	Yes	Yes	No	No	No
Records to be kept in CD register	Yes	No	No	No	No
Pharmacist must ascertain the identity of the person collecting CD	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbital for epilepsy*	Yes*	Yes*	Yes*
Validity of prescription	28 days from the appropriate date**	28 days from the appropriate date**	28 days from the appropriate date**	28 days from the appropriate date**	6 mths (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	

Table adapted from (previous edition) Medicines, Ethics and Practice Guide (MEP). Further information can be found in the MEP, in the British National Formulary (www.bnf.org/bnf/) and on PSNI website www.psni.org.uk/documents/600/GuideLegalRequirements+MedsHumanUseControlledDrugs.pdf

* Up to a quantity sufficient for 5 days treatment
** "Appropriate date" means the later of the date on which the prescription was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied.

2.2 Supply and administration of controlled drugs

There are a number of mechanisms for the supply and administration of controlled drugs in secondary care. Controlled drugs can be

- Prescribed by a doctor, dentist, nurse independent prescriber or pharmacist independent prescriber
- Supplied and administered under Patient Group Directions
- Supplied and administered by a midwife

Certain restrictions apply to each of these routes of supply.

2.2.1 Supply and/or administration of controlled drugs under Patient Group Directions

A Patient Group Direction (PGD) allows a range of specified healthcare professionals to supply and/or administer a medicine directly to a patient with an identified clinical condition within an identified set of circumstances without the patient first seeing a prescriber. Individual professionals who are to work within a PGD must be named on it and have received appropriate training for operating the PGD.

Named nurses, paramedics and other specified health professionals can supply and administer certain controlled drugs in restricted circumstances in accordance with a PGD and the additional requirements of the Misuse of Drugs (Amendment) (No.3) Regulations (Northern Ireland) 2003 (SR 2003 No. 420) www.uk-legislation.hmso.gov.uk/sr/sr2003/nisr_20030420_en.pdf (See also for background information the *Home Office Circular 049 / 2003. Controlled Drugs Legislation - Nurse Prescribing And Patient Group Directions*.) www.homeoffice.gov.uk/about-us/corporate-publications-strategy/home-office-circulars/circulars-2003/049-2003/

There are currently only limited circumstances in which certain controlled drugs may be administered or supplied under a PGD by certain named health professionals. These are:

- Registered nurses and pharmacists (but no other healthcare practitioners) can supply or offer to supply diamorphine or morphine where administration of such drugs is required for the immediate, necessary treatment of sick or injured persons in accordance with a PGD.
- Registered nurses, pharmacists, paramedics, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists, radiographers, occupational therapists and orthotists or prosthetists can supply or administer any schedule 4 or 5 controlled drug or midazolam in accordance with a PGD, except

- The anabolic steroids in Schedule 4, part 2
- Injectable formulations for the purpose of treating a person who is addicted to a drug

2.2.2 Midwife's exemptions

Registered midwives may administer parenterally, a number of specified controlled drugs in the course of their professional practice. These are:

- Diamorphine
- Morphine
- Pethidine hydrochloride

(See - The Human Medicines Regulations 2012 (SI 2012 No. 1916). The Misuse of Drugs Regulations (Northern Ireland) 2002 (SR 2002 No. 1))

(See also paragraph 5.8 Controlled drugs for midwives)

Governance arrangements

2.3 Accountability and responsibility

At local level, all healthcare organisations or designated bodies {see the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009; (SR 2009 No. 225) available at the website www.legislation.gov.uk} are accountable, through the Accountable Officer (AO, see below), for ensuring the safe management of controlled drugs. In Northern Ireland, the following are designated bodies:

- The Regional Health and Social Care Board
- A Health and Social Care Trust
- The Northern Ireland Ambulance Service Trust
- An Independent Hospital

All designated bodies, including HSC Trusts, and independent healthcare organisations, are accountable for the monitoring of all aspects of the use and management of controlled drugs by all healthcare professionals whom they employ, with whom they contract or to whom they grant practice privileges. This will be done through normal governance arrangements such as analysing baseline data and clinical governance visits (for example by clinical governance leads).

Where one organisation provides services to another, responsibility for governance arrangements should be specified in the contract (or service level agreement). Reporting should be to the Accountable Officer for the organisation that is receiving the service. (Once the Controlled drugs have been received responsibility for them passes to receiving organisation.) In setting up and reviewing these governance arrangements, the AO will want to

pay particular attention to and prioritise key areas of risk which will include the interface with other health and social care providers.
Each designated body may also consider establishing a Controlled Drug Review Group. Such groups may be part of the arrangements that AOs are required to have in place for analysing and responding to adverse incidents involving the management or use of controlled drugs.

2.4 The Accountable Officer

The Accountable Officer is responsible for all aspects of the safe and secure management of controlled drugs in his organisation. This includes ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigation of concerns and incidents related to controlled drugs.

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations Northern Ireland) 2009; (SR 2009 No.225) and a summary of the main provisions is provided at Appendix 3 of this document. See also 'Safer Management of Controlled Drugs: A Guide to Strengthened Governance Arrangements in Northern Ireland' in the Accountable Officer section of the Department website www.dhsspsni.gov.uk

2.5 Monitoring and inspection

Regular inspections of hospital pharmacies related to the management of controlled drugs are conducted by inspectors from the DHSSPS. Core activities examined include secure storage facilities, statutory and informal record keeping and the arrangements made for robust audit trails.

2.6 Standard operating procedures

Each of the activities that relate to controlled drugs, regardless of where in the organisation they occur, should be described in a standard operating procedure (SOP). SOPs for controlled drugs became mandatory in Northern Ireland, rather than good practice, with the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, which came into operation on 1st October 2009. SOPs are particularly important if tasks are delegated to others. For example, issue and receipt of stock controlled drugs in the pharmacy may be delegated to a competent pharmacy technician. However, responsibility lies with the pharmacist who authorised the activity.

SOPs must be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived.

All staff who are involved in the prescribing, supplying, administering or disposing of controlled drugs must be familiar with the SOPs.

The standard operating procedures must, in particular, cover the following matters:

(a) who has access to the controlled drugs;

(b) where the controlled drugs are stored;

(c) security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;

(d) disposal and destruction of controlled drugs;

(e) who is to be alerted if complications arise; and

(f) record keeping, including:

(i) maintaining relevant controlled drugs registers under misuse of drugs legislation,

(ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2002 (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

SOPs within a health care organisation should be formally approved by the Accountable Officer for that organisation. This task may be delegated to a suitably qualified person, however, the final responsibility lies with the Accountable Officer.

Additional Information

A comprehensive list of drugs included within the Schedules to the Misuse of Drug Regulations 2002 can be accessed at:

- www.legislation.gov.uk/
- Home Office www.homeoffice.gov.uk/publications/alcohol-drugs/drugs/drug-licences/controlled-drugs-list?view=Binary
- Medicines and Healthcare products Regulatory Agency (MHRA) www.mhra.gov.uk

Some of the following sites may contain material which may be useful to inform practice in Northern Ireland.

- DHSSPS will also publish guidance for the safer management of controlled drugs in primary care. www.dhsspsni.gov.uk/safer-management-of-controlled-drugs-a-guide-to-good-practice-in-primary-care-version-2-july-2011.pdf
- The Care Quality Commission is responsible for overseeing the management of controlled drugs by healthcare organisations in England and a section of the website is dedicated to controlled drugs: www.cqc.org.uk
- Department of Health Controlled Drugs pages: www.dh.gov.uk/controlleddrugs
- Pharmaceutical Society of Northern Ireland www.psni.org.uk

- Pharmaceutical Services Negotiating Committee (PSNC) www.psnc.org.uk
- Nursing and Midwifery Council (www.nmc-uk.org). Standards for Medicines Management (February 2008); NMC Circular 25/2005 *Midwives Supply Orders*; NMC Circular 1/2005, *Medicine legislation: what it means for midwives.*

3 General principles

There are a number of overarching principles that guide the use of medicines in general and controlled drugs in particular. They underpin and inform the decisions that are made about the safe management of controlled drugs within the current legal framework. The following principles should apply in relation to the management of controlled drugs.

3.1 Patients have timely access to the medicines prescribed for them

3.2 Organisations and individuals comply with the current legal requirements for controlled drugs

3.3 Patients are partners in their treatment and share decision-making with healthcare professionals about their treatment.

3.4 Patients are adequately informed about their treatment

3.5 Controlled drugs are used and managed safely and securely

3.6 There is a clear audit trail for the movement and use of all controlled drugs

3.7 The use of controlled drugs is audited and action is taken if necessary

3.8 Controlled drugs are prescribed by professionals who are competent to do so and who receive regular training and support on the safe management of controlled drugs

3.9 Local procedures and protocols are designed to be as clear and accurate as possible. They should be practical in use and not impose an intolerable administrative burden

3.10 The stock levels of controlled drug preparations held in wards and departments match what is routinely used in that clinical area

3.11 Healthcare staff have access to up-to-date information about CD legislation and official (Home Office, DHSSPS, professional body and other) guidance

3.12 Healthcare staff in the organisation work to standard operating procedures, approved by the Accountable Officer, that are appropriate to their area of work

3.13 Healthcare and appropriate ancillary staff receive adequate training and are competent in the management of controlled drugs (appropriate to their sphere of activity and level of responsibility)

3.14 Access to controlled drugs is restricted to appropriate, designated and legally authorised personnel

4 Management of controlled drugs in wards and departments

This chapter deals with the management of controlled drugs in wards and departments. The management of controlled drugs in operating theatres is covered in Chapter 6.

Contents of this chapter:

This section deals with measures concerned with the management of controlled drugs that are applicable in most wards and departments, including diagnostic departments. The requirements for pharmacy departments can be found in Chapter 7.

Where additional information can be found in other paragraphs, cross-references are also included.

4.1 Accountability and responsibility

4.1.1 Accountable individuals

The senior registered nurse or registered operating department practitioner (ODP) in charge of a ward or department is responsible for the safe and appropriate management of controlled drugs in that area. The senior registered nurse or ODP in charge can delegate control of access (i.e. key-holding) to the CD cabinet to another, such as a registered nurse or another ODP. However, responsibility remains with the registered nurse or ODP in charge. Whilst the task can be delegated, the responsibility cannot.

4.1.2 Standard operating procedures

There must be standard operating procedures (SOPs) covering each of the activities concerned with controlled drugs such as requisitioning, receipt, administration, record keeping and destruction.

SOPs must be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Relevant staff should be conversant with the SOPs.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains finally accountable for all the systems for the safe management of Controlled drugs. (See Appendix 3)

4.2 Controlled drug stocks

There should be a list of the controlled drugs to be held in each ward or department as stock items. The contents of the list should reflect current patterns of usage of controlled drugs in the ward or department and should be agreed between the pharmacist or pharmacy technician responsible for stock control of medicines on the ward and the senior registered nurse or registered operating department practitioner in charge.

4.2.1 The list should be modified if practices change and should be subject to regular review at agreed intervals.

4.3 Requisitioning of controlled drugs

The senior registered nurse or registered operating department practitioner (ODP) in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in that area.

4.3.1 The senior registered nurse or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or another ODP (See Chapter 6; The management of controlled drugs in operating theatres and Appendix 2). However, legal responsibility remains with the senior registered nurse or ODP in charge.

4.3.1.1 Orders must be in writing and should be on suitable stationery (e.g. a controlled drug requisition book with duplicate or triplicate pages) and must be signed by an authorised signatory. Stationery should be designed to facilitate a robust audit trail. (See also 4.3.3 Electronic systems)

4.3.1.2 A copy of the signature of each authorised signatory should be available in the pharmacy department for validation. Where electronic systems are in use, there should be a reliable means of validating the identity of individuals who requisition controlled drugs.

4.3.1.3 Requisitions must contain the following:

- Name of hospital
- Name of Ward / Department
- Drug name, form, strength, ampoule size if more than one available
- Total quantity
- Signature of senior registered nurse or ODP in charge

The requisition should also contain:

- Date on which it was written
- The printed (as in a legible version) of the name of the senior registered nurse or ODP in charge who signed the requisition

When the drug has been supplied the requisition must:

- Be marked in such a manner to show that it has been complied with.

4.3.1.4 The person making the supply should sign and date the requisition when it has been complied with, if that has not been part of the compliance marking, above.

4.3.1.5 The person who accepts the controlled drugs for transit should sign for receipt. This may be on the duplicate requisition (if space permits) or may be in a separate book kept for this purpose.

4.3.1.6 The person who receives the controlled drugs on the ward should sign the duplicate copy of the requisition.

4.3.1.7 Requisitions must be retained at the dispensary at which the drug was supplied and a copy of the requisition or a note of it must be retained by the recipient (the senior registered nurse or ODP in charge.)

4.3.2 CD Top-up schemes

In some situations pharmacy-led CD top-up schemes for replenishing stocks of controlled drugs on wards and departments are a practical and convenient mechanism of stock control. These are usually carried out by a pharmacy technician or senior assistant technical officer (SATO), but may also be carried out by other suitably-trained, competent members of the pharmacy staff.

4.3.2.1 When a CD top-up scheme is in operation, the responsibility for controlled drugs in a ward or department remains with the senior registered nurse or ODP in charge.

4.3.2.2 In a top-up scheme a member of the pharmacy staff is responsible for checking the stock balances in the ward controlled drug record book against the levels in the agreed stock list and preparing the CD requisition forms in order to replenish the stock. These requisition forms should be signed by the senior registered nurse or ODP in charge.

4.3.3 Electronic systems

Where electronic systems for the requisitioning of controlled drugs are introduced, safeguards in the software should be put in place to ensure that:

- Only individuals who are authorised to requisition controlled drugs from the pharmacy can do so
- The author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

4.4 Receipt of controlled drugs

When controlled drugs are delivered to a ward or department they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of controlled drugs). A local procedure should define the appropriate persons who are permitted to receive controlled drugs and the way in which messengers identify them. As a matter of good practice the receiving person should not be the same person who ordered the controlled drugs. The person receiving the supply should sign the duplicate sheet in the requisition book, having checked the items received.

4.4.1 As soon as possible after delivery the senior registered nurse or ODP in charge should:

- Check the controlled drugs against the requisition – including the quantity ordered and received. If this is correct then the duplicate sheet in the controlled drug requisition book should

be countersigned in the "received by" section. If the controlled drugs received do not accord with the requisition then the pharmacy should be contacted immediately. Any tamper-evident seals on packs should be left intact when they are received from pharmacy. (Note, however, that some pharmacies open sealed packs to check for breakage before issue to wards.) Intact seals will simplify and speed up routine checks. A seal should only be broken when the pack is required for administration.

- Place the controlled drugs in the appropriate CD cabinet
- Enter the controlled drugs into the controlled drug record book, update the running balance and check that the balance tallies with quantity that is physically present.
- If, when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the senior registered nurse or ODP in charge should contact the pharmacy department as soon as possible.
- Ensure that appropriate records are made in the ward controlled drug record book and all necessary action taken to resolve the discrepancy. See 5.9 Discrepancies and diversion.

4.4.2 Depending on local circumstances, some healthcare organisations may wish to stipulate that receipt of controlled drugs and updating of the controlled drugs record book should be witnessed by a second competent professional.

See also paragraph 6.4 Receipt of controlled drugs in Theatre

4.5 Storage of controlled drugs

The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 (SR 1973 No 179) cover the safe custody of controlled drugs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store controlled drugs. Apart from specified excepted circumstances, the Regulations also require that all controlled drugs to which the Regulations apply, must be in locked storage which can only be opened by a person who can lawfully be in possession of the controlled drugs or a person working under their authority.

4.5.1 Ward CD cupboards should conform to the British Standard reference BS2881:1989 ("Specification for cupboards for the storage of medicines in healthcare premises" ISBN 058017216 3) or be otherwise approved by the pharmacy department. Cupboards should provide a level of security at least comparable to that laid down in the Safe Custody Regulations. This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case further security measures should be introduced.

4.5.2 In certain circumstances, for example when controlled drug discharge medicines are sent to the ward several hours before the patient leaves, the medicines should be stored securely in the CD cupboard. These medicines should be segregated from the ward CD stock. (See paragraph 5.4 Management of controlled drugs that are patients' property)

4.5.3 General measures for the storage of controlled drugs include the following:

- Controlled drugs must be locked away when not in use
- Cupboards must be kept locked when not in use
- The lock must not be common to any other lock in the hospital
- Keys must only be available to authorised members of staff and at any time the key-holder should be readily identifiable
- There must be arrangements for keeping the keys secure. This is particularly important for areas such as day surgery units and five-day wards that are not operational at all times.
- No other medicines or items should normally be stored in the CD cupboard. Occasionally, in response to local circumstances healthcare organisations may decide to allow other drugs that are not controlled drugs to be stored in the CD cupboard. Trusts should carry out a risk assessment and have clear guidelines and SOPs in place to cover this

4.6 Key-holding and access to controlled drugs

4.6.1 **Responsibility for CD keys**

The senior registered nurse or ODP in charge is responsible for the CD key.

4.6.1.1 Key-holding (in the sense of giving the key to another for immediate access to the cupboard) may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the senior registered nurse or ODP in charge.

4.6.1.2 The controlled drug key should be returned to the senior registered nurse or ODP in charge immediately after use by another registered member of staff.

4.6.1.3 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff (e.g. the pharmacy technician responsible for stock control of medicines on the ward).

4.6.2 Missing CD keys

If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible e.g. by contacting staff who have just gone off duty.

4.6.2.1 A procedure should be in place to ensure that an appropriate level of nursing/midwifery/theatre management and the duty pharmacist are informed as soon as possible. The procedure should specify the arrangements for preserving the security of CD stocks and for ensuring that patient care is not impeded e.g. by issuing a spare key.

4.6.2.2 If the keys cannot be found then the Accountable Officer should be informed. Depending on the circumstances, a decision may be made to contact the police. The DHSSPS Head of Medicines Regulatory Group should be made aware of the situation. Locks may need to be replaced to prevent unauthorised access to the drugs.

4.7 Record-keeping

Each ward or department that holds stocks of controlled drugs should keep a record of controlled drugs received and administered in a controlled drug record book (CDRB).

The senior registered nurse, or ODP, in charge is responsible for keeping the CDRB up to date and in good order.

4.7.1 Controlled drug record books

4.7.1.1 The controlled drug record book (CDRB) should be bound (not loose-leaf) with sequentially numbered pages and it should have separate pages for each drug and each strength, so that a running balance can be easily maintained. Entries should be made in chronological order, in ink or be otherwise indelible.

4.7.1.2 All entries should be signed by a registered nurse, midwife or ODP and should be witnessed preferably by a second registered nurse, midwife or ODP. If a second registered nurse, midwife or ODP is not available, then the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist,) or by a pharmacy technician, or an appropriately trained healthcare assistant, who has been assessed as being competent for the purpose. In defining local policy NMC Medicines Management Standards may be consulted related to witnessing by student nurses or midwives.

4.7.1.3 On reaching the end of a page in the CDRB, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. The finished page number should be indicated

at the top of the new follow-on page. As a matter of good practice this transfer should be witnessed.

4.7.1.4 If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed by a second registered nurse, midwife, ODP or other registered professional or by an appropriately trained healthcare assistant. The witness should also sign the correction. An explanation may be made if necessary by a marginal note or footnote.

4.7.2. Records of controlled drugs received

A record should be kept of all Schedule 2 controlled drugs that are received or administered.

4.7.2.1 For controlled drugs received, the following details should be recorded on the appropriate page in the CDRB:

- Date on which the controlled drug was received.
- Name of pharmacy making supply and the serial number of requisition
- Quantity received
- Form (name, formulation and strength) in which received
- Name/signature of nurse/authorised person making entry
- Name/signature of witness
- Balance in stock

4.7.2.2 When recording controlled drugs received from pharmacy, the number of units received may be recorded in words not figures (e.g. ten, not 10) to reduce the opportunity for entries to be altered.

4.7.2.3 After every administration, the stock balance of an individual preparation should be confirmed to be correct and the new balance recorded in the CDRB. The entry should be signed and dated.

For records of controlled drugs administered see paragraph 4.11 Administration

4.8 Controlled drug stock checks

The stock balance of all controlled drugs entered in the CDRB should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out. If reconciliation is being conducted related to shift change, where possible, a representative from each shift may be involved. In addition, regular documented stock checks should be carried out by pharmacy staff (see paragraph 7.7.2 - Checks of CD stocks held in wards, theatres or departments).

4.8.1 The senior registered nurse or ODP in charge is responsible for ensuring that the regular CD stock check is carried out by staff in the ward or department

4.8.1.1 Two registered nurses, midwives, ODPs or other registered health professionals should perform this check. Both must see the drugs and the records for witnessing to be meaningful. Where possible, the staff assigned to do this check should be changed periodically. The check should take account of the following points:

- Checking of controlled drugs involves the checking of the balance in the CDRB against the contents of the CD cupboard, not the reverse, to ensure that all balances are checked.
- It is not necessary to open packs with intact tamper-evident seals for stock-checking purposes.
- Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks may be helpful. The balance must be confirmed to be correct on completion of a bottle.

4.8.1.2 A record indicating that this reconciliation check has been carried out and confirming the stock is correct may be kept in a separate bound record book or in the CDRB. This record should as a minimum state the date and time of the reconciliation check and include wording such as, “check of stock level” and be signed by the registered nurse, midwife, ODP or other registered health professional and the witness.

4.8.1.3 If a discrepancy is found it should be investigated without delay. (See paragrapht 5.9 Discrepancies and diversion) The local investigation and reporting procedures should be followed.

4.9 Archiving of controlled drug records

Healthcare organisations must make arrangements to store records in accordance with legislation and the schedules in *Good Management Good Records*. www.dhsspsni.gov.uk/gmgr The current guidance that applies to retention of hospital pharmacy CD registers is eleven years. This retention period also applies to ward CDRBs. The retention period is reckoned from the date when the last entry was made.

Many local documents designed to track and/or monitor controlled drug usage should be kept for two years after the last entry/date of use.

See also paragraph 7.9 - Archiving of controlled drug records (and 4.3.1.7 and 5.1.5.2)

4.10 Prescribing

4.10.1 Prescribing for inpatients

For hospital inpatients directions for administration of controlled drugs from ward stocks may be written on the inpatient medicines chart or case sheet (sometimes called the inpatient prescription and administration chart) or the anaesthetics card in line with local policies and procedures.

4.10.1.1 The written requirements for controlled drugs on these charts are the same as for other medicines and include:

- Start date
- Drug name, form and strength where appropriate
- Route of administration, and where appropriate, the site of application
- Dose
- Time of administration or frequency (if prescribed "when required" e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum daily dose)
- Include a finish date where appropriate
- Signature of prescriber

The patient's name, date of birth, unit number and/or address and any known drug sensitivities or drug allergies should also be written on the chart.

4.10.1.2 If controlled drugs are administered or self-administered from supplies prescribed and dispensed for individual patients (rather than from items ordered as ward stock), then in addition to the requirements of 4.10.1.1, in order to comply with the Misuse of Drugs Regulations (Regulation 15), the total quantities of the controlled drugs prescribed for the individual patients must be present in both words and figures on the patient chart. (See section 5.4.4 Self-administration of controlled drugs.)

4.10.2 Prescribing for discharge patients

Prescriptions for controlled drugs for patients who are going home (discharge medicines) should be written on locally-approved prescription forms for dispensing by the pharmacy. These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a controlled drugs prescription (see section 4.10.3).

4.10.2.1 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe controlled drugs (and other POM medicines) on these prescription forms for

inpatient use so far as this is necessary for the purposes of their employment as defined in the Medical Act 1983. In line with GMC guidance for general practice, it is recommended that such issues of delegation by supervising practitioners must be clearly documented to avoid any confusion. Further guidance with some explanation of the legislation is available from the GMC at www.gmc-uk.org/Provisionally_registered_doctors_on_GP_placements_prescribing_rights.pdf_26990223.pdf

4.10.2.2 A clinically appropriate amount, up to a maximum of 30 days supply should be prescribed, as a matter of good practice. There may be circumstances where there is a genuine need to prescribe for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a record of the reasons in the patient's notes. Pharmacists may legally supply a prescribed quantity of greater than 30 days' supply, if appropriate. (Prescriptions for methadone or buprenorphine for treatment of opiate dependence for instalment dispensing in the community are limited by legislation to a maximum of 14 days supply.)

4.10.3. Prescribing for outpatients

Prescriptions for controlled drugs for outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations (Regulation 15). Such prescribing must occur within locally agreed frameworks. The prescription document can either be a locally-approved outpatient prescription form for the hospital pharmacy to dispense or, in the case of Substitution Treatment for opiate dependence with methadone or buprenorphine, an SP1 or SP2 form for a community pharmacy to dispense.

4.10.3.1 A prescription for Schedule 2 and 3 controlled drugs (with the exception of temazepam and preparations containing it) must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated

- The patient's full name and address
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures

In addition, it is good practice to include the patient's age and NHS number on the prescription.

4.10.3.2 The prescription must be signed by the prescriber with his usual signature, in his own handwriting (this must be handwritten) and dated (the date does not have to be handwritten).

Amendments to the Misuse of Drugs Regulations 2002, which came into force on 16th January 2006, removed the requirement for prescriptions for Schedule 2 and 3 controlled drugs to be written in the prescriber's own handwriting (other than their signature).

CD prescriptions may be computer-generated but **do not have** to be computer-generated. Appropriate prescribers may issue computer-generated prescriptions for all controlled drugs in Schedules 2 and 3. Only the signature has to be in the prescriber's own handwriting. The prescriber should sign any manuscript changes.

4.10.3.3 If the prescription is produced, prior to signature by the prescriber, by someone other than the prescriber then that person should, ideally, be a registered healthcare professional.

4.10.3.4 The use of pre-printed adhesive labels on prescriptions is not recommended. Technically the new legislative requirements for computer generated prescriptions for controlled drugs do not prevent the use of preprinted adhesive labels on prescriptions. If, and where, they are used, such labels should be tamper-evident (i.e. it is obvious if an attempt has been made to remove them). If an adhesive label is used, prescribers should also sign across each label. This is a further safeguard to ensure that such labels are not tampered with or that another label is not placed on top of the one that the prescriber signed for. Relevant procedures should include measures to minimize further risks related to adhesive labels and copies of prescriptions.

4.10.3.5 A clinically appropriate amount up to a maximum of 30 days supply should be prescribed as a matter of good practice. There may be circumstances where there is a genuine need to prescribe a supply for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe a supply for more than 30 days and would not pose an unacceptable threat to public safety, the prescriber should make a record of the reasons in the patient's notes. Pharmacists may legally supply a prescribed quantity of greater than 30 days' supply, if appropriate. (Prescriptions for methadone or buprenorphine for treatment of opiate dependence for instalment dispensing in the community are limited by legislation to a maximum of 14 days supply.)

4.10.4 Supplementary prescribers

Regulations were amended in 2005 to permit supplementary prescribers, when acting under and in accordance with the terms of an agreed individual clinical management plan (CMP) to prescribe and administer and/or supply or direct any person to administer any controlled drug provided that the controlled drug is included in the CMP.

4.10.5 Non-medical independent prescribers

Nurse independent prescribers

Following amendments to the Prescription Only Medicines Order 1997 (SI 1997 No. 1830), the range of drugs that Nurse Independent Prescribers were able to prescribe independently was extended. From 1st May 2006, the Nurse Prescribers' Extended Formulary was discontinued and qualified Nurse Independent Prescribers were able to prescribe any licensed medicine for any medical condition within their competence, including some controlled drugs for specific conditions. The Misuse of Drugs Regulations 2002 were again amended in May 2012 to allow a nurse independent prescriber to prescribe any controlled drug in Schedule 2, 3, 4, and 5 of the Regulations, but not in relation to cocaine, diamorphine or dipipanone for addicts, otherwise than for the purpose of treating organic disease or injury.

4.10.6 Pharmacist independent prescribers

The Misuse of Drugs Regulations 2002 were amended in May 2012 to allow a pharmacist independent prescriber to prescribe any controlled drug in Schedule 2, 3, 4, and 5 of the Regulations, but not in relation to cocaine, diamorphine or dipipanone for addicts, otherwise than for the purpose of treating organic disease or injury.

4.11 Administration

See also paragraph 4.7 Record keeping.

The administration of controlled drugs should comply with all local policies and procedures for the administration of medicines.

Nurses and midwives must follow Nursing and Midwifery Council standards and guidance. (www.nmc-uk.org)

In terms of the Misuse of Drugs Regulations (MDR) any person can administer to a patient any drug specified in Schedule 2, 3 or 4 provided they are acting in accordance with the directions of an appropriately qualified prescriber. (MDR 2002, Regulation 7(3)). Any person can administer to another person any drug specified in Schedule 5 – MDR 2002- Regulation 7 (1)

4.11.1 Healthcare organisations that do not have a system of double checking for administration of controlled drugs should carry out a risk assessment to determine whether the introduction of double checking as an additional risk-reduction measure is necessary, within their organisation.

4.11.1.1 Where two practitioners are involved in the administration of controlled drugs, one of them should be a registered nurse, midwife, doctor or ODP. Both practitioners should be present during the whole of the administration procedure. They should both witness:

- The preparation of the controlled drug to be administered.
- The controlled drug being administered to the patient.
- The destruction of any surplus drug (e.g. part of an ampoule or infusion not required).

A record should be made in the ward or department controlled drug record book (CDRB) when a controlled drug is removed from the CD cupboard.

4.11.1.2 For controlled drugs administered the following details should be recorded:

- Date and time when dose administered (or refused in the case of a controlled drug that was prepared for the patient)
- Name of patient
- Quantity administered and quantity wasted (see 4.11.1.3)
- Form (name, formulation and strength) in which administered
- Name/signature of nurse/authorised person who administered the dose
- Name/signature of witness (where there is a second person witnessing administration)
- Balance in stock

4.11.1.3 If part of a vial is administered to the patient, the registered nurse, midwife or other registered health professional should record the amount given and the amount wasted e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted.*" The destruction should be witnessed by a second registered nurse, midwife or other registered health professional who should also sign the record. If a second registered nurse, midwife or other registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist) or by an appropriately trained pharmacy technician or healthcare assistant. In defining local policy NMC Medicines Management

Standards may be consulted related to witnessing by student nurses or midwives.

4.11.1.4 Individual doses of controlled drugs which have been prepared but not administered should be destroyed by a registered nurse, midwife or other registered health professional on the ward or department in the presence of a witness and the reason documented in the CDRB.

(For appropriate methods of destruction see paragraph 4.16 Disposal and destruction of Controlled drugs).

4.12 Management of controlled drugs when patients are admitted

See paragraph 5.4 Management of Controlled Drugs that are the patient's property

4.13 Management of controlled drugs when patients are transferred to other wards or departments

See paragraph 5.2 Transfer of controlled drugs

The circumstances are limited where a controlled drug will move with a patient. This is due to the restriction in the Misuse of Drugs Regulations 2002 which prevents controlled drugs being supplied from ward to ward. Patient controlled analgesia will be one of the cases where a controlled drug may need to move with the patient. There should be a local procedure (see section 6.11, Patient Controlled Analgesia, for details) which covers all aspects of the safe management of patient-controlled analgesia. This should include:

- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved between theatre and/or wards
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

4.14 Management of controlled drugs when patients are discharged

See paragraph 4.10.2 Prescribing for discharge patients and 7.10 Supply to outpatients and discharge patients

4.15 Returning controlled drugs to the pharmacy

4.15.1 Unused CD stock from wards or departments may be returned to the pharmacy. Such CD stock may be re-issued by the pharmacy provided it was initially issued by that pharmacy, is in good condition

and has at all times been under the control of that hospital. The pharmacy department should carry out an assessment of controlled drugs returned to pharmacy to ensure they are fit for re-use.

Controlled Drugs that are time-expired or otherwise unfit for use (e.g. opened liquids) should also be returned to the pharmacy for safe destruction and onward disposal.

Any other controlled drug that is no longer needed on the ward should be returned to pharmacy. This should be done as soon as is practicable. Local policies may define time limits.

4.15.2 Records of controlled drugs returned

The ward or department should keep a record of drugs returned to pharmacy. This may be in the form of a returns advice book with duplicate pages so that both the pharmacy and the ward have a record of the transaction.

The following details should be recorded when controlled drugs are returned to the pharmacy:

- Date
- Name, form, strength and quantity of drug being returned
- Reason for return
- Name and signature of the senior registered nurse or ODP in charge

The top copy will be taken from the book and transported with the drugs to the pharmacy.

In addition, an entry should be made on the relevant page of the ward or department CDRB, showing:

- Date
- Reason for return
- Names and signatures of the senior registered nurse, or ODP responsible and a competent witness
- Quantity removed
- Name, form and strength of drug
- Balance remaining

The drugs should be transferred to the pharmacy in a safe and secure way. (See paragraph 5.2 Transfer of controlled drugs)

4.16 Disposal of controlled drugs in wards and departments

See also paragraph 7.15 Disposal of controlled drugs in pharmacies

In the interests of safety and containment of environmental pollution, controlled drugs should, as far as is practicable, be returned to the pharmacy for safe denaturing and disposal.

Controlled drugs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used. Where denaturing is carried out on wards and departments, the methods used should be those currently recommended by the Pharmaceutical Society of Northern Ireland
See the Pharmaceutical Society of Northern Ireland website:
www.psni.org.uk/documents/600/GuideLegalRequirements+MedsHumanUseControlledDrugs.pdf

Some healthcare organisations may wish to provide denaturing kits for use on wards to destroy controlled drugs that have been used for patients. This may be appropriate on wards or departments where large quantities of controlled drugs are used and where the volume of part-used vials, ampoules, syringes and infusion bags may be high. A risk assessment should be carried out before a decision is made whether denaturing kits should be available on wards. Where denaturing kits are provided to wards or departments, an SOP should be developed for this practice.

4.16.1 Disposal of small amounts of Controlled drugs

4.16.1.1 In principle, only small amounts of Controlled drugs should be destroyed on wards and departments, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used. Policy should be agreed locally regarding denaturing and disposal of larger quantities of controlled drugs, for example, discontinued infusions or patient-controlled analgesia (PCA) syringes. An assessment should be made of risks involved in transport, and of the impact on infection control, prior to establishing any policy that indicates that these items be returned to the pharmacy for safe denaturing and disposal.

4.16.1.2 All destruction must be documented in the appropriate section of the CD record book (see below). It should be witnessed by a second competent professional such as a registered nurse, midwife or ODP. Both persons should sign the CD record book.

4.16.2 Method of disposal

Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer, so long as the terms of the agreement are complied with.

5 Management of controlled drugs – general processes and specific circumstances

Contents of this chapter:

5.1 Controlled drug stationery

All stationery which is used to order, return or distribute controlled drugs (CD stationery) should be stored securely and access to it should be restricted. These measures are important to guard against unauthorised use of the stationery to obtain controlled drugs for inappropriate purposes.

5.5.1 Definition of CD stationery

CD stationery includes:

- CD requisition books
- CD record books
- Local CD documents such as CD returns advice notes, pharmacy distribution documents
- Prescription forms

5.1.2 Secure storage of CD stationery

CD stationery which is kept in wards, theatres or departments should be kept in a locked cupboard or drawer.

Stocks of CD stationery held in pharmacy departments should be kept in a secure area that is locked when there is no one present.

5.1.3 Supply of CD stationery

CD stationery should be issued from the pharmacy against a written requisition signed by an appropriate member of staff. Local policy should define the form of requisition that is required to order such stationery. The local policy should also define the groups of staff who can sign requisitions for CD stationery. It may be appropriate to use the same duplicate book for ordering CD stationery that is used to order controlled drugs. This will ensure that the requisition forms themselves are stored securely.

5.1.3.1 A record should be kept in pharmacy of the supply of CD stationery. It should include:

- Date
- Ward/department
- Name of person ordering the stationery
- Type of stationery issued
- Quantity
- The serial numbers of the stationery
- Signature of the member of pharmacy staff making the supply
- Signature of member of staff receiving the stationery

5.1.3.2 Any unused stationery returned to pharmacy will be recorded as a return, with the details above, in the stationery supply record.

5.1.3.3 Healthcare organisations may wish to number CD requisition books to provide an additional means of tracking.

5.1.4 Loss or theft of CD stationery

Loss or theft of any controlled stationery which may be used to order controlled drugs should be reported immediately to the chief pharmacist and the Accountable Officer. The police should be informed, if appropriate.

5.1.5 Use of CD stationery

Only one CD requisition book per ward or department should normally be in use.

5.1.5.1 When a new CD Record Book is started, the balance of controlled drugs in stock should be written into the new book promptly by ward staff. This transfer should be witnessed by a registered nurse, midwife, ODP or authorised member of staff e.g. pharmacy technician.

5.1.5.2 Completed ward requisition books must be retained for a minimum of two years from the date of the last entry. CD record books should be kept for a period of 13 years from the date of the last entry. (See paragraphs 4.9 and 7.9 Archiving of records)

5.2 Transfer of controlled drugs within and outside the hospital

Transfer of controlled drugs is likely to involve the following situations:

- Collection by ward staff from the pharmacy
- Collection by porters from the pharmacy
- Delivery by pharmacy staff to wards, departments, theatres
- Collection by patient or representative for outpatient items only
- Delivery by Trust porter/driver
- Delivery by commercial courier (e.g. taxi out-of-hours)
- Delivery using (trackable) recorded delivery Postal Service (The use of postal services should not be routine but should be limited to exceptional situations such as when there is an urgent clinical need.)

5.2.1 Methods of transfer

Wherever possible, controlled drugs should be transferred or conveyed in a secure, locked or sealed, tamper-evident container.

5.2.1.1 Depending on local circumstances, some healthcare organisations may choose to use bags with numbered seals for delivery and require a signature for receipt of the bag with the correctly numbered seal. Whichever system is used it must be fully auditable and explicit as to who has custody of the controlled drugs at any point in time.

5.2.1.2 Controlled drugs may not be transported in pneumatic tubes. If consideration is being given to the use of such a system, prior discussion should take place with the Department inspectors.

5.2.2 Records of transfer

At each point where a controlled drug moves from the authorised possession of one person to another, a signature for receipt should be obtained by the person handing over the drug and the person receiving it.

5.2.2.1 Healthcare organisations may wish to design local distribution/transport documentation as a means of keeping a full audit trail.

5.2.3 Messengers

The person who conveys the controlled drug acts as a messenger, that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container.

5.2.3.1 The person acting as the messenger should:

- Ensure destination is known
- Be aware of safe storage and security, the importance of handing over the item to an authorised person and obtaining a signature for delivery on the delivery document.
- Have valid ID badge

5.2.3.2 Healthcare organisations may wish to stipulate that controlled drugs should only be handed to members of staff who are wearing valid ID badges.

5.2.3.3 Where a commercial courier or taxi driver is responsible for conveying a controlled drug he should be asked to show his valid company ID, as he would for any other medicine.

- Taxi drivers or commercial couriers should not be made aware that controlled drugs are being transported as this may increase the potential for diversion.
- As a matter of good practice the taxi registration or taxi licence number may also be recorded.

5.2.3.4 Healthcare organisations may wish to keep a list of porters who are authorised to transfer controlled drugs. A list of their names with sample signatures may be kept in pharmacy for validation purposes.

5.2.4 Transfer from ward to ward or theatre to ward

In general, the Misuse of Drugs Regulations 2002 prevent controlled drugs being supplied from ward to ward. However, local procedures should define safe, secure and auditable methods to transfer controlled drugs from ward to ward in circumstances where a controlled drug is required to move, for example, when a patient moves to another ward. The three situations in which this is most likely to arise are:

- When a patient is receiving a controlled drug by means of syringe pump (patient controlled analgesia) or infusion or a transdermal patch
- When a patient has his/her own controlled drugs for self-administration
- When a controlled drug has been dispensed on a “named-patient” basis

5.2.4.1 Patients' own controlled drugs should be transferred from ward to ward with the patients in line with local procedures for transferring all other medicines and property belonging to those patients.

5.2.4.2 There should be a local procedure (see section 6.11, Patient Controlled Analgesia, for details) for all aspects of the management of patient controlled analgesia. This should include:

- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved from theatre/ward to ward
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

See also paragraph 5.4 Managing controlled drugs that are the patient's property

5.2.5 Transfer from ward to pharmacy

When controlled drugs have to be returned to the pharmacy they should be placed in a secure container and handed to an authorised messenger. (See paragraph 4.15 Returning controlled drugs to the pharmacy)

5.3 Clinical trials

The procedures for the use of controlled drugs in clinical trials must comply with the Misuse of Drugs Regulations 2002 and with local policies governing the management of clinical trial medicines, in addition to clinical trials legislation and Medicines and Healthcare products Regulatory Agency (MHRA) guidance on clinical trials (www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/index.htm)

5.3.1 Storage and records

5.3.1.1 All clinical trial controlled drugs should be stored separately from stock controlled drugs. They do not necessarily need to be stored in a separate CD cupboard. A separate page in the register should be used to record receipt and issues in addition to clinical trial documentation so that a running balance of trial stock can be kept.

5.3.1.2 If a discrepancy is identified then it should be reported on the internal incident reporting system in accordance with local

procedures. A note to file should be stored with all the clinical trials documentation. The sponsor and investigator should be informed and also the chief pharmacist and Accountable Officer. (See also paragraph 5.9 Discrepancies and diversion)

5.3.1.3 For double blind trials in which only one arm involves a controlled drug, pharmacy staff may be unaware which packs contain controlled drugs. In this situation, all supplies should be treated as controlled drugs until the end of trial.

5.3.1.4 For trials that involve the use of Schedule 1 controlled drugs, such as cannabinoids, a licence from the DHSSPS must be obtained before the item is received into stock or supplied. The licence should normally be held by the chief pharmacist. A copy should be kept with the trial protocol.

5.3.2. Labelling

All clinical trial controlled drugs must be labelled and dispensed in accordance with the specific trial protocol in addition to the Misuse of Drugs Regulations 2002 requirements.

5.3.3 Disposal

Clinical trial controlled drugs must be destroyed in the same way as other controlled drugs. (See section 7. 15 Destruction of controlled drugs in pharmacies) However, this destruction may need to be carried out following the monitoring instructions from the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation (in addition to the check and reconciliation carried out by the pharmacy department) prior to any destruction.

5.3.4. Clinical trial controlled drugs returned by patients

The pharmacy should establish secure arrangements for the storage (and destruction) of CD clinical trial medicines returned by patients. Drug accountability records should be completed promptly when a patient returns the CD clinical trial medicine and opportunities for diversion should be minimised.

5.3.5 Arrangements for research departments

If a hospital pharmacy supplies controlled drugs to a research department, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

5.4 Management of controlled drugs that are the patient's property

A local procedure should be in place for the management of controlled drugs that are the patient's property.

5.4.1 Use of a patient's own controlled drugs on the ward

It may be appropriate to use a patient's own controlled drugs (i.e. controlled drugs brought into the hospital by the patient on admission) whilst they are in hospital, for example, if the patient is self-administering other medicines. On such occasions the drugs should be checked for suitability according to the local procedure for patients' own drugs (PODs) to ensure that they are fit for purpose. (See paragraph 5.4.4 Self-administration of controlled drugs)

5.4.1.1 If patients' own controlled drugs are not required for use in this way then one of the following procedures should be followed and all actions should be recorded:

- If the patient or the patient's representative agrees, medicines may be sent to the pharmacy for safe destruction. Such assent may be recorded with the signature of the patient or their representative if appropriate. The pharmacist should take responsibility for destruction.
- If the patient wishes, the medicines may be returned home via an identified adult. That adult should be given advice regarding the necessity for safe storage of the medicines and that other people must not use them. If the medicines are no longer safe and/or appropriate for future use by the patient, then the patient and/or patient's representative should be advised, and they should be encouraged to allow them to be destroyed in the hospital pharmacy (or to take them to a community pharmacy for safe destruction.)

5.4.1.2 Patients' own controlled drugs that are not to be used for self-administration should not routinely be stored on the ward.

5.4.1.3 Temporary storage of patients' own controlled drugs on the ward may be necessary whilst they are awaiting collection and removal to the pharmacy or to the patient's home. In this situation, they should be placed in the CD cupboard but should be clearly marked and kept separate from ward stock. The presence on, and departure from, the ward of these controlled drugs should be recorded according to local policy.

5.4.1.4 Patient's own controlled drugs must never be used to treat other patients.

5.4.2 Controlled drug discharge medicines

When CD discharge medicines are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. These medicines should be segregated from the ward CD stock and clearly marked and should remain in a sealed bag. Healthcare organisations may wish to stipulate that a record of the receipt and supply of these medicines from the ward should be maintained.

When Schedule 2 controlled drug discharge medicines are collected from the pharmacy, the person collecting them should be asked to sign for receipt as a matter of good practice.

5.4.3 Receipt of controlled drugs by outpatients

Patients or their representatives may be asked to provide evidence of identity when collecting controlled drugs.

From July 2006, there has been a requirement for persons asked to supply controlled drugs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the supplier:

- **May** request evidence of that person's identity and
- **May** refuse to supply the medicine if he is not satisfied as to the identity of the person
- Where it is a healthcare professional acting in his professional capacity on behalf of the patient, the supplier:

- **Must** obtain the person's name and address
- **Must,** unless he is acquainted with that person, request evidence of that person's identity; but
- **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The new requirement placed on the supplier therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if, for example, they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicines dispensed.

From 1st February 2008, it has been a requirement to record the following information in the CD register for Schedule 2 controlled drugs supplied:

- Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional
- If the person who collected the drug was a healthcare professional, that person's name and address [*Guidance* – work address - not home]
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the supplier did not ask may be included, but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

Depending on local circumstances, some healthcare organisations may wish to stipulate that outpatients receiving controlled drugs should sign for receipt of a specified number of doses.

5.4.4 Self-administration of controlled drugs

A local procedure should be in place for wards or departments where patients self-administer their own medicines including controlled drugs.

5.4.4.1 When patients who self-administer controlled drugs require additional supplies, these should be dispensed as for discharge controlled drugs. Prescription details must comply with the requirements of the Misuse of Drugs Regulations 2002. Healthcare organisations may wish to consider whether the administration of these controlled drugs is recorded in the CDRB or in a separate book for recording of controlled drugs that are self-administered.

5.4.4.2 Patients receiving controlled drugs for self-administration should sign for receipt of a specified number of doses.

5.4.4.3 Healthcare organisations may wish to stipulate that these controlled drugs are entered in and out of the ward CDRB so that there is an auditable record of their arrival on the ward. A daily count of the quantity of the controlled drugs in the patient's individual medicines cabinet may be made by the registered nurse, midwife or other healthcare professional and recorded on the medicines chart or in the CDRB.

5.4.4.4 The controlled drugs for patients who self-administer their medicines should be kept in a locked metal receptacle immediately adjacent to their bed, or in their bedside locker. The receptacle should not be easily portable. Healthcare organisations may wish to consider the use of electronic patient medicines lockers accessed by means of programmable transponders. Such systems provide a high

level of security and a clear record of who accessed the locker and when.

5.4.4.5 Useful sources of information about controlled drugs for patients are listed at Appendix 5.

5.5 Out-of-hours supply

Under the current Regulations, the senior registered nurse in charge of a ward can only supply controlled drugs to a patient on that ward or department, in accordance with the written instructions of an authorised prescriber.

Every effort should be made to ensure that adequate stock levels are maintained to meet likely needs.

Local arrangements for emergency issues of controlled drugs should be discussed with the Accountable Officer and/or chief pharmacist. Where such systems exist, a standard operating procedure should be developed.

5.6 Temporary ward closure and transfer of wards

5.6.1 Temporary ward closure

There should be a local procedure for the management of controlled drugs during short and long term ward closures. The procedure should ensure the security of the controlled drugs and should be auditable.

5.6.1.1 The procedure should include:

- A provision for a risk assessment to be carried out
- Documented stock reconciliation conducted by senior registered nurse and ward pharmacist
- Arrangements for removal and temporary storage of controlled drugs by the pharmacy, if appropriate
- Arrangements for return of controlled drugs to the pharmacy for re-use, if appropriate
- Specification of the entries required in the CDRB
- Arrangements for secure storage of current (i.e. in use) CD stationery during closure
- Arrangements for return of stocks, including reconciliation with list of controlled drugs removed, if appropriate
- Arrangements for restocking, if appropriate

5.6.1.2 As a matter of good practice, the list of authorised signatories for the ward that is kept in the pharmacy should be annotated by the pharmacist or pharmacy technician responsible for stock control of medicines on the ward so that the pharmacy and audit staff are aware that the ward is temporarily closed. The list will need to be reviewed by the ward pharmacist when the

ward reopens, to ensure that signatures are valid and up to date.

5.6.2. Transfer of wards

When a ward moves to another location, a decision must be made as to whether its controlled drugs and CDRBs may be transferred or, where swapping of wards occurs, left on the ward. This will depend upon the appropriateness of the stock list, the periods for which ward premises will be unoccupied and the security of the drugs during this time. (See paragraph 5.6.1 Temporary ward closures).

5.6.2.1 There should be a local procedure for the management of controlled drugs during ward moves. This procedure should ensure the security of the controlled drugs and should be auditable.

5.6.2.2 The procedure, which should have been agreed with the pharmacy department should include:

- A provision for a risk assessment to be carried out
- Arrangements for transfer of controlled drugs and CDRBs, if appropriate
- Arrangements for checking and reconciliation of stocks, in particular when ward staff transfer but controlled drugs and CDRBs are left in place
- Specification of the entries required in the CDRB, in particular when ward staff transfer but controlled drugs and CDRBs are left in place

5.6.2.3 The pharmacist or pharmacy technician responsible for stock control of medicines on the ward should ensure that the ward signatory lists and stock lists are updated to reflect the new ward location/name/number.

5.7 Paediatrics

The management of controlled drugs in paediatrics does not differ significantly from the management in adult care and so all the general provisions apply. There are, however, a few specific situations when the management of controlled drugs may require a slightly different approach.

5.7.1 Part vials of controlled drugs

On many occasions in paediatrics, the dose required for the patient is smaller than that which is contained in a single vial or ampoule. When a dose is given to a child, an amount may be left, which needs to be discarded. In order to minimise the opportunities for diversion, the following steps should be taken:

- When a dose is given, the nearest suitable dose volume should be selected, so that the minimum volume has to be discarded.
- When only part of the contents of a vial or ampoule is used, the entry made in the ward CD record book (CDRB) should clearly show how much was given to the patient and how much was discarded. For example, if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, “2.5mg given and 2.5mg wasted.” This should be witnessed by a second registered health professional who should also sign the record.
- The controlled drug to be discarded should be rendered irretrievable, in the presence of a witness as above, by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the “CD waste receptacle” is sent for destruction, it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer, so long as the terms of the agreement are complied with.
- A risk assessment should be carried out before a decision is made as to whether denaturing kits should be available on the wards. This is particularly relevant within children’s services. Where denaturing kits are provided, an SOP should be developed for this practice.
- The person who administers the dose is responsible for making the entry in the CDRB and this must be done immediately or as soon as is practicable after administration.

- The destruction should be recorded in the CDRB by both the person who undertook the destruction and the witness.

5.7.2 Child protection

Parents who are substance misusers sometimes bring their prescribed controlled drugs on to hospital premises. Healthcare organisations may wish to consider whether, on a parent's request, they may want to store the controlled drug in the CD cupboard and the parent requests the nurse to supply when a dose is required. These controlled drugs should be clearly labelled and kept separate from other controlled drugs.

Where there are concerns about potential diversion, staff should be alert that this may be a possibility and if appropriate, reference should be made to the appropriate child protection services

5.8 Controlled drugs for midwives

A registered midwife may possess diamorphine, morphine and pethidine in her own right so far as is necessary for the practice of her profession.

5.8.1 Acquisition of controlled drugs by midwives

Supplies of diamorphine, morphine and pethidine may only be made to a midwife on the authority of a midwife's supply order signed by the Supervisor of Midwives, or other Appropriate Medical Officer who is a doctor authorised in writing by the local supervising authority.

5.8.1.1 The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate).

5.8.1.2 The order must specify the name and occupation of the midwife, the purpose for which the controlled drug is required and the total quantity to be obtained.

5.8.1.3 Supplies of pethidine, morphine and diamorphine may be obtained from a hospital pharmacy if the midwife is engaged in the business of the Trust. (Matters of pharmacy registration or wholesale dealing must be considered if the midwife is not engaged in the business of the Trust.) The pharmacist who makes the supply must ensure that medicines are only supplied on the instruction of an authorised person.

5.8.1.4 The pharmacy must retain the midwife's supply order for two years.

5.8.2 Storage and records

Midwives must record full details of supplies of diamorphine, morphine and pethidine received and administered in their controlled drugs register. This register should be used solely for that purpose and be made available for inspection as required by the Supervisor of Midwives.

5.8.2.1 Once medicines are received by midwives working in the community or self-employed midwives, they become the responsibility of the midwife, and must be stored safely and securely.

5.8.2.2 Where it is necessary for midwives to keep medicines in their homes, the medicines must be placed in a secure, locked receptacle. If necessary, this should be provided by the employing body.

5.8.2.3 Administration of controlled drugs by midwives should be in accordance with locally agreed procedures.

5.8.2.4 A record of administration of the controlled drugs should also be kept in the woman's records.

5.8.3 Returns and disposal

When a midwife is in possession of controlled drugs that are no longer required they may be surrendered to the Appropriate Medical Officer, who should make arrangements for safe disposal, or the drugs may be returned to the pharmacy from which they were obtained. (The Appropriate Medical Officer is a doctor authorised in writing by the Health and Social Care Board who may sign midwives' supply orders, or the person appointed by the Board to exercise supervision over registered midwives.) A record of the return should be made in the midwife's controlled drugs register.

5.8.3.1 When a Schedule 2 controlled drug has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current guidance. Where possible a member of the family should witness the destruction. A record of the destruction should be made in the midwife's register. Some healthcare organisations may wish to provide denaturing kits to midwives to ensure safe destruction.

5.8.3.2 Controlled drugs that have been prescribed for a woman by her doctor for use in her home confinement are her own property and are not the midwife's responsibility. Even when no longer required they should not be removed by the midwife, but the woman should be advised to return them to a community pharmacy for destruction. Where this is not possible, the midwife should obtain the patient's agreement in writing before removing it from the patient's home and

returning it to a pharmacy for safe disposal, on behalf of the woman.

5.9 Discrepancies and diversion

The balances in the controlled drug record books (CDRBs) should always tally with the amounts of controlled drugs in the cupboard. If they do not, the discrepancy must be reported, investigated and resolved. It is important to remember that a discrepancy can indicate diversion. There should be a procedure for dealing with discrepancies and this should specify the arrangements for reporting and investigation.

In the first instance checks should be carefully made that:

- All requisitions received have been entered into the correct page of the CDRB
- All controlled drugs administered have been entered into the CDRB correctly
- Items have not been accidentally put into the wrong place in the cupboard
- Arithmetic is correct, to ensure that balances have been calculated correctly

If the error or omission is traced, the registered nurse or ODP in charge should make an entry in the CDRB, clearly stating the reason for the entry and the corrected balance. This entry should be witnessed by a second registered health professional. Both persons will sign the CDRB.

If no errors or omissions are detected then the discrepancy should be reported to the chief pharmacist and the Accountable Officer without delay and a local incident form completed in line with the healthcare organisation's policy or procedure for reporting incidents. Depending on the seriousness of the discrepancy and the early investigation findings, the DHSSPS Inspectorate and the police should be informed.

5.10 Illicit substances

DHSSPS has issued guidelines to help in the development of local policy and associated documents with respect to suspected illicit controlled substances recovered from patients. Although the guidance was provided for mental healthcare settings it will be of relevance to any secondary care facility. The DHSSPS Head of Medicines Regulatory Group should be consulted with respect to destruction of illicit substances. Please refer to *Drug and Substance Misuse in Mental Healthcare Settings – Guidelines for Service Providers*, DHSSPS, September 2004
www.dhsspsni.gov.uk/substance-misuse-guidance.pdf

6 Management of controlled drugs in in-house operating theatres

Contents of this chapter:

This chapter describes measures for management of controlled drugs in in-house operating theatres and departments where controlled drugs are used primarily by anaesthetists.

6.1 Accountability and responsibility

6.1.1 Accountable individuals

The senior registered nurse or Operating Department Practitioner (ODP) in charge of an operating theatre or theatre suite is responsible for the safe and appropriate management of controlled drugs.

The senior registered nurse, or ODP in charge can delegate control of access (i.e. key-holding) to the CD cupboard to another, such as a registered nurse or another ODP. A nurse or ODP may then only remove controlled drugs from the cupboard and/or return them to the cupboard on the specific authority of either the senior registered nurse or ODP in charge. Legal responsibility remains with the senior registered nurse or ODP in charge. Whilst the task can be delegated, the responsibility cannot. (The person to whom the task has been delegated is still professionally accountable for his/her actions).

Similar considerations apply to requisitioning and checking of controlled drugs.

6.1.2 Standard operating procedures

Healthcare organisations should ensure that all the procedures for the management of controlled drugs in in-house operating theatres and recovery wards are included in written standard operating procedures and that all staff, including anaesthetists, are aware of these procedures. It is good practice to ensure all staff who have to work in accordance with SOPs have an opportunity to comment on draft versions before the SOPs are finalised to ensure ownership. This is especially important in areas where many different staff are working for, perhaps, only a small part of their working week. Relevant staff must be conversant with the SOPs.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains accountable for the safe management of controlled drugs

6.2 Controlled drug stocks

There should be a list of controlled drugs to be held in each theatre as stock items. The contents of the list should reflect current patterns of usage of controlled drugs in the theatre and should be agreed between the pharmacy technician or pharmacist responsible for stock control of medicines in the theatre and the Operating Department manager, appropriate medical staff and the senior registered nurse or ODP in charge.

The list should be modified if practices change and should be subject to regular review at agreed intervals.

6.3 Requisitioning of controlled drugs

The senior registered nurse or ODP in charge of an operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in the theatre. (See Appendix 2)

The senior registered nurse, or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or another ODP. However, legal responsibility remains with the senior registered nurse, or ODP in charge.

Wherever practicable, different persons should be responsible for requisitioning and receipt of controlled drugs.

Requisitions must comply with the requirements for stationery, authorised signatories and content set out in paragraph 4.3 Requisitioning of controlled drugs

Healthcare organisations may consider the introduction of a pharmacy-led top-up scheme as an efficient way of maintaining adequate stock levels of controlled drugs in theatres

6.4 Receipt of controlled drugs

When controlled drugs are delivered to a theatre or theatre suite they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of Controlled drugs). A local procedure should define the persons who are permitted to receive controlled drugs and the way in which messengers identify them. As a matter of good practice the receiving person should not normally be the same person who ordered the controlled drugs.

Receipt of controlled drugs in theatre should follow the provisions set out in section 4.4 Receipt of controlled drugs

6.5 Storage of controlled drugs

The storage arrangements for controlled drugs in theatres should conform to the general provisions set out in section 4.5 Storage of controlled drugs

It may also be necessary to install separate, secure, CD fridges for aseptically-prepared parenteral doses of controlled drugs.

6.6 Record-keeping

The records for controlled drugs in theatres should conform to the general provisions set out in section 4.7 Record-keeping

There should be a separate CD record book for each theatre.

In addition to the standard CD record books, some healthcare organisations may wish to stipulate the use of stationery that permits more detailed records of controlled drugs issued, administered and destroyed.

6.7 Controlled drug stock checks

The stock balance of all controlled drugs entered in the CD Record Book should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out.

The senior registered nurse or ODP in charge is responsible for ensuring that stock checks are carried out and recorded. Pharmacy staff should carry out a documented stock check at regular intervals. This should be at least every three months.

Controlled drug stock checks should follow the provisions set out in paragraph 4.8 Controlled drug stock checks

6.8 Archiving of controlled drug records

The archiving of CD records in theatres should conform to the general provisions set out in paragraph 4.9 Archiving of controlled drug records

6.9 Prescribing of controlled drugs

The anaesthetist on duty is usually responsible for prescribing controlled drugs but other prescribers may also be involved. Nurse Independent Prescribers may also be responsible for prescribing or administration of diamorphine and morphine for post-operative pain.

Where separate charts are used e.g. epidural charts, anaesthetic charts, they should be cross-referenced on the patient's main medicines chart.

Prescribing of controlled drugs should follow the general provisions set out in paragraph 4.10 Prescribing of controlled drugs.

6.10 Administration

The practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the theatre CD record book, should be avoided. [See *Controlled Drugs in Perioperative Care. January 2006. www.aagbi.org*] An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed and witnessed e.g. if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted* "

- Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*". Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer so long as the terms of the agreement are complied with.
- Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.
- A record of administration should be made on the appropriate chart immediately after administration by the person who administered the controlled drug. This should include the identity of the person, the dose administered and the time of administration.

6.11 Patient-controlled analgesia

There should be a local procedure for all aspects of the management of patient controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (e.g. pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved from theatre/ward to ward
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

6.12 Returning controlled drugs to the pharmacy

The arrangements for return of controlled drugs to the pharmacy should conform to the provisions set out in paragraph 4.15 Returning controlled drugs to the pharmacy

In general, date-expired or controlled drugs that are otherwise unfit for use should be returned to pharmacy for safe disposal.

Surplus stock should be returned to the pharmacy as described in section 4.15.

6.13 Disposal of controlled drugs

The disposal of controlled drugs in theatres should conform to the general provisions set out in section 4.16 Disposal of controlled drugs in wards and departments.

Unused part-doses should be destroyed promptly and witnessed by a registered nurse or ODP.

- Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in

a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*". Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer so long as the terms of the agreement are complied with.

- If large quantities of part used controlled drugs are routinely generated, some healthcare organisations may wish to provide denaturing kits for use in theatres to destroy controlled drugs that have been used for patients. A risk assessment should be carried out before a decision is made as to whether denaturing kits should be available in theatres. Where denaturing kits are provided to theatres, an SOP should be developed for this practice.

7 Management of controlled drugs in hospital pharmacies

Contents of this chapter:

This chapter deals with the management of controlled drugs in hospital pharmacies and between pharmacies and other departments or health and/or social care bodies.

7.1 Accountability and responsibility

The chief pharmacist is responsible for the safe and appropriate management of controlled drugs in the pharmacy. Day-to-day management of controlled drugs (e.g. receipt into and issue from dispensary stock) in the pharmacy may be delegated to a suitably-trained, competent pharmacy technician or another pharmacist. Where technicians are delegated the management function, legal responsibility for the controlled drugs remains with the delegating pharmacist.

7.2 Security of controlled drugs/Standard Operating Procedures

The pharmacy should have standard operating procedures (SOPs – see also page 15) covering each of the aspects of the safe management of controlled drugs including: ordering, receipt, safe custody, record-keeping, auditing, issuing of stock, dispensing prescriptions, transporting of supplies, and destruction of unwanted drugs.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived.

SOPs should be approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains finally accountable for all the systems for the safe management of Controlled drugs. (See Appendix 3)

Relevant staff should be conversant with the SOPs.

7.3 Ordering and receipt

Ordering of controlled drugs from wholesalers and manufacturers and receipt of controlled drugs should follow the principles of good procurement. Local procedures should ensure that there is a robust audit trail and that the opportunities for diversion are minimised.

7.3.1 Ordering

Routine orders to wholesalers and manufacturers for controlled drugs for stock are usually placed electronically. Some healthcare organisations may, for reconciliation and accounting purposes, make a decision to produce paper records.

Stock levels should be determined by need and kept to a minimum, but should not be so low that there is a danger of running out at busy periods. This will normally be calculated by the pharmacy stock management system. It may be necessary to increase stock levels temporarily when it is anticipated that demand may outstrip the normal supply arrangements, for example, during long holiday breaks.

7.3.2 Receipt

There should be a locally agreed procedure for the receipt of controlled drugs into the pharmacy department. The procedure should ensure the security of controlled drugs and should be auditable. It should include:

- Who should sign for receipt (- ideally not the same person who generated the order.)
- How the goods should be checked (e.g. matching of the details on the delivery note to the goods and the original order) and appropriate stock control documentation completed. Any tamper-evident seals on packs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks.
- What action is to be taken if a tamper evident seal is broken or the contents of a pack do not match the stated amount
- What action is to be taken if the item received is incorrect

- What arrangements are made for storage of incorrect items for return, if appropriate
- The specifications for the record required in the CD register, including who should make the register entry and whether a witness is required

7.3.2.1 It is good practice to record receipt at the first opportunity, and in any event the record must be made no later than the day next following the day of receipt.

7.3.2.2 As a matter of good practice the balance in stock should be checked and recorded as correct by the person making the entry.

7.3.2.3 The stock must be put away promptly into the appropriate section of the CD cabinet. Controlled drugs must never be left outside of the cabinet unsupervised.

7.4 Storage

Pharmacy CD cabinets must conform to, or exceed the requirements of the Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973.

The Regulations should be regarded as a minimum security standard and may not be sufficient for areas where there are large amounts of controlled drugs in stock at a given time and/or there is not a 24-hour staff presence or easy control of access. When new hospital pharmacies are being designed, purpose built, compliant strong-rooms should be incorporated in the plans and it is essential to consult in this respect with the DHSSPS Head of Medicines Regulatory Group.

7.5 Issuing of Controlled drugs to wards and departments

There should be a local procedure for the issuing of controlled drugs to wards and departments. The procedure should ensure the security of the controlled drugs and should be auditable. It should include:

- The procedure for checking that the requisition is valid (complete and signed by an authorised signatory)
- The mechanism for correcting an incomplete or inaccurate requisition
- Specifications of the details required on labels (see below)
- Specification of entry required in the register including who should make the register entry
- Whether a witness is required. The decision as to whether a witness is required or not should be made following a risk assessment.
- Arrangements for transfer of the controlled drugs to the ward or department

7.5.1 Electronic systems

Where electronic systems for the requisitioning of controlled drugs are introduced, safeguards in the software should be in place to ensure that:

- Only individuals who are authorised to requisition controlled drugs from the pharmacy can do so
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes

7.5.2 Labelling of Controlled drugs (Stock)

There should be a standardised procedure for labelling controlled drugs.

The label should state:

- Drug name, form and strength
- Quantity
- “Store in CD cupboard”
- Department / ward name or number
- Date of issue
- Expiry date if dispensed from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g., Oramorph).
- Manufacturer’s Batch Number if dispensed from bulk
- “Keep out of reach and sight of children”
- Address of pharmacy

Depending on local circumstances, some pharmacies may also wish to add

- The requisition number

Each carton, syringe or bottle must be labelled individually. In addition, labels may also be placed on outer wrappers or containers.

7.6 Record-keeping

7.6.1 CD registers

Pharmacy departments are required to keep registers of receipts and supplies of Schedule 2 controlled drugs.

7.6.1.1 Register entries must be made in consecutive, chronological order. The entry must be made on the day when the drug is received or supplied, or on the next day. Entries must be in ink or be otherwise indelible

7.6.1.2 If a mistake is made the entry should not be crossed out, deleted, obliterated or defaced; liquid paper must not be used. Correction must be made by footnote or marginal note. The note must specify the date on which it was made and should be accompanied by the signature of the person making the correction. It is acceptable to bracket the incorrect entry. The resulting record in the register must be unambiguous.

7.6.1.3 The following staff may complete the CD register:

- Any registered pharmacist under their own authority
- Any competent member of Pharmacy staff, ideally a regulated healthcare professional, under the authority of the chief pharmacist, provided this is included in the SOP
- Any person who is being trained by a competent member of pharmacy staff such as a trained technician or a pharmacist, under their supervision. The supervisor should countersign the entry

7.6.1.4 The Misuse of Drugs Regulations 2002 were amended in 2007 with changes which came into force **from 1 February 2008**. The "Form of the Register" as specified in Schedule 6 of the 2002 Regulations was removed and replaced with a requirement to maintain, where appropriate, a CD Register with specified headings/ titles by which to capture mandatory fields of information. Additionally in the CD Register or separate part of the CD Register used for each class of drug, separate pages for each strength and form of controlled drug are now required. The name, strength and form of the drug must be entered at the top of each page and the mandatory fields of information recorded under the specified headings. An index should be maintained, together with "carried forward to/from page" details on register pages where appropriate, to enable easy navigation through the register.

7.6.1.5. The fields of information are somewhat expanded from the previous requirements. Entries in respect of drugs supplied and drugs obtained may be made on the same page or separate pages within the CD Register. The fields are as follows:

7.6.1.6 For controlled drugs **supplied** the register entry must include:

- Date supplied
- Name/Address of person or firm supplied
- Details of authority to possess - prescriber or licence holder's details
- Quantity supplied
- Person collecting Schedule 2 controlled drug (patient/patient's rep/healthcare professional) and if healthcare professional, name and address *[Guidance – work address - not home address]*
- Was proof of identity requested of patient/patient's rep (Yes/No)
- Was proof of identity of person collecting provided (Yes/No)

7.6.1.7 For Controlled drugs **obtained** the following details must be recorded in the CD Register:

- Date supply received
- Name and address from whom received
- Quantity received

7.6.1.8 The stock balance in the register should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system. The frequency of such checks should be determined locally following a risk assessment.

7.6.1.9 The Misuse of Drugs Regulations 2002 were amended in July 2006 to make clear that the details required to be kept in a controlled drug register are a minimum and do not prevent any person required to keep a register from including additional relevant information. This principle is unchanged.

7.6.1.10 The Misuse of Drugs And Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007 can be found at www.legislation.gov.uk/nisr/2007/348/pdfs/nisr_20070348_en.pdf

7.6.2 Liquid preparations

Discrepancies can arise with liquid controlled drugs as a result of manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations should be recorded and the running balance adjusted. In dealing with discrepancies, be alert to the possibility of, or potential for, diversion. Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle. It may be appropriate to carry out volume checks at regular intervals. When spillages occur, every effort should be made to find another person who can verify that the spillage has occurred and this should be recorded and initialled by both the person making the spillage and the second person, if there is one. Spilled product should be treated as controlled drug waste; denatured and rendered irretrievable.

7.6.3 Computerised registers

The Misuse of Drugs Regulations 2002 were amended in January 2006 to allow (not require) the CD register to be held on an approved computerised system. The Regulations require that entries in computerised registers must be attributable and auditable.

If the CD register is held in computerised form, the following should be in place:

- Safeguards should be incorporated in the software to ensure the author of each entry is identifiable
- Entries cannot be altered at a later date

- All entries are attributable to an individual making the entry
- A log of all data entered is kept and can be recalled for audit purposes
- Adequate backups are made
- Systems are in place to minimize the risk of unauthorised access to the data
- Systems which permit inspection of the register by authorised persons without disruption to the workflow of the pharmacy.

For further details see The Misuse of Drugs and the Misuse of Drugs (Notification of and Supply to Addicts) (Amendment) Regulations (Northern Ireland) 2005. (SR 2005 No. 564)
www.opsi.gov.uk/**Sr**/**sr2005**/ni**sr_2005**0**564**_en.pdf

7.7 Checks of CD stocks performed by pharmacy staff

7.7.1 Checks of CD stocks held in the pharmacy

All controlled drugs in the pharmacy should be checked periodically e.g. every three months. The frequency of such checks should be determined following a risk assessment by the pharmacist with operational responsibility for managing controlled drugs and this should be included in an SOP.

7.7.1.1 This check may be undertaken by any competent person approved by the pharmacist with operational responsibility for controlled drugs, the store supervisor, or by a trainee working under their direct supervision and this should be included in an SOP.

7.7.1.2 The check should be recorded indelibly in the CD register by means of signature, date and an appropriate entry, e.g., "*Stock checked. Balance correct*".

7.7.1.3 Some healthcare organisations may also wish to stipulate periodic checks of controlled drugs by pharmacy managers who do not routinely work in the dispensary.

7.7.2 Checks of CD stocks held in wards, theatres or departments

All stocks of controlled drugs held in wards and departments should be checked by a pharmacist or pharmacy technician at least every three months and at other times when requested by the ward or department manager.

7.7.2.1 The stock check procedure should cover the following:

- A check that the levels of drugs in stock tally with the balances recorded in the CDRB.
- A check of a sample of CD requisition originals (brought from pharmacy) together with sample supply/administration

information to ensure that records have been correctly made in the CDRB

- A review of the security and quality of record keeping
- Checking and updating (if required) of the list of authorised signatories for CD requisitions
- A check for exceptional usage or peculiar patterns of usage of controlled drugs
- A check of the physical security arrangement for the storage of controlled drugs, CD stationery and the key-holding policy.

7.7.2.2 The procedure may also include a check of patients' own controlled drugs held on the ward at the time.

7.7.2.3 A record of the stock check should be made clearly and indelibly in the CDRB. The entry should be signed and dated by the person who carried it out.

7.7.2.4 Local documentation may be designed to record all aspects of the CD stock-check procedure (e.g. ward CD inspection report forms) for audit purposes.

7.8 Discrepancies

The balance recorded in the hardcopy register and/or, where relevant, the electronic register/pharmacy stock control system, should be reconciled against the stock of every product in the CD cupboard. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate diversion. The discrepancy should be reported to a senior pharmacist within one working day.

There should be a careful check of transactions in the register and in the stock control system to trace an error or omission.

If an error is traced then a register entry should be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and the witness.

If no error or omission can be traced the Chief Pharmacist and the Accountable Officer should be informed. They should decide what action to take.

7.9 Archiving of controlled drug records

Every requisition, order or private prescription on which a controlled drug is supplied must be preserved by the Pharmacy department in accordance with legislation **and** the guidance contained in *Good Management Good Records* (GMGR) (www.dhsspsni.gov.uk/gmgr). The extensive disposal schedule to the GMGR document contains detailed information about retention of records, not only in pharmacy, but throughout HPSS. It is important to be aware of the wider content in addition to the section on "Pharmacy". Healthcare organisations

should note that even though a short mandatory period of retention may be specified in regulations, cases often come to court at a much later date.

The time periods in GMGR for archiving CD documentation are:

Requisitions	2 years
Registers and CDRBs	11 years from last entry
Extemporaneous preparation worksheets	6 years
Patient Controlled Analgesia worksheets	5 years (or 11 years after expiry where product liability exists)
Discharge and specialist medicines prescriptions	2 years
Clinical trials	See GMGR

Refer to GMGR for detailed guidance on retention of records relating to children. www.dhsspsni.gov.uk/gmgr

Future Regulations may increase the period of time for the storage of records. Readers are advised to refer to the DHSSPS website for up-to-date information.

7.10 Supply to outpatients and discharge patients

For outpatient prescriptions being given directly to the patient or their representative:

- Patients or their representatives may be asked to provide evidence of identity when collecting controlled drugs

From July 2006, there has been a requirement for persons asked to supply controlled drugs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the supplier:

May request evidence of that person's identity and

- **May** refuse to supply the medicine if he is not satisfied as to the identity of the person

Where it is a healthcare professional acting in his professional capacity on behalf of the patient, the supplier:

- **Must** obtain the person's name and address
- **Must**, unless he is acquainted with that person, request evidence of that person's identity; but
- **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The requirement placed on the supplier therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.

From 1 February 2008, it has been a requirement to record the following extra information in the CD register for Schedule 2 controlled drugs supplied:

- Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional
- If the person who collected the drug was a healthcare professional, that person's name and address
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

The patient's date of birth may be used as a second check if necessary.

Depending on local circumstances, some healthcare organisations may wish to stipulate that outpatients and discharge patients should not only sign for receipt of a dispensed item but also for receipt of a specific number of doses.

7.11 Supply to external units

Section 10(7) of the Medicines Act 1968 was repealed in August 2012 to comply with EU legislation. Section 10(7) provided an exemption for registered pharmacies from the requirement to hold a Wholesale Dealers Licence when medicines were traded in certain circumstances. A hospital pharmacy wishing to make a supply to an external organisation must now ensure that it follows the MHRA guidance for supply of medicines by pharmacy to healthcare professionals or it must hold a Wholesale Dealers Licence. The guidance may be found at: www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON152604

Before making a supply to an external unit the hospital should satisfy itself that it may lawfully supply the controlled drug and that the recipient may lawfully possess controlled drugs. A private hospital that is not maintained by voluntary funds or by a registered charity needs a DHSSPS Licence to hold schedule 2 CD stocks. The supplier should only make the supply if such a licence is held. (For further information see the Home Office Drug Laws and Licensing pages: www.homeoffice.gov.uk The DHSSPS Head of Medicines Regulatory Group may be consulted regarding local licence holders.

Where the external unit or body is a designated body as defined in the Regulations it will have an Accountable Officer and the AO must ensure that his designated body has up-to-date SOPs for the use and management of Controlled drugs. Where the external unit acts on behalf of, or provides services under arrangements made with, the Trust, the Trust's Accountable Officer must ensure that the external unit has established and operates appropriate arrangements for securing safe management and use of controlled drugs. These arrangements include adequate and up-to–date SOPs.

Where a service level agreement (SLA) is drawn up for a service to supply controlled drugs to an external body or unit, the SLA should specify the SOPs that are to be followed (i.e. those of the provider or purchaser).

7.11.1 Supply to external units

External units include, for example, hospices, prisons and the ambulance trust.

The other unit must comply with the legislation for controlled drugs and should also follow the guidance in this document.

7.11.2 Written agreement (Service Level Agreement [SLA])

When the hospital pharmacy is providing services to another health and social care body the details should be specified in a written agreement or contract (service level agreement).

In relation to controlled drugs the following points should be included in the written agreement (SLA):

- What is to be supplied; stock controlled drugs and/or patients' own controlled drugs (e.g., for external units where patients are encouraged to self-administer their own medicines including controlled drugs).
- An outline of the ordering and supplying processes and the documentation used.
- The arrangements for obtaining supplies of controlled drugs in emergencies and out of hours.
- Specification of responsibilities and accountability in relation to controlled drugs medicines management including governance arrangements.
- A statement that the pharmacy department and receiving unit produce SOPs for the ordering and issuing processes including transit at their respective facilities. This should include the different ordering processes for stock controlled drugs and patient-specific controlled drugs (see below).
- It is good practice for the other health and social care body to ensure that its SOPs have been reviewed and agreed by a pharmacist. (Note that not all external organisations employ a pharmacist).

- That both parties review each others' SOPs to ensure a consistent, safe and auditable management process for controlled drugs.
- If two different Accountable Officers cover the issuing and receiving units then each Accountable Officer should take responsibility for the SOPs relating to his organisation.
- That the representatives from the issuing pharmacy and the other health and social care body meet on a regular basis to discuss any problems and agree any remedial action to resolve these and review services.
- That the issuing pharmacy and receiving unit conduct audits across the interface to ensure that processes and procedures follow the SOPs and that any gaps in the systems, processes and procedures are identified and rectified. It is good practice to provide the Accountable Officer(s) with the audit reports and action plans.

7.11.3 Ordering of stock controlled drugs by another hospital or a nursing home

Ordering of controlled drugs must comply with the current Misuse of Drugs Regulations.

Where a pharmacist is employed, the purchase of controlled drugs must be under his or her direct supervision and this includes authorising orders to suppliers. Where no pharmacist is employed a doctor or dentist employed by or engaged by the body must countersign orders for controlled drugs raised by the person in charge or acting person in charge of the other hospital or nursing home.

All stock controlled drugs should be ordered as stock items only and contain no patient names.

7.11.3.1. Arrangements when the hospital pharmacy provides a supply service only to another hospital or nursing home

The person or acting person in charge of a hospital or nursing home, can complete the controlled drugs requisition book and sign this order, which must also be countersigned – see below. The stock controlled drugs order must contain:

- Signature of the person to whom the drug is to be supplied (the recipient),
- The name, address and profession or occupation of the recipient
- Name, formulation, strength and quantity (whole pack sizes) of the controlled drug,
- Purpose for use,
- Countersignature of a doctor (or dentist) who is employed or engaged at the other hospital or nursing home.

The requisition should be dated and should include sufficient information to identify the hospital or nursing home and the ward or department.

The doctor will sign the order as an independent verification that the controlled drugs ordered are to be used within the requesting ward or department within the other hospital or nursing home. Responsibility and accountability should be written into the SLA and be in accordance with the Misuse of Drugs Regulations.

There are circumstances where a doctor may request controlled drugs and is also responsible for the management of the controlled drugs within the department of the other organisation.

7.11.4 Ordering of patient specific controlled drugs by external units

7.11.4.1 Ordering from a hospital pharmacy

Patient specific controlled drugs can be ordered for either use within an inpatient unit (e.g. as part of self-administration scheme) or as discharge medication.

It is acceptable for the external unit to use locally designed and approved prescription forms for prescribing a patient's medication. The hospital pharmacy should manage these prescription forms in the same way as they would internal prescription forms.

A full audit trail should be maintained when transferring the dispensed controlled drugs to the external unit.

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

7.11.4.2 Ordering from a community pharmacy

A similar arrangement of using locally designed and approved prescription forms can be used when a community pharmacy is supplying patient-specific controlled drugs under a written agreement to an inpatient unit such as a prison or hospice.

(It should be noted that these prescriptions are not private prescriptions but part of a system for supplying patients/prisoners with appropriate dispensed and labelled medicines including controlled drugs on discharge from that unit or as part of a patient self-administration scheme).

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

7.12 Transfer of controlled drugs

At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties.

Wherever possible, the drug must be transported in a secure, lockable container and
a suitable delivery document completed to provide a full audit trail.

See paragraph 5.2 - Transfer of controlled drugs

7.13 Controlled drugs returned from wards

There should be a local procedure and auditable documentation for the management of controlled drugs returned from wards.

See also paragraph 4.15 – Returns to Pharmacy

7.14 Production and Quality Control

Where pharmacy production or aseptic units are preparing products that contain controlled drugs, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

7.15 Disposal/destruction

See also section 4.16 disposal of controlled drugs in wards and departments

Unwanted controlled drugs should be denatured in a pharmacy, and when required by legislation, in the presence of an authorised witness. Treated waste should be placed in appropriate containers for eventual incineration and should not be allowed to enter the sewerage system. [See *Handling and Disposal of Pharmaceutical and Clinical Waste* (Health Estates 2002) www.dhsspsni.gov.uk/pharmaceutical-waste-guidance.pdf] Reference has previously been made (e.g. section 4.16.2) to circumstances whereby small quantities of waste liquid controlled drugs at ward or department level may be disposed of to sewer. Note that this pertains where hospitals have individual agreements with Northern Ireland Water, and act within the parameters of those agreements.

Controlled drugs should be disposed of in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used again.

There should be a local policy for disposal of controlled drugs and this policy must be in accordance with current Home Office guidance, Waste Management Regulations and Environment and Heritage Service guidance. The methods used for denaturing should be in accordance with PSNI guidance.

The Environment Agency (EA), which covers England and Wales, has decided that it is not in the public interest to expect pharmacies to obtain a waste management licence for denaturing Controlled drugs as this is seen by the EA as a 'low risk' activity. The Environment and Heritage Service in Northern Ireland has taken the following position: "EHS have considered the risks posed by the destruction of controlled drugs in a pharmacy and have concluded that it will not normally take enforcement action against persons carrying out this activity providing the subsequent movement and disposal of the denatured drugs is in compliance with all relevant waste legislation… Pharmacies must ensure that the activities they undertake to denature controlled drugs protect the environment, workers and others within the pharmacy." The EHS may take appropriate action where it considers that there is a risk to human health and/or the environment. It may also amend its position if there are regulatory changes, future government guidance or in the

light of experience of this type of activity. It is therefore essential that local policies and procedures for destruction of Controlled drugs not only ensure effective destruction but also protect the environment and people in the pharmacy.

7.15.1 Destruction of stock controlled drugs

Any pharmacy-held stock of obsolete, expired or unwanted Schedule 2 controlled drugs not returned by patients, that requires destruction can only be destroyed in the presence of a person authorised by the DHSSPS.

7.15.1.1 Authorised witnesses currently include pharmacy inspectors,and other named persons employed by Trusts, who have been authorised and trained by DHSSPS.

7.15.1.2 Until they can be destroyed, obsolete, expired and unwanted stock controlled drugs requiring safe custody, according to arrangements appropriate to their schedule, must be kept segregated from other controlled drugs in the CD cupboard. Stock controlled drugs awaiting destruction should be clearly marked in order to minimise the risk of errors and inadvertent supply.

7.15.1.3 When stock Schedule 2 controlled drugs are destroyed, the following details must be entered into the CD register:

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed
- Date of destruction
- Signature of the authorised person in whose presence the drug was destroyed

7.15.1.4 It is good practice for the person carrying out the destruction to also sign against this record.

7.15.2 Destruction of controlled drugs returned by patients

These are controlled drugs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used by the patient or their representative to the pharmacy.

Controlled drugs that have been returned by patients do not form part of the pharmacy stock and can be destroyed without the presence of an Authorised Person.

7.15.2.1 Although recording of patient-returned controlled drugs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2002 it is good practice to keep a record.

7.15.2.2 A record of controlled drugs returned by patients should be kept as above and a record of their destruction should be made. As a matter of good practice, destruction should be witnessed, preferably by a pharmacist or pharmacy technician.

7.15.2.3 The record of these destructions should be made somewhere other than the CD register – for example in a separate "Destruction Book" designated for that purpose. It is recommended that the following details are recorded:

- Date of return of the controlled drugs
- Name, quantity, strength and form of the controlled drugs
- Role of the person who returned the controlled drugs (if known)
- Name and signature of the person who received the controlled drugs
- Patient's name and address (if known)
- Names, positions and signatures of the person destroying the controlled drugs and the witness
- Date of destruction
- Any other comments relevant to the receipt or destruction of that particular dispensed medicine

7.15.2.4 Controlled drugs requiring safe custody awaiting destruction should be stored in the CD cabinet separately from pharmacy stock controlled drugs.

7.15.2.5 Destruction of controlled drugs should occur regularly and with sufficient frequency to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment.

7.15.3 Methods of disposal for Controlled drugs

Denatured controlled drugs for disposal should be placed in suitable waste containers which are then sent for incineration and should not be disposed of in the sewerage system. The containers of waste should be labelled, "*contains pharmaceutical waste – for incineration*".

The Home Office has advised that Schedule 2, 3 and 4 Part I controlled drugs must be denatured before being placed into waste containers.

7.15.3.1 Wherever practicable, CD denaturing kits should be used to denature controlled drugs. Where this is not possible or practical other methods of denaturing may be used. Used denaturing kits should be placed in pharmaceutical waste bins that are destined for incineration. Regardless of the methods used, measures should be taken to ensure safety of personnel and non-contamination of the environment.

7.15.3.2 Details of suitable methods for destruction of Controlled drugs in different dosage forms can be found in Pharmaceutical Society of Northern Ireland guidance www.psni.org.uk/documents/600/GuideLegalRequirements+MedsHumanUseControlledDrugs.pdf and it is strongly recommended that these methods are used.

7.15.3.3 Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

Where denaturing kits are used, their use should be included in an SOP.

Small unrequired excesses are most likely to arise when products are being prepared. In these circumstances, the controlled drug has already been issued to the extemporaneous preparation area or aseptic preparation area and is no longer part of the pharmacy CD stock. A full audit trail should be maintained. The worksheet should show the amount used and the amount wasted, for example: "2.5ml used 0.5ml wasted".

As a matter of good practice, the disposal of the part dose should be witnessed and recorded on the worksheet. Both people should sign the worksheet.

8 Staff training for management of controlled drugs

The Accountable Officer is responsible for ensuring that members of staff who are involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training to enable them carry out their duties.

Staff should receive appropriate training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs and then regularly thereafter. The frequency of training should be determined locally.

Staff should be informed and, if necessary, receive additional training when SOPs are revised or amended and when new CD products or systems are introduced.

Glossary of terms

Administer	To give a medicine either by introduction into the body, whether by direct contact with the body or not, (eg orally or by injection) or by external application (eg application of an impregnated dressing). There are specific definitions in medicines legislation as follows: “external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations; "parenteral administration" means administration by breach of the skin or mucous membrane.
Chief Pharmacist	In the context of this document the term is used to describe the pharmacist with overall responsibility for the hospital pharmacy. In some circumstances consultation may be necessary with a higher level of pharmacy management.
Controlled Drugs (CDs)	The drugs listed in Schedule 2 to the Misuse of Drugs Act 1971. These drugs are categorised in schedules 1-5 of the Misuse of Drugs Regulations (Northern Ireland) 2002 (as amended). Drugs listed in the different MDR schedules are subject to differing levels of control but all are controlled drugs.
CD record book (CDRB)	Bound book in which records are made of controlled drugs received and supplied in wards, theatres and departments.
CD register	A “register” as specified in the Misuse of Drugs Regulations 2002 (as amended) means either a bound book, which does not include any form of loose leaf register or card index, or an approved computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.
Discrepancy	Difference between the amount shown in the register or record book and the amount that is physically present.
Designated body/bodies	Health care organisations - the Board, HSC Trusts, the Northern Ireland Ambulance Service, Independent Hospitals – as defined in Regulation 3 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.
Dispense, dispensing	Dispensing of controlled drugs: preparation (including compounding, dissolving, diluting, packing and labelling.) In some contexts it may include the transfer (supply) of medicines to individual patients.

Diversion	Removal of controlled drugs for unauthorised use; theft
Duty Pharmacist	Senior pharmacist on duty for the time being
Healthcare organisations	Organisations responsible for the delivery of healthcare. Includes Trust hospitals and independent hospitals.
Local Intelligence Network	A network lawfully established by the Accountable Officers for sharing information regarding the management and use of controlled drugs.
"may"	Used in this document in connection with recommendations concerned with good practice if they are relevant to local circumstances.
MDR	Misuse of Drugs Regulations – Regulations made under the Misuse of Drugs Act (1971).
"must"	Used in this document in connection with legal requirements e.g. "records of schedule 2 controlled drugs received and supplied by a pharmacy must be kept in a CD register."
Operating Department Practitioner (- Registered Operating Department Practitioner)	Operating Department Practitioner whose name is on the register of the Health Professions Council and should be a member of the College of Operating Department Practitioners – see Appendix 2
Order	In the context of controlled drugs: To make a formal order for controlled drugs. Can only be done by someone who is entitled to be in possession of controlled drugs (as defined in current MDR). Must be addressed to a suitable pharmaceutical supplier.
Patient Group Directions (PGD).	Written directions from a senior doctor (or dentist) and a senior pharmacist and a representative of the appropriate organisation giving specified registered nurses, pharmacists and other specified health professionals a general authority to supply and administer specified medicines to patients, who are not individually identifiable, in specified clinical situations.
PCA	Patient-controlled analgesia
Pharmacist (– Registered Pharmacist)	Person registered in the register of pharmacists maintained by the Pharmaceutical Society of Northern Ireland
Pharmacy technician	Pharmacy technicians in Northern Ireland are not currently registered with the Pharmaceutical Society of Northern Ireland and are not, therefore, regulated professionals. Their activities related to controlled drugs should be circumscribed by standard operating procedures and must be carried out under the authority of a pharmacist.
PODs	Patient's own drugs. In this context - controlled drugs brought into the hospital by the patient on admission.
Prescribe	Prescribing is the ordering of a medicine for an individual patient. In medicines legislation, certain medicines may be supplied only in accordance with a prescription by a doctor, dentist or other appropriate practitioner, and which meets the conditions specified in the Human Medicines Regulations 2012. The term has however become commonly used to describe authorising - by means of an NHS prescription - the

	supply of any medicine (Prescription Only Medicine, Pharmacy or General Sales List medicine) at public expense to a named patient;
Registered nurse in charge	The registered nurse who is in charge for the time being (senior registered nurse on duty) and is therefore responsible for management of controlled drugs.
Relevant persons	Are defined in the Health Act 2006 and see also the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009
Requisition	In the context of controlled drugs: To make a formal, written request, compliant with Regulation 14(6) of the Misuse of Drugs Regs (NI) 2002, for a supply of a controlled drug for use in a ward or department. The requisition must be signed by an authorised signatory. Requisitions are usually made on stationery designed specifically for that purpose. Confusingly these books are often called "Controlled Drug Order Books".
Responsible body	Bodies listed in regulation 22 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. Includes: Designated bodies, the Department, the Regulation and Quality Improvement Authority, the Regional Business Services Organisation, the Police Service, Regulatory Bodies.
Senior Assistant Technical Officer	In this context, a member of the pharmacy staff who has received in-house training for specific duties. Not a pharmacy technician.
Service Level Agreement (SLA)	Written agreement between two parties that specifies the service to be provided
"should"	Used in this document in connection with recommendations concerned with good practice
Standard Operating Procedure (SOP)	A standard operating procedure specifies in writing what should be done, when, where and by whom in order to manage safely and accountably any set of processes, in this case around the total management of controlled drugs.
Supervisor of midwives	A person appointed by the local supervising authority to exercise supervision over midwives in its area in accordance with rule 11(1) of the Nursing and Midwifery Council (Midwives) Rules 2004 (SI 2004/1764) www.hmso.gov.uk
Supply	In the context of legal supply of controlled drugs: making a supply against a signed order, requisition, Patient Group Direction or a prescription.
Transcribe	To copy the details of one document on to another.

Appendix 1: Legislation for the management of Controlled drugs

Misuse of Drugs Act 1971

The Misuse of Drugs Act (MDA) 1971 and its Regulations provide the statutory framework for the control and regulation of controlled drugs. The primary purpose of the MDA is to prevent misuse of controlled drugs. The MDA 1971 makes it unlawful to possess or supply a controlled drug unless an exception or exemption applies. A controlled drug is defined as any drug listed in Schedule 2 to the Act.

Misuse of Drugs Regulations (Northern Ireland) 2002 (MDR)

The use of controlled drugs in medicine is permitted by the Misuse of Drug Regulations (MDR). The MDR classify the drugs in five schedules according to the different levels of control required (see below). Schedule 1 controlled drugs are subject to the highest level of control, whereas Schedule 5 controlled drugs are subject to a much lower level of control.

The MDR are periodically amended and revised. The MDR currently in force and its amendments can be found at the website of the Office of Public Sector Information (www.opsi.gov.uk)

Schedule 1 (CD Licence)

Schedule 1 drugs include hallucinogenic drugs such as coca leaf, lysergide and mescaline. Production, possession and supply of drugs in this Schedule are limited, in the public interest, to research or other special purposes. In Northern Ireland only certain persons can be licensed by the DHSSPS to possess them for research purposes. Practitioners (e.g. doctors, dentists and veterinary surgeons) and pharmacists may not lawfully possess Schedule 1 drugs except under licence from the DHSSPS.
The drugs listed in Schedule 1 have no recognised medicinal use although Sativex© (a cannabis based product), for which there is an open general licence, is currently being supplied on a named-patient basis.

Schedule 2 (CD POM)

Schedule 2 includes more than 100 drugs such as the opioids, the major stimulants, secobarbital and amphetamine.

Safe custody
Schedule 2 controlled drugs (except secobarbital) are subject to safe custody requirements (under the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973, (see below)). They must be stored in a locked receptacle, such as

an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the controlled drug or a person authorised by them**.**

Schedule 2 controlled drugs may be manufactured or compounded by a licence holder, a practitioner, a pharmacist or a person lawfully conducting a retail pharmacy business acting in their capacity as such.

A nurse independent prescriber acting in her capacity as such, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2, 3, 4 and 5 for the purposes of administration in accordance with regulations and any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2, 3, 4, and 5 for the purposes of administration in accordance with the regulations.

A pharmacist may supply schedule 2 controlled drugs to a patient only on the authority of a prescription in the required form issued by an appropriate prescriber.

Schedule 2 controlled drugs may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of an appropriately qualified prescriber who is authorised to prescribe Schedule 2 controlled drugs

Nurse Independent Prescribers and Pharmacist Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer any controlled drug in Schedule 2, 3, 4, and 5 of the Regulations, but not in relation to cocaine, diamorphine or dipipanone for addicts, otherwise than for the purpose of treating organic disease or injury.

Record-keeping
There is a statutory requirement for pharmacy departments to keep a register for Schedule 2 controlled drugs and this register must comply with the requirements of the Misuse of Drugs Regulations 2002. Wards and departments should also keep a Controlled Drugs Record Book (often loosely referred to as a register) for Schedule 2 controlled drugs
Midwives must keep a register for the Schedule 2 controlled drugs that they are permitted to possess and administer.

A licence is required to import or export drugs in Schedule 2.

Destruction
The destruction of Schedule 2 CD stock must only take place in the presence of an appropriately authorised person.

Schedule 3 (CD No Register)

Schedule 3 includes a small number of minor stimulant drugs and other drugs, which are less likely to be misused than drugs in Schedule 2, or are less harmful if misused.

Safe custody
Some Schedule 3 controlled drugs are exempt from safe custody requirements and may be stored on the open dispensary shelf. Non-exempt examples include flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

Record keeping
There is no legal requirement to record transactions involving Schedule 3 controlled drugs in a CD register. Some organisations keep a non-statutory register as a matter of good practice.

Invoices must be retained for a minimum of two years.

Schedule 3 controlled drugs are subject to full import and export control.

Destruction
The requirements for destruction do not apply unless the controlled drugs are manufactured by the entity in legal possession. However, Home Office has advised that drugs in Schedules 3 and 4 Part 1 should be denatured before disposal.

Schedule 4 (CD Benz and CD Anab)

Schedule 4 is split into two parts.

Part 1 (CD Benz) contains most of the benzodiazepines, plus eight other substances including zolpidem, fencamfamin and mesocarb.

Part 2 (CD Anab) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoreceptor stimulant) and growth hormones (5 polypeptide hormones).

Unauthorised possession or supply of a drug in Schedule 4 Part 1 (CD Benz) is an offence. Possession and supply by practitioners and pharmacists acting in their professional capacities is authorised.

There is no restriction on the possession of a Schedule 4 Part 2 (CD Anab) drug. Unauthorised supply to a third party is unlawful.

Drugs in Part 1 (CD Benz) are subject to full import and export control and a DHSSPS licence is also required for the importation and exportation of substances in Part 2 (CD Anab) unless the substance is imported in person and is for administration by the person to himself.

All substances in Schedule 4 are exempt from safe custody requirements, with destruction requirements only applying to importers, exporters and manufacturers. It is good practice to store securely excess stock of Schedule 4 controlled drugs.

Prescription-writing requirements for these controlled drugs do not apply, except those requirements laid out in the Human Medicines Regulations 2012. CD registers do not need to be kept for Schedule 4 drugs, although records should be kept if such controlled drugs are compounded, or if a licensed person imports or exports such drugs (see Regulation 22 of the Misuse of Drugs Regulations 2002).

Schedule 5 (CD Invoice)

Schedule 5 contains preparations of certain controlled drugs (e.g. codeine, pholcodine, morphine), which are exempt from full control when present in medicinal products of low strengths, as their risk of misuse is reduced.

There is no restriction on the import, export, possession, administration or destruction of these preparations and Safe Custody Regulations do not apply.

Preparations containing not more than 0.1% cocaine are no longer exempt from prohibitions on import, export and possession.

A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any controlled drug in Schedule 5.
A nurse independent prescriber acting in her capacity as such, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2, 3, 4, and 5 for the purposes of administration in accordance with regulations and any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2,3,4, and 5 for the purposes of administration in accordance with the regulations.

Invoices must be retained for a minimum of two years.

Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973

The Safe Custody Regulations 1973 impose controls on the storage of controlled drugs. The degree of control depends on the premises within which the drugs are being stored.

All Schedule 2 and certain non-exempted Schedule 3 controlled drugs should be stored securely in accordance with the Misuse of Drugs (Safe Custody) Regulations. These Regulations state that such controlled drugs must be stored in a cabinet or safe, locked with a key. It should be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts that are not accessible from outside the cabinet.

Misuse of Drugs (Notification of and Supply to Addicts) (Northern Ireland) Regulations 1973

These Regulations prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under DHSSPS licence. A licence is not required with such drugs for the treatment of organic disease or injury. Doctors must notify the DHSSPS of patients whom they consider to be addicted to specified controlled drugs.

Medicines Act 1968 and the Human Medicines Regulations 2012

This Act (much of it repealed in August 2012), and particularly the Human Medicines Regulations 2012 set out the requirements for the legal sale, supply and administration of medicines. They also allow certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, enable midwives to supply and/or administer diamorphine, morphine, or pethidine. A number of healthcare professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups, but not all, are permitted to possess, supply or administer controlled drugs in accordance with a PGD under Misuse of Drugs legislation

Health Act 2006

The key provisions of the Act are:

- Designated bodies (as prescribed by regulations) are required to appoint an Accountable Officer with responsibilities (prescribed by regulations) in connection with the safe and effective management of controlled drugs
- A duty of collaboration is placed on responsible bodies (as prescribed by regulations) to share intelligence on controlled drug issues
- A power of entry and inspection is granted for the police and other nominated people to enter premises to inspect stocks and records of controlled drugs

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

These regulations, made under the Health Act 2006, set out the requirements for certain healthcare organisations and independent hospitals to appoint an Accountable Officer and describe the duties and responsibilities of Accountable Officers related to the management and use of controlled drugs.
The Regulations also require specified bodies to co-operate with each other, including with regard to sharing of information about concerns related to the use and management of controlled drugs, and set out further arrangements relating to powers of entry and inspection.

Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007

This Regulation amends the Misuse of Drugs Regulations (Northern Ireland) 2002 and the Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973 to (among other matters):

Update the references to premises covered by the Safe Custody Regulations

Update references to “sister” to “senior registered nurse”

Replace the prescribed form of the CD register with prescribed headings for entries in the register

Permit ODPs to possess and supply Controlled drugs in accordance with prescriber directions

Appendix 2: Operating Department Practitioners

Operating Department Practitioner (ODP) is defined in the Misuse of Drugs Regulations 2002 (as amended by SR 2007/348) as a person who is registered under the Health Professions Order 2001 (SI 2001/254 as amended by SI 2004/2033) as an operating department practitioner. The amendment to the Misuse of Drugs Regulations afforded to this group of registered professionals similar (but not identical) authority to that already granted to the "senior register nurse (formerly 'sister') or acting senior registered nurse for the time being in charge of a ward, theatre or other department…" The ODP was granted authority to possess and supply controlled drugs supplied to him by the person responsible for dispensing and supply of medicines at the hospital. The ODP may supply to a patient in a ward, theatre or other department only in accordance with the directions of an appropriate prescriber who may legally prescribe that drug. The amendment to the Misuse of Drugs Regulations did not specify that the ODP had to produce the same requisition as required of the senior registered nurse in charge. Because the ODP's authority to "possess and supply" implies the ability to obtain the drugs, the Home Office has stated that the ODP's authority is sufficient to "order" controlled drugs from the hospital pharmacy. Until such time as the Misuse of Drugs Regulations are further amended to require the same requisition from the ODP as the nurse in charge of a ward, hospitals should ensure that, as a matter of good practice and/or in order to comply with SOPs, supply of controlled drugs to ODPs should still be dependant upon the receipt by the hospital pharmacy of a requisition of exactly the same nature that a nurse in charge of a ward would present. Furthermore hospitals should specify in policy and SOPs which registered professional (senior nurse in charge or ODP) is responsible for the stock of controlled drugs in the particular ward, theatre or other department. Whereas the legislation grants authority to the senior (or acting senior) registered nurse in charge, **any** ODP is permitted to possess and supply controlled drugs under certain conditions. This guidance document has followed the position of the Department of Health document in referring to the senior registered nurse in charge or **ODP in charge** although it is recognised that this goes beyond the actual wording of the legislation. The intention is to indicate that it should be crystal clear in policy and procedures who is responsible for the controlled drug stock held in any theatre, ward or other department.

Appendix 3: The Accountable Officer

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 SR2009/225 ; www.legislation.gov.uk Further detail is also given in 'Safer Management of Controlled Drugs: A Guide to Strengthened Governance Arrangements in Northern Ireland' in the Accountable Officer section of the Department website www.dhsspsni.gov.uk

The following paragraphs provide a summary of the main provisions.

Persons who may be appointed as Accountable Officers

Each HSC Trust and other designated bodies must appoint an Accountable Officer who is a fit, proper and suitably experienced person in a senior role within the organisation. Where designated bodies are large organisations, the Accountable Officer may consider appointing Designated Officers to assist in the day-to-day discharge of responsibilities.

The Accountable Officer should not be personally involved in the routine prescribing, supply, administration or disposal of controlled drugs. An organisation can have an Accountable Officer who has occasional need to handle Controlled drugs (for example, in emergencies), but if this is the case, their use of Controlled drugs should be open to the scrutiny of another senior member of the organisation or Accountable Officer of another body. Individuals such as Chief Nurses, Medical Directors and Chief Pharmacists can be appointed as Accountable Officers if they meet these criteria. Accountable Officers should call on other Accountable Officers if a conflict of interest arises.

The organisation's controlled drugs policy should specify the person whom staff should approach if they have concerns about the practice of their Accountable Officer.

The Accountable Officer for an HSC Trust should liaise with the Chair of the Local Intelligence Network.

Responsibilities of the Accountable Officer

In discharging his responsibilities, an Accountable Officer must have regard to best practice in relation to the management and use of controlled drugs.
The Accountable Officer must:

- Secure the safe and effective use and management of controlled drugs within local organisations subject to his oversight (i.e. the organisation and those with which it contracts).

(For some of the following duties and responsibilities the regulations frequently use the form of words, "The Accountable Officer must ensure/establish …, or ensure that his designated body ensures/establishes …")

- Establish, operate and periodically review appropriate systems for the safe management of controlled drugs
- Ensure that all arrangements comply with relevant statutory requirements
- Ensure that adequate and up-to-date standard operating procedures are in place for the management and use of controlled drugs
- Establish and operate appropriate arrangements for securing the safe destruction and disposal of controlled drugs
- Ensure monitoring and auditing of the management and use of controlled drugs within the organisation and take action where necessary. The following must be in place:
    - Systems to alert the Accountable Officer to complaints or concerns involving the management of controlled drugs
    - An incident reporting system to capture untoward incidents involving the management or use of controlled drugs
- Establish and operate arrangements for analysing and responding to untoward incidents involving the management or use of controlled drugs
- Ensure that individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training. Arrangements must be in place for relevant individuals:
    - to receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs
    - to be informed when any local standard operating procedures for controlled drugs are subsequently reviewed or amended
- Monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance. The Accountable Officer must, where appropriate, provide for the following:
    - Recording concerns raised in relation to the management or use of controlled drugs by a relevant individual
    - Assessing and investigating concerns raised regarding the management or use of controlled drugs by a relevant individual
    - Determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers should be shared with a responsible body.

The Accountable Officer should be aware that unusually high usage of some Controlled drugs or unusually high numbers of breakages could indicate misuse.

The Accountable Officer in Secondary Care should also monitor prescriptions that are written in hospital but dispensed in the community.

- Maintain a record of concerns regarding relevant individuals. Such records may be paper-based or electronic. The Accountable Officer must:
    - Establish and operate appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a relevant individual. This must include a system to ensure that access to such records is limited to the Accountable Officer, his staff and others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.
    - Ensure that adequate records are compiled, which must include (but not be limited to), as appropriate:
        - the date on which the concern was made known to the accountable officer;
        - dates on which the matters that led to the concern took place;
        - details regarding the nature of the concern;
        - details of the relevant individual in relation to whom the concern was expressed;
        - details of the person who, or body which, made known the concern;
        - details of any action taken by the designated body in relation to the concern;
        - the assessment of whether information in relation to the concern should be disclosed to another responsible body
        - if information regarding the concern is disclosed to another responsible body, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.

- Assess and investigate concerns. The accountable officer must:
    - Establish and operate appropriate arrangements for assessing and investigating concerns about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual
    - Take appropriate action if there are well-founded concerns

- Establish and operate appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards designated body, a relevant individual, appear to be well-founded.

- Establish arrangements for sharing information. The Accountable Officer must:
  - Establish and operate appropriate arrangements for ensuring the proper sharing of information, by his designated body with other responsible bodies regarding the management and use of controlled drugs
  - Provide a quarterly report to the Chair of the Local Intelligence Network
  - Cooperate with other organisations including the Department, the RQIA, the Business Services Organisation and the police as circumstances require.

- Participate in the Local Intelligence Network

Appendix 4: Useful contacts

British Medical Association
BMA House
Tavistock Square
London
WC1H 9JP

Tel: 0207 387 4499
Fax: 0207 383 6400
Website: www.bma.org.uk/

Community Practitioners' and Health Visitors Association
33-37 Moreland Street
London
EC1V 8HA

Tel: 0207 505 3000
Website:
www.amicustheunion.org/cphva/

Council for Healthcare Regulatory Excellence
157-197 Buckingham Palace Road
London
SW1W 9SP

Tel: 0207 389 8030
Fax: 0207 389 8040
Website: www.chre.org.uk

Department of Health
Richmond House
79 Whitehall
London
SW1A 2NS

Tel: 0207 210 4850
Website: www.dh.gov.uk

Department of Health, Social Services and Public Safety
Pharmaceutical Advice and Services
Room D4.5,
Castle Buildings
Stormont
Belfast
BT4 3SQ

Tel: 028 9052 8688
Fax: 028 9052 2335
Website: www.dhsspsni.gov.uk

Dispensing Doctors' Association
Low Hagg Farm
Starfitts Lane
Kirbymoorside
North Yorkshire
YO62 7JF

Tel: 01751 430835
Fax: 01751 430836
Website: www.dispensingdoctor.org

General Medical Council
Regent's Place
350 Euston Road
London
NW1 3JN

Tel: 0845 357 3456
Website: www.gmc-uk.org

Health and Social Care Board
Headquarters
12-22 Linenhall Street
Belfast
BT2 8BS
Tel: 028 9032 1313
Website: www.hscboard.hscni.net

Home Office Drugs Licensing Branch
2 Marsham Street
London
SW1P 4DF
Tel: 0207 035 0483
Website: www.homeoffice.gov.uk/drugs/licensing/

Home Office Drug Legislation Team
2 Marsham Street
London
SW1P 4DF
Tel: 0207 035 0464
Website: www.homeoffice.gov.uk

Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Tel: 0207 084 2000
Fax: 0207 084 2353
Website: www.mhra.gov.uk

National Clinical Assessment Service
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn BT28 1TW
Tel: 02892663241
Website: www.ncas.nhs.uk

National Patient Safety Agency
4-8 Maple Street
London
W1T 5HD
Tel: 0207 927 9500
Website: www.npsa.nhs.uk

National Pharmacy Association
Mallinson House
38-42 St Peter's Street
St Albans
Hertfordshire
AL1 3NP
Tel: 01727 832161
Fax: 01727 840858
Website: www.npa.co.uk

National Prescribing Centre
The Infirmary
70 Pembroke Place
Liverpool
L69 3GF
Tel: 0151 794 8134
Fax: 0151 794 8139
Website: www.npc.co.uk (Internet)
www.npc.nhs.uk (NHSNet)

National Treatment Agency
8th Floor, Hercules House
Hercules Road
London
SE1 7DU
Tel: 020 7261 8801
Fax: 020 7261 8883
Website: www.nta.nhs.uk

Nursing and Midwifery Council
23 Portland Place
London
W1B 1PZ
Tel: 020 7637 7181
Fax: 020 7436 2924
Website: www.nmc-uk.org

Pharmaceutical Society of Northern Ireland
73 University Street
Belfast
BT7 1HL
Tel: 028 9032 6927
Fax: 028 9043 9919
Website: www.psni.org.uk

Prescribing Support Unit
The Health and Social Care
Information Centre
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE
Tel: 0113 254 7041
Fax: 0113 254 7097
Website**:** www.ic.nhs.uk/psu

Regional Business Services Organisation
2 Franklin Street
Belfast
BT2 8DQ
Tel: 028 9032 4431
Website: www.hscbusiness.hscni.net/

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT
Tel: 028 9051 7500
Website: www.rqia.org.uk

Royal Pharmaceutical Society
1 Lambeth High Street
London
SE1 7JN
Tel: 0207 572 2737
Fax: 020 7735 7629
Website: www.rpharms.com

Appendix 5: Patient Information

NHS Direct

The NHS Direct website has developed a Common Health Question about Controlled drugs specifically to inform the public. It is entitled 'What is a controlled drug (medicine)?' and is available at
www.nhs.uk/chq/Pages/1391.aspx?CategoryID=73&SubCategoryID=101
The text defines a controlled drug in legal terms, how the Regulations apply to them and directs patients to information about requirements for travelling abroad.

HOME OFFICE
Useful advice for patients travelling with controlled drugs can be accessed at
www.homeoffice.gov.uk/drugs/licensing/personal/

Medicines Guides

Medicine Guides provide a source of information for members of the public who are looking for information about individual medicines that is up-to-date, reliable and easy to understand. Medicine Guides are being developed as part of the Medicines Information Project which aims to provide people with information about medicines, conditions and the different treatment options available.

The Medicine Guides on controlled drugs can be found on the
www.medicines.org.uk website which is published by Datapharm Communications. There is a link to the NHS Direct Common Health Question within each Guide. Guides for the controlled drugs that have been published to date can be accessed at
www.medguides.medicines.org.uk/cd.

Appendix 6: Contributors

The following individuals and organisations are among those who contributed to the design and content of this guidance and/or the original Department of Health document:

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Appendix 7

Suggestions for Future Revisions

Name:	
Organisation:	
Section number Indicate **page/section heading** or **'general'** if your comment relates to the whole document	**Comments** **Please insert each new comment in a new row.**
P.24, Record keeping	*In our hospital we refer to…*

Belfast Health and Social Care Trust

Standards and Guidelines Committee

Controlled Drugs Policy.	
Summary	The purpose of this policy is to ensure the safe and effective use and management of controlled drugs in secondary care sites within BHSCT and should be read in conjunction with the BHSCT Medicines Code.
Operational date	February 2011
Review date	February 2013
Version Number	V 1.0
Director Responsible	Dr Tony Stevens
Lead Author	Julia Tolan
Lead Author, Position	Deputy Head of Pharmacy, Pharmacy Services Manager (BCH, Musgrave, KBN)
Department / Service Group	Pharmacy Department / Clinical Services
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Additional Author(s)	Eimear McCusker [redacted] Rhona Fair [redacted]

REFERENCE NUMBER	SG 01/11
Supersedes	All legacy Medicines Policies relating to controlled drugs.

Version Record

Date	Version	Author	Comments
04/01/10	0.1	J Tolan	Initial Draft
25/7/10	0.2	J Tolan	BHSCT draft. Inclusion of CD template prescription (Steven McNeill & Orla Daly)
06/09/10	0.3	J Tolan	Reference to strong potassium infusion removed from policy appendix 2
31/10/10	0.4	J Tolan	Revisions following review by central nursing and Dr Susan Atkinson
24/11/10	0.5	J Tolan	Final comments from central Nursing (Bernadette Gribben) Final comments from Dr Julian Johnston (Standards and Guidelines BHSCT)
10/12/10	0.6	J Tolan	Addition of dentist as prescriber Addition of requirement for risk assessment if two practitioners not involved in administration of CD. Addition of cannabis (Sativex™)
14/12/10	0.7	J Tolan JRJohnston	Only format changes
14/12/10	0.8	J Tolan O MacLeod	Final BHSCT submitted for approval Final revisions
			Approved – for dissemination
10/1/2011	0.9	J Tolan	Updated Discharge prescription form as pdf.
15/2/2011	1.0	J Tolan	Addition of Midwives exemptions

Policy Record

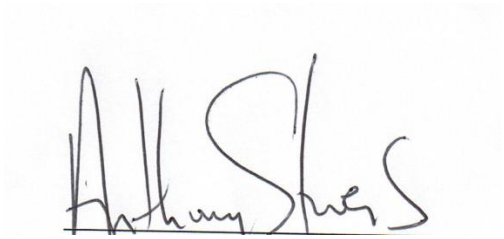
		Date	Version
Author (s)	Approval	24/11/10	V0.6
Director Responsible	Approval		

Approval Process – Clinical Standards and Guidelines

Drugs and Therapeutics Committee	Approval	04/09/10 13/12/10	V0.3 V0.6
Standards and Guidelines Committee	Ratify	19/01/11	V0.8
Policy Committee	Ratify	21/02/11	V1.0
Executive Team	Authorise	22/02/11	V1.0
Appropriate Director	Sign Off	23/02/11	V1.0

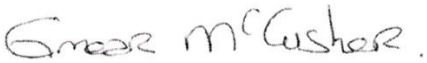
Dissemination

Areas :	



Director
Printed name: AB Stevens
Date: Feb 2011

Author
Printed Name; Julia Tolan
Date: Feb 2011



Accountable Officer – Controlled Drugs
Head of Pharmacy and Medicines Management
Printed name Eimear McCusker
Date: Feb 2011

Contents **Page**

[1] Including areas where anaesthesia involving the administration of controlled drugs is practiced

1. Title:

Controlled Drugs Policy

2. Introduction:

There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care. However, as a result of the actions of Harold Shipman, and the recommendations arising from the Shipman Inquiry, significant changes have been made in both governance and legislation surrounding the use and management of controlled drugs.

Controlled drugs (CDs) are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm.

The Misuse of Drugs Regulations 2001 define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities and lay down the conditions under which these activities may be carried out. In the regulations drugs are divided into five schedules each specifying the minimum requirements governing such activities as import, export, production, supply, possession, prescribing, storage and record keeping which apply to them. The BHSCT management of controlled drugs in relation to prescribing, storage and record keeping may exceed the Misuse of Drugs Regulations or non-CDs may be managed in the same way as CDs. This is to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

- **Schedule 1** includes drugs such as cannabis and lysergide. Possession and supply are prohibited except in accordance with Home Office authority.
- **Schedule 2** includes drugs such as diamorphine (heroin), morphine, remifentanil, pethidine, secobarbital, glutethimide, amfetamine, and cocaine. Schedule 2 CDs are subject to the full controlled drug requirements relating to prescriptions, safe custody (except for secobarbital), the need to keep registers, etc. (unless exempted in Schedule 5).
- **Schedule 3** includes the barbiturates (except secobarbital), buprenorphine, diethylpropion, mazindol, meprobamate, **midazolam**, pentazocine, phentermine, and temazepam. They are subject to the special prescription requirements (except for temazepam) but not to the safe custody requirements (except for buprenorphine, diethylpropion, and temazepam) nor to the need to keep registers (although there are requirements for the retention of invoices for 2 years).
- **Schedule 4** includes in Part I benzodiazepines (except temazepam and midazolam, which are in Schedule 3) and zolpidem, which are subject to minimal control. Part II includes androgenic and anabolic steroids,

clenbuterol, chorionic gonadotrophin (HCG), non-human chorionic gonadotrophin, somatotropin, somatrem, and somatropin. Controlled drug prescription requirements do not apply and Schedule 4 Controlled Drugs are not subject to safe custody requirements.

- **Schedule 5** includes those preparations which, because of their strength, are exempt from virtually all Controlled Drug requirements other than retention of invoices for two years e.g. co-codamol 8/500

The Health Act 2006 provided for regulations to be made relating to strengthened governance and monitoring arrangements for CDs. The Health Act 2006 is primary legislation and applies to the whole of the UK. The Regulations developed under the Health Act may differ to some extent in the different administrations. The Northern Ireland legislation, The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, came into operation on 1st October 2009.

All healthcare organisations are accountable, through the Accountable Officer, for ensuring the safe management of CDs. **The Accountable Officer (AO) for controlled drugs for the BHSCT is the Head of Pharmacy and Medicines Management.** The AO is responsible for all aspects of the safe and secure management of CDs in the organisation. This includes ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents related to CDs.

3. Purpose:

The purpose of this policy is to ensure the safe and effective use and management of controlled drugs in secondary care sites within BHSCT and should be read in conjunction with the BHSCT Medicines Code.

This policy is for all staff working within the BHSCT and aims to provide clear instructions for storing, supplying, transporting, prescribing, administering, recording, monitoring and disposing safely of controlled drugs in accordance with legislation, professional standards and best practice standards. Managers/Team Leaders / ward and department Sister/Nurse or Midwife in Charge are responsible for ensuring that their staff, especially new employees, locum staff and agency staff, have access to and adhere to this policy. It is the responsibility of all staff to familiarise themselves with this policy and associated procedures and adhere to same.

4. The Scope:

This policy applies to all BHSCT medical, dental, nursing and midwifery and pharmacy staff involved in the use and / or management of controlled drugs and to all staff contracted by the Trust who may be involved in the transport of controlled drugs or those trained and authorised to witness destruction of pharmacy stock.

The policy is primarily intended for secondary care however the principles may be adopted by community facilities when appropriate.

The policy is not intended specifically to address clinical trials involving CDs however the principles may be adopted in addition to legislation governing clinical trials.

5. Objectives:

To ensure;

1. CDs are used and managed safely and securely whilst ensuring patients have timely access to the medicines prescribed for them
2. Standard Operating Procedures (SOPs) are in use across BHSCT and ensure compliance with the current legal requirements for CDs
3. a clear audit trail exists for the movement and use of all controlled drugs.
4. processes are in place to protect the security of the stock of CDs held in the ward or department and to ensure that stocks of CDs correspond with the details shown in the controlled drug record book..
5. access to CDs is restricted to appropriate, designated and legally authorised personnel as outlined in the policy and associated procedures.
6. the use of CDs is audited and action taken as necessary
7. all staff involved in the use and management of CDs are aware of their roles and responsibilities in relation to medicines management.

6. Roles and Responsibilities:

6.1 The Accountable Officer for controlled drugs – Head of Pharmacy and Medicines Management BHSCT

- The AO is responsible for all aspects of the safe and secure management of CDs in the BHSCT. This includes ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents related to CDs.
- To ensure that members of staff who are involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training to enable them to carry out their duties
- Attendance at the Northern Ireland Local Intelligence Network (LIN) and to submit quarterly occurrence reports identify concerns and incidents relating to controlled drug management in BHSCT and annual Declaration and Self assessment

6.2 Nursing and midwifery staff

The ward/department Sister/Nurse or Midwife in Charge is responsible for;

- **the safe and appropriate management of controlled drugs in that area.**
- ensuring that staff comply with the Trust systems and that procedures are in place for the management of CDs within their area of responsibility.
- ensuring stock levels of CD preparations held in wards, departments and facilities match what is routinely used in that clinical area
- ensuring that their staff, especially new employees, locum staff and agency staff, have access to and adhere to this policy and procedures herein
- the completion of quarterly observational audit of practice.

The senior registered nurse or midwife in charge is responsible

- for the CD key(s) which should be held on their person
- for keeping the Controlled Drug Record Book (CDRB) up to date, accurate and in good order.
- for ensuring the stock balance of all CDs entered in the CDRB are checked and reconciled in accordance with the Trust Standard Operating Procedure (SOP)

6.3 Prescribers (medical, dental and non-medical prescribers)

- Adherence to the BHSCT Policy for Management of Controlled drugs and the Standard Operating Procedures therein.
- Compliance with CD prescription writing requirements as described in BHSCT Standard Operating Procedure.
- To avoid creating dependence by introducing drugs to patients without sufficient reason and to avoid being used as an unwitting source of supply for addicts.
- Medical staff with limited registration, that is Foundation year 1 (FY1) doctors, are only permitted to prescribe medicines, including CDs, as part of their required duties in their post and should not prescribe for private patients or their own use.
- Non-medical independent prescribers - Nurse independent prescribers. To prescribe within their competence, administer, or direct anyone to administer a limited range of controlled drugs solely for specified medical conditions (see latest edition of the British National Formulary).
- Supplementary prescribers. To act under and in accordance with the terms of an agreed individual clinical management plan (CMP). To prescribe and administer and/or supply or direct any person to administer any controlled drug provided that the controlled drug is included in the

CMP.

6.4 Pharmacy Staff

- The Head of Pharmacy and Medicines Management through the Pharmacy Services Managers and the Pharmacy Procurement and Production lead is responsible for the safe and appropriate management of controlled drugs in BHSCT pharmacy sites
- Standard Operating Procedures are developed and maintained and cover each of the aspects of the safe management of controlled drugs including ordering, receipt, safe custody, record-keeping, auditing, issuing of stock, dispensing prescriptions, transporting of supplies, and destruction of unwanted drugs. SOPs should be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived. SOPs should be approved by the AO or by the person to whom he has delegated this task.
- All relevant pharmacy staff must be trained in the SOPs and must adhere to the SOPs.
- Pharmacy stocks of controlled drugs must be checked and reconciled each month by a competent person and recorded indelibly in the CD register.

6.5 CD messengers (nursing auxiliaries, student nurses or student midwives, porters or drivers)

- Ensure the destination is known, be aware of safe storage and security, the importance of handing over the intact and sealed container to an authorised person and obtaining a signature for delivery
- Have a valid ID badge (e.g. BHSCT photographic ID, valid university ID, taxi photographic ID)

6.6 Designated Governance leads

Designated governance leads trained and authorised by DHSSPSNI are responsible for witnessing the destruction of pharmacy-held stock of obsolete, expired or unwanted Schedule 2 controlled drugs and associated record keeping in accordance with pharmacy SOP.

7. The definition and background of the policy:

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

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

All staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in this policy.

8. Policy

8.1 Management of non-controlled drugs identified as high risk medicines

Certain high risk medicines should be ordered, stored or recorded as controlled drugs to ensure a higher level governance and risk management. Appendix 1 summarises the ordering, storage and record keeping requirements of relevant high risk drugs. Refer to the relevant sections in the Standard Operating Procedure (Appendix 2) for more detailed guidance on the restrictions that apply.

8.2 Management of Schedule 2 and certain schedule 1, 3 and 5 Controlled Drugs

A Standard Operating Procedure (SOP) is available for the ordering, transport, receipting, prescribing, administration, disposal and return of Schedule 2 and certain schedule 1, 3 and 5 Controlled Drugs for Belfast Health and Social Care Trust (BHSCT). The SOP is provided in Appendix 2.

The Standard Operating Procedure covers the following activities:

1. Accessing and Storage of Controlled Drugs (CDs)
2. Record keeping
3. Ordering CDs for ward/dept stock
4. Transportation and receipt of CDs
5. Prescribing of CDs
6. Administration of CDs (except in theatres[1] – see point 7)
7. Prescribing, administration and destruction of CDs in theatres and recovery
8. Destruction on wards/departments
9. Method of disposal
10. Returns
11. Patients' own CDs
12. Arrangements for CDs required outside pharmacy opening hours
13. Transfer of CDs with a patient
14. Discrepancies with stock balance
15. Ward / dept CD stock checks
16. Three monthly CD checks by pharmacy

[1] Including areas where anaesthesia involving the administration of controlled drugs is practiced

9. Policy statements:

9.1 All CDs in BHSCT must be used / managed in accordance with this policy and the BHSCT Medicines Code whilst ensuring patients have timely access to the medicines prescribed for them

9.2 Healthcare professionals authorised to prescribe, administer or manage controlled drugs must do so in accordance with professional standards of practice, relevant legislation, this Controlled Drugs Policy and associated Standard Operating Procedures

9.3 All medicines including controlled drugs available in BHSCT are for use only for patients within BHSCT.

9.4 **Healthcare professionals are not permitted to use stocks of medicines on wards, departments or facilities for their personal use.**

9.5 A clear audit trail exists for the movement and use of all CDs. At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties

9.6 Controlled drugs **MUST NOT** be supplied from one ward/dept to another ward/dept. A controlled drug may be transferred only (when attached to a patient) when a patient receiving a controlled drug by means of a syringe, infusion, epidural or transdermal patch is transferred to another ward/dept. Patients own CDs (admission or discharge supplies) may be transferred with a patient to another ward/dept.

9.7 Controlled drugs **MUST NOT** be administered following only a verbal order even if in the presence of a doctor.

9.8 Processes are in place to protect the security of the stock of CDs held in the ward or department and to ensure that stocks of CDs correspond with the details shown in the controlled drug record book.

9.9 There should be a separate CDRB for each CD cabinet where the CD cabinets are in separate ward/dept or separate rooms within a ward/dept.

9.10 Access to CDs is restricted to appropriate, designated and legally authorised personnel.

9.11 The use of CDs is audited and action taken as necessary

10. Implementation / Resource requirements:

Education and Training on the implementation of the Controlled Drugs Policy and BHSCT Medicines Code

11. Source(s) / Evidence Base:

- Safer Management of Controlled Drugs. A guide to good practice in secondary care (Northern Ireland), DHSSPS August 2009
- Misuse of Drugs (Safe Custody) Regulations 1973

- Medicines Act 1968
- Misuse of Drugs Act 1971
- Misuse of Drugs Regulations 2001 (MDR) and Misuse of Drugs Regulations Northern Ireland (NI) 2002
- Prescription Only Medicines (Human Use) Order 1997
- Controls Assurance Medicines Management Framework DHSSPSNI (2008)
- Health Act 2006
- NMC Standards for Medicines Management August 2008
- Use and Control of Medicines DHPSS 2008

Related BHSCT Policies

- BHSCT Medicines Code (December 2010)
- Non-medical Prescribing Policy (December 2008)
- Use of Abbreviations Policy 2008

12. Consultation Process:

Pharmacy Executive Team
Central Nursing and Midwifery Group
Clinical Director of theatres and Anaesthetics
Drugs and Therapeutics Risk management Committee
Drugs and Therapeutics Committee
Medical Director and Assistant Medical Directors for dissemination to lead clinicians
Standards and Guidelines Committee

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.

Appendix 1

Management of non-controlled drugs identified as High Risk Medicines. Storage, ordering and record keeping requirements.

Certain high risk medicines should be ordered, stored or recorded as controlled drugs to ensure a higher level governance and risk management. The table below summarises the ordering, storage and record keeping requirements of relevant high risk drugs.

	Strong Potassium Chloride 15% injection	Addiphos injection (30mmol potassium / 20ml)
Requisition Book	CD Requisition book	CD Requisition book
Permitted on top-up?	No	No
Prescription writing requirements	No	No
Ward storage	CD cabinet	CD cabinet
Ward register	Yes	Yes
Pharmacy storage	CD room	CD room
Pharmacy register	No	No
Permitted in Emergency cabinet	No	No
Returns	Return unused stock to pharmacy when no longer required	Return unused stock to pharmacy when no longer required

Appendix 2

Standard Operating Procedure

Title:	**Standard Operating Procedure (SOP) for the ordering, transport, receipting, prescribing, administration, disposal and return of Schedule 2 and certain Schedule 1, 3 and 5 Controlled Drugs for Belfast Health and Social Care Trust (BHSCT)**		
Ownership:	BHSCT Pharmacy and relevant ward/dept Sister/Nurse/Midwife in Charge	Status:	**Current**
Publication Date:	**February 2011**	Next Review:	**February 2013**
Ward:		Site:	
Version 0.2 Nov-09	Evidence Base: The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.		
Approval by: (SOP approved by Accountable Officer as part of CD policy)	Ward/Dept Sister/Nurse/Midwife in Charge:		**Date:**
	Pharmacist responsible for quarterly CD checks:		**Date:**

Objective

To ensure that the management of Schedule 2, and certain schedule 1, 3 and 5, controlled drugs (CDs) across BHSCT is carried out to agreed standards and meets the requirements of the Controlled Drugs Legislation 2009.

Scope

Standard Operating Procedures (SOPs) are required for every activity relating to every stage of the CDs journey from ordering, transport, receipt, safe storage, supply, administration, destruction to guidance for dealing with an incident. This SOP will encompass all these elements in turn.

In BHSCT the management of certain schedule 1, 3 and 5 controlled drugs may exceed the Misuse of Drugs Regulations to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust. SOP Appendix (a) summarises the ordering, storage and record keeping requirements of relevant schedule 1, 3 and 5 controlled drugs with guidance provided within the SOP.

Responsibility

The ward/department Sister / Nurse / Midwife in Charge is responsible for the safe and appropriate management of CDs in that area. The senior registered nurse or midwife in charge can delegate control of access (i.e. key holding) to the CD cabinet to another, such as a registered nurse or Midwife. However, the responsibility remains with the registered nurse or midwife in charge. Whilst the task can be delegated, the responsibility can not.

The ward/department Sister / Nurse or Midwife in Charge of a ward, department, operating theatre or theatre suite is responsible for ensuring the staff comply with the Trust systems and that procedures are in place for the management of CDs within their area of responsibility.

The ward/department Sister / Nurse or Midwife in Charge must ensure that all relevant staff are appropriately trained in the procedures. All staff have a responsibility to notify the ward/dept Sister / Nurse or Midwife in Charge of any variations or inability to follow the SOP which must be discussed with pharmacy in order to resolve the issues.

This SOP should be used in conjunction with the guidance in the BHSCT Medicines Code.

Document control

The ward/dept Sister / Nurse or Midwife in Charge responsible for ensuring all relevant staff are notified of any changes to the SOP and for removing the superseded SOP from the clinical area.

This SOP will be reviewed every 2 years but in the event of any incident or near miss of a serious nature it will be reviewed immediately.

Procedures

The following procedures are detailed within this SOP:

1. Accessing and storage of CDs
2. Record keeping
3. Ordering CDs for ward/dept stock
4. Transportation and receipt of CDs
5. Prescribing of CDs
6. Administration of CDs (except in theatres[1] – see point 7)
7. Prescribing, administration and destruction of CDs in theatres and recovery
8. Destruction on wards/departments
9. Method of disposal
10. Returns
11. Patients' own CDs
12. Arrangements for CDs required outside pharmacy opening hours
13. Transfer of CDs with a patient
14. Discrepancies with stock balance
15. Ward / dept CD stock checks
16. Three monthly CD checks by pharmacy

[1] Including areas where anaesthesia involving the administration of controlled drugs is practiced

1. Accessing and storage of CDs

CDs must be stored separately from all other drugs in a cabinet identified solely for this purpose which must be kept locked when not in use. Controlled drugs must be locked away when not in use. No other medicines or items should be stored in the CD cabinet except in accordance with this Controlled Drug Policy.

Certain high risk medicines (Potassium chloride 15% injection, addiphos inj) and certain Schedule 1, 3 and 5 CDs (SOP appendix a) must also be stored in a CD cabinet.

Standards of Controlled drug cabinets and locks

- Ward CD cabinets should conform to the British Standard reference BS2881:1989 ("specification for cabinets for the storage of medicines in healthcare premises" ISBN 058017216 3) or be otherwise approved by the pharmacy department.
- The cabinet must provide in its construction a level of security at least comparable to that laid down for CD cabinets in the Misuse of Drugs (Safe Custody) Regulations 1973.
- The lock must not be common to any other lock in the hospital.

Key-holding and access to CDs

- The key of the CD cabinet must be carried on the person of the nurse or midwife in charge whilst on duty in the ward environment and must be handed over personally to the registered nurse/midwife responsible for taking over custody of the cabinet.
- The nurse or midwife in charge is responsible for the CD key and should know its whereabouts at all times.
- Key-holding may be delegated to other suitably trained nurse or midwife but the legal responsibility rests with the nurse or midwife in charge. Whilst the task of key holding can be delegated, the responsibility cannot. The CD key should be returned to the nurse or midwife in charge immediately after use by another nurse or midwife.
- The key of the CD cabinet must be held separately from other medicine cabinet keys i.e. separate key ring so that medicine cabinet keys may be given to an authorised member of staff but with CD key retained by nurse or midwife in charge.
- The nurse or midwife in charge of a ward, department or facility is responsible for ensuring the CD keys are secure when the ward, department or facility is closed.
- If the keys of the CD cabinet cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible e.g. by contacting staff who have just gone off duty. If the search is not successful then pharmacy should

be informed immediately. It may be possible to arrange to get a spare key to ensure that patient care is not impeded. However, if the loss of the keys remains unexplained, estate services must be informed within two hours to get the lock changed. The Pharmacy Services Manager must be informed who, depending on the circumstances, may decide to contact security and / or the police. The accountable officer and the Head of Inspection and Investigation should be made aware of the situation.

- The storage and management of spare CD keys is the responsibility of the ward/dept Sister / Nurse or Midwife in Charge and will usually be in a central location for a site and accessible by a senior nurse/midwife for the site. Issue of spare keys should be documented. If a spare key is accessed and used for interim access to a CD cabinet it must be replaced as soon as possible after the CD keys are found.
- Any breach in the security of the keys means that a stock check must be carried out as soon as access to the cabinet contents is obtained.

A ward or department may be closed at night or weekends and therefore unmanned for periods of time. A risk assessment should determine if the CDs should remain on the ward or department or whether they should be returned to pharmacy. The risk assessment should include the length of time the ward/dept is unmanned, the location of the ward/dept to manned areas, the barriers to entry to the ward/dept, the presence of an intruder alarm and the range and quantity of CDs in storage. In general, wards or departments should return CDs to pharmacy in a locked or tamper evident container if the area is closed for greater than 48 hours.

Storage of discharge medication

When CD discharge medicines are sent to the ward several hours before the patient leaves, the medicines should be stored in the CD cabinet. These medicines should be segregated from the ward CD stock and clearly marked and should remain in a sealed bag.

If the discharge is delayed, the CD discharge medicines should be recorded onto the ward CD register or a separate register for that purpose. A record of their supply to the patient, transfer with the patient to another ward or return to pharmacy should be documented in the register.

If the medication is no longer needed then the medication should be returned to pharmacy as soon as possible (see section 10).

Storage of epidural infusions containing controlled drugs

The NPSA alert ‘Safer practice with epidural injections and infusions’ recommends that epidural infusions are stored in separate cabinets or refrigerators from those holding intravenous and other types of infusions.

2. Record keeping

CD Stationery

All stationery used to order, return or record CDs must be stored securely in a locked cabinet or drawer and access to them should be restricted to guard against unauthorised use.

Controlled Drug Record Books (CDRBs)

- Each ward or department that holds stocks of CDs must keep a record of the CDs received and administered in Controlled Drug Record Book (CDRB) which is available from pharmacy. The CDRB must be a bound book with sequentially numbered pages.
- There should be a separate CDRB for each CD cabinet where the CD cabinets are in separate ward/dept or separate rooms within a ward/dept.
- Each page in use must be titled with the generic name of the medicine, brand name, strength and form of the product. The title entries should be made in capital letters.
- Entries must be made in chronological order, in ink or be otherwise indelible. All entries must be signed by two registrants. Exceptionally, the second signature can be by another practitioner (e.g. doctor or pharmacist) provided they have witnessed the administration of the drug.
- The index at the front of the CDRB should reflect the current pages in use for all CDs that have been ordered by the ward/dept.
- **For each drug a running total of the stock should be maintained. Each time a CD is removed from the CD cabinet, the stock balance of an individual preparation should be confirmed to be correct and the new balance recorded in the CDRB. The entry should be signed and dated.**
- When a CD is received from pharmacy, record;
    - Date received
    - Amount (quantity) received (e.g. quantity of tabs/caps/inj/patch, total volume of liquid)
    - Name of pharmacy & serial number of requisition/order
    - Name and signature of person making the entry and witness
    - Stock balance including signature and date
- **Correction of mistakes**. If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. Tippex or labels must not be used to delete or amend the entries. A brief explanation of the error must be written on the next line of the register with the balance confirmed. This entry must be signed and dated by the person making the entry and witnessed preferably by a second registered nurse or midwife. If a second registered nurse or midwife is not available, then the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist).

- **Transfer of balance to a new page.** On reaching the end of a page in the CDRB, the balance must be transferred to a new page. The balance must be written in the top line of the new page and this page number must be added to the bottom of the finished page (i.e. complete the 'balance transferred to page' section). The balance being transferred must be written on the first line of the new page in the allocated space stating clearly which page the balance was transferred from. As a matter of good practice balance transfers should be signed by a witness who can be a registered nurse or midwife or a pharmacist (if available on the ward). The index must be updated.
- **Transfer to a new CDRB** must be carried out by an appropriately trained pharmacist or pharmacy technician. A ward or department must estimate when a new CDRB will be required and contact pharmacy, providing at least one week's notice, to arrange a suitable time to transfer to a new CDRB. A new CDRB should be ordered in the CD order book. The balances must be transferred to the new book and each entry for current stock balances must be signed and dated by a pharmacist, or appropriately trained pharmacy technician, and witnessed by a registered nurse or midwife. In the appropriate section of the CDRB the pharmacist will enter the date and write 'Opening balance checked and verified by' and the stock in the 'Stock balance' column on the first line of the page. The pharmacist and nurse/midwife will sign and print name in appropriate columns.
  An entry should be made in the old CDRB that stock has been transferred to a new CDRB. The pharmacist should write the 'quantity' of drug transferred and the statement 'Transferred to new register' e.g. '24 tablets transferred to new register'. In addition, the pharmacist should sign and print name together with the date of transfer. Any unused lines / pages should be scored out and therefore 'close' the CDRB. The completed CDRB must be stored securely by the ward/department for a period of **13 years** from the date of last entry (26 years for paediatric wards).

Controlled Drug Order Book

- A controlled drug order book must be used for ordering stock of a controlled drug from pharmacy
- For a new CD order book to be issued, the ward or department must order a new book on the last page of the current book. CD order books must be retained, either by pharmacy or the ward/dept for two years after the date of the last entry.
- Completed CD order books must be retained for a minimum of two years from the date of the last entry.
- There should be a separate CD record book for each ward / department / theatre.

3. Ordering CDs for ward/dept stock

Each ward should hold a stock list (with minimum stock levels) which reflects current use of CDs in the ward or department. This should be regularly reviewed (at least annually) and the stock levels agreed between the Sister / Nurse or Midwife in Charge of a ward, department, operating theatre or theatre suite and the pharmacist responsible for monitoring the ward CDs.

The senior registered nurse or midwife in charge of ward, department, operating theatre or theatre suite is responsible for the ordering of CDs for use in that area. The senior registered nurse or midwife in charge can delegate the task of preparing an order to another, such as a registered nurse or midwife. However, legal responsibility remains with the senior registered nurse or midwife in charge.

The ward/dept Sister / Nurse or Midwife in Charge must retain a record of staff authorised by them to order CDs from pharmacy (suggested format – SOP Appendix b). This list should be regularly updated and should include a sample signature. A copy of this record of authorised signatories will be kept in pharmacy for validation.

Procedure

3.1 Orders for CDs are made by writing a requisition(s) in the ward CD order book ensuring each copy (original and duplicates) of the requisition is completed. The requisition(s) must be signed by an authorised signatory. The CD order book should be sent to pharmacy by ward messenger.

3.2 Requisitions must include:

- the date of ordering
- the name of the hospital and the ward/theatre or clinical area
- the drug name
- the drug form (i.e. capsules, injection etc)
- the drug strength
- ampoule size (if more than one available)
- total quantity required
- name of patient (if appropriate)
- name in block capitals and signature of the member of staff placing the order

3.3 When the drug(s) has been supplied the requisition must be signed and dated by pharmacy staff to show that it has been complied with. The original copy of the requisition must be retained at the dispensary at which the drug was supplied.

4. Transportation and receipt of CDs

At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties.

CDs will be transferred to the ward/department in a secure, locked or sealed, tamper-evident container, usually an envopak sealed with a tamper-evident seal, by a member of ward/dept staff, pharmacy porter, hospital porter, hospital driver or contracted taxi driver who must be wearing a valid photographic identification badge. The ward/dept staff, porter or driver will sign for the CDs before leaving the pharmacy department.

Procedure

4.1 If a nurse/midwife or ward messenger **collects** the order from the pharmacy, they will be required to sign the CD requisition(s). It is good practice that the person who collects the CDs should not be the person who ordered the CDs. Staff will be asked to confirm their identity and produce a valid photographic identity badge.

4.2 When CDs are **delivered** to a ward/dept the nurse/midwife at ward/dept level who accepts the sealed bag must sign the relevant duplicate CD requisition in the CD order book or in a separate book/delivery log kept for this purpose. CDs must never be left unattended and must be locked in the CD cabinet.

4.3 As soon as possible after **delivery/collection** the senior registered nurse or midwife in charge should check the CDs against the original requisition to ensure that the correct drug and quantity have been supplied. All tamper-evident seals should be left intact; however, pack seals should be checked to ensure they are intact. If the CDs are correct then the duplicate requisition in the CD order book should be countersigned in the received by section. The duplicate requisition must be returned to the pharmacy department. If there are any discrepancies between the CDs and the original requisition the registered nurse or midwife performing the check should contact pharmacy immediately.

4.4 The index of the CDRB should be checked to ascertain the appropriate page for the recording of the CDs or if the CD is a new item, create an entry in the index and fill out a new page with the details of generic drug name, brand name, strength and form. Receipt of CDs should be recorded on the appropriate page in the CDRB by a registered nurse or midwife. The ‘date received’, the ‘amount received’, the ‘name of pharmacy’ making the supply, ‘serial number of requisition’, ‘name and signature of staff member’ and ‘stock balance’ should be entered in the appropriate columns of the CDRB.

4.5 Once the stock balance has been updated, the nurse or midwife should check that the balance tallies with the quantity that is physically present in the CD cabinet. The entry should be signed and dated in the ‘stock balance confirmed as correct’ column by the nurse/midwife and witness.

5. Prescribing of CDs

Prescribing for inpatients

Prescribers must comply with the relevant legislation when prescribing controlled drugs. In addition, prescribers must adhere to the BHSCT Medicines Code and the British National Formulary (BNF) under 'General Information and Prescription writing'.

Controlled drugs must not be prescribed for personal use.

Medical staff with limited registration, that is Foundation year 1 (FY1) doctors, are only permitted to prescribe medicines, including CDs, as part of their required duties in their post and should not prescribe for private patients.

For hospital inpatients directions for administration of controlled drugs from ward/dept stocks must be written on the inpatient Medicine Prescription and Administration record or the anaesthetic chart kardex. Prescriptions for controlled drugs for administration by subcutaneous syringe driver must be prescribed on the 'Prescription and administration record of medicines via subcutaneous syringe driver' chart and reference must be made on the main inpatient Medicine Prescription and Administration record. The written requirements for controlled drugs on these charts are the same as for other medicines and are described in the BHSCT Medicines Code.

On the rare occasion that controlled drugs are administered from supplies prescribed and dispensed for individual patients (rather than from items ordered as ward stock), then in addition to the requirements as stated in the BHSCT Medicines Code, and in order to comply with the Misuse of Drugs Regulations (Regulation 15), the total quantities of the controlled drugs prescribed for the individual patients must be present in both words and figures on the prescription.

Prescribing for discharge patients and outpatients

Schedule 2 and certain schedule 1, 3 and 5 CDs (see SOP Appendix a) for patients on discharge must be prescribed using the BHSCT Discharge Prescription for Controlled Drugs (SOP Appendix c) and must also be referenced on the main discharge prescription form.

These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a controlled drug prescription. It is a criminal offence for a pharmacist to dispense a CD against a prescription that does not meet the criteria below. Incorrectly written CD prescriptions will not be dispensed and will be returned to the prescriber for amendment, which may result in a delay in the patient receiving their discharge medication

A prescription for Schedule 2 and certain Schedule 1, 3 and 5 controlled drugs must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated

- The patient's full name and address. **The use of pre-printed adhesive addressogram labels on prescriptions is not permitted.**
- The patient's age and hospital number
- The name and pharmaceutical form of the drug. The form must be stated irrespective of whether it is implicit in the proprietary name (e.g. MST Continus) or of whether only one form is available.
- The strength of the preparation, where appropriate. Check the available strengths of the preparation as two strengths may be required to obtain the prescribed dose. If this is the case use words and figures for the total quantity required for each strength.
- The dose to be taken. The instruction 'One as directed' constitutes a dose but 'as directed' does not
- Either the total quantity (in both words and figures) of the preparation for the total number of days (usually 7) or the number (in both words and figures) of dosage units, as appropriate, to be supplied. In exceptional circumstances where more than 7 days supply is required, the prescribing doctor must contact the pharmacy to discuss.
- All controlled drug prescriptions MUST be dated and are only valid for 28 days from the date on the prescription.
- The prescriber must sign the prescription, in his own handwriting, and print their name (include bleep number if applicable).

Midwives Exemptions

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.
http://www.nmc-uk.org/Get-involved/Consultations/Midwives-rules/Medicines-legislation-what-it-means-for-midwives-/

6. Administration of CDs (except in theatres[1] – see point 7)

Registered nurses and midwives must follow Nursing and Midwifery Council standards and guidance (http://www.nmc-uk.org) and the BHSCT Medicines Code in relation to the administration of medicines. The BHSCT management of controlled drugs in relation to prescribing, storage, administration and record keeping may exceed the Misuse of Drugs Regulations or non-CDs may be managed in the same way as CDs. This is to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

Controlled drugs MUST not be administered on the basis of only a verbal order even if the verbal order is given in the presence of a doctor.

Two practitioners, authorised to administer/witness administration of CDs, must be involved in the administration of CDs. The practitioner who witnesses the administration cannot be the same person(s) that administered the drug. Both practitioners **must be present during the whole administration procedure** and both should witness:

- The preparation of the CD to be administered.
- The CD being administered to the patient.
- The destruction of any surplus drug (e.g. part of an ampoule or infusion not required)

Designation of staff who may administer/destroy or witness the administration/destruction of controlled drugs;

Activity	Administration / destruction by;	Witnessed by;
Administration of a CD & destruction of unused portion	Registered nurse or midwife	• Registered nurse or midwife • Doctor including pre-registration / FY1 doctor • Student nurse or student midwife AND supervising registered nurse or midwife • Pharmacist (exceptionally)
	Doctor including pre-registration / Foundation year 1 (FY1) doctor	• Registered nurse or midwife • Pharmacist (exceptionally)
	Student nurse or student midwife AND supervising registered nurse or midwife	• Registered nurse or midwife • Doctor including pre-registration / FY1 doctor • Pharmacist (exceptionally)

[1] Including areas where anaesthesia involving the administration of controlled drugs is practiced

Where wards/departments do not have a system of second checking the administration of a controlled drug, the ward/department sister/ nurse/ or midwife in charge should undertake a risk assessment with their professional line manager and Pharmacy Services Manager to determine whether the introduction of second checking as an additional risk reduction measure is necessary. A ward/department/facility/site may consider the use of an unregistered healthcare worker to provide a second check within the risk assessment. A written record of this risk assessment should be made and forwarded to the Pharmacy Services Manager.

Record of administration in the CDRB

It is the responsibility of the registered nurse or midwife who supplies a CD to a doctor, for administration, or who administers a CD to ensure that all sections of the CDRB are completed appropriately.

The following details should be recorded in the CDRB:

- 'Date given' and 'time given, of when dose administered (or refused in the case of a CD prepared for a patient). **Times should be recorded using 24-hour clock notation when administering controlled drugs.**
- Patient's name and unit (hospital) number
- Amount given/quantity administered. **An oral syringe must always be used to accurately measure volumes of oral liquids / suspensions**.
- Name, formulation and strength – should already be recorded on top of page.
- Name and signature of nurse, midwife or authorised person who administered the dose.
- Name and signature of witness.
- **Balance of stock.** The stock balance must be confirmed as correct. The entry should be signed and dated.
- In the event **of a patient not** requiring a full dose or refusing medication i.e. wastage of CD it should be disposed of appropriately by a registered nurse, midwife or doctor in the presence of a witness and the volume/dose wasted recorded in the 'Amount wasted' column of the CDRB with the signatures of the registered nurse, midwife or doctor and witness involved. A student nurse or student midwife may destroy or witness the destruction of a controlled drug under supervision by a registered nurse or midwife in the presence of a second registered nurse or midwife. Individual doses of controlled drugs which have been prepared but not administered should be destroyed by following the above procedure and the reason documented in the CDRB.

Pharmacy must be contacted immediately if, on opening the box, ampoules are found to be broken or any other discrepancy occurs.

7. Prescribing, administration, destruction and record keeping of CDs in theatres and recovery

The Sister / Nurse or Midwife in Charge of an operating theatre or theatre suite is responsible for ensuring that staff comply with the Trust systems and that procedures are in place for the management of CDs within their area of responsibility. The requirements for storage and access, record keeping and prescribing of controlled drugs, described previously, and in the BHSCT Medicines Code apply equally to theatres.

Registered nurses and midwives must follow Nursing and Midwifery Council standards and guidance (http://www.nmc-uk.org) and the BHSCT Medicines Code in relation to the administration of medicines. The BHSCT management of controlled drugs in relation to prescribing, storage, administration and record keeping may exceed the Misuse of Drugs Regulations or non-CDs may be managed in the same way as CDs. This is to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

Controlled drugs MUST not be administered on the basis of only a verbal order even if the verbal order is given in the presence of a doctor.

General principles for the supply, administration and destruction of CDs in theatres

- There should be a separate CD record book for each theatre.
- Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.
- The supply of a CD to an anaesthetist must be witnessed by a registered nurse or midwife. This must be recorded in the CDRB.
- The anaesthetist is responsible for the safe and appropriate preparation and administration of a CD to the patient, in the presence of, but not necessarily witnessed by, a registered nurse/midwife.
- The destruction of any surplus drug (e.g. part of an ampoule or infusion not required) must be safely disposed of and witnessed by a registered nurse/midwife, before the anaesthetist leaves the theatre with the patient. The anaesthetist and registered nurse/midwife must record the destruction of the controlled drug in the CDRB (see ‘record keeping’ below).

General principles for managing epidural / IV PCA infusions commenced in theatre

The checking and connection of an epidural/ IV PCA infusion into an epidural/IV PCA pump by a registered nurse/midwife in recovery ward must be witnessed by another registered nurse/midwife, following written prescription by an anaesthetist. Both will record the preparation of the CD in the recovery CDRB. One of these nurses or

midwives is responsible for transferring the epidural/IV PCA infusion into theatre, to check the labelled contents of the pre filled bag and the programme settings on the pump for epidural infusion with the prescribing anaesthetist in the presence of the theatre nurse/midwife. The responsibility for the controlled drug transfers from the recovery nurse/midwife (discharging ward/dept) to the theatre nurse/midwife (receiving ward/dept). A record of the transfer from one area to another must be recorded on the epidural observations chart by both the recovery and theatre nurse/midwife. The anaesthetist must connect the epidural infusion to the patient's epidural catheter in the presence of, but not necessarily witnessed by, a registered nurse or midwife in theatre.

Anaesthetic chart / anaesthetic chart kardex

The anaesthetic chart is used to record the prescribing and administration of any drugs, including controlled drugs, intra-operatively and immediately post-operatively. The anaesthetic chart is also referred to as the anaesthetic chart kardex. The anaesthetic chart kardex is used in conjunction with the main Medicine Prescription and Administration Chart (main kardex) when the patient is in theatre or recovery ward.

Record keeping

Intra-operative documentation and handover

- Controlled drugs prescribed and administered during surgery including epidural / IV PCA infusions must be recorded on the intra-operative section of the anaesthetic chart kardex. Times must be recorded using the 24-hour clock annotation when prescribing / administering controlled drugs
- The witnessed supply of controlled drugs and witnessed destruction of waste must be recorded in the controlled drug record book (CDRB). **Anaesthetists are responsible for any CD supplied to them and registered nurses and midwives must not dispose of any syringes or infusions labelled as containing CDs at the end of a list. This is the anaesthetist's responsibility. A registered nurse or midwife must witness the destruction and both must record the witnessed destruction in the CDRB**

Immediate post-operative documentation and handover (recovery ward)

- The anaesthetist and anaesthetic nurse provide a handover to the recovery nurse/midwife which includes the medications, including controlled drugs, administered intra-operatively and confirmation of pump settings if an epidural / IV PCA pump is present.
- When a patient is transferred from theatre to recovery, with an epidural or IV PCA infusion containing a controlled drug, the responsibility for the controlled drug transfers from the theatre nurse or midwife (discharging ward/dept) to the

recovery nurse or midwife (receiving ward/dept). A record of the transfer from one area to another must be recorded on the epidural / IV PCA observations chart by both the recovery and theatre nurse/midwife. The following details must be recorded on the Epidural / IV PCA Observations Chart: date, time, the remaining volume of the controlled drug, signature and ward/dept name of discharging nurse/midwife and signature and ward/dept name of receiving nurse/midwife.

- Medications, including controlled drugs, required during the immediate post-operative period, usually recovery ward, should be prescribed on the section of the anaesthetic chart kardex entitled 'Postoperative instructions'.
- The witnessed administration of controlled drugs in recovery and witnessed destruction of waste must be recorded in the controlled drug record book (refer to section 6)
- **All medications, including injections or infusions of controlled drugs for postoperative administration after the patient leaves recovery ward must be prescribed in the patient's main Medicine Prescription and Administration Chart (main kardex).**

Patient transfer to ward

- The recovery nurse/midwife must provide a verbal handover to the ward nurse or midwife. The handover must include;
  - a review of medicines prescribed and administered during surgery
  - a review of medicines prescribed and administered immediately post-operatively (recovery)
  - a review of any additions / amendments made to the medications prescribed on the main Medicine Prescription and Administration Chart (main kardex)
- When a patient is transferred from recovery to ward, with an epidural or PCA infusion containing a controlled drug, the responsibility for the controlled drug transfers from the nurse/midwife in the discharging ward/dept to a registered nurse/midwife from the receiving ward/dept. A record of the transfer from one area to another must be recorded on the epidural/ IV PCA observations chart by both the recovery and ward nurse/midwife. The following details must be recorded on the Epidural / IV PCA Observations Chart: date, time, the remaining volume of the controlled drug, signature and ward/dept name of discharging nurse/ midwife and signature and ward/dept name of receiving nurse/midwife.
- Medications, including controlled drugs, required on return of the patient to the ward are prescribed by the anaesthetist on the main Medicine Prescription and Administration Chart (main kardex).

Controlled drugs prescribed as Patient Controlled Analgesia (PCA) or for epidural administration

All controlled drug infusion bags for PCA and epidural analgesia must be prescribed on the patient's Medicine Prescription and Administration Chart (main kardex) in the section headed 'Regular Injectable'. The minimum prescription details required is shown in the following examples:

For IV PCA
MORPHINE SULPHATE 250 mg in 250 ml sodium chloride 0.9%
Start date: (e.g.) 27.07.10
Signature of prescribing doctor or independent nurse prescriber.....
Signature for administration (connection to the patient and infusion initiated)

For epidural analgesia
LEVOBUPIVACAINE 1 mg/ml FENTANYL 2 micrograms/ ml in 250 ml sodium chloride 0.9%
Start date: (e.g.) 27.07.10
Signature of prescribing doctor or independent nurse prescriber.....
Signature for administration (connection to the patient and infusion initiated)

In addition to prescribing an epidural or IV PCA on the main Medicine prescription and Administration chart the above information is also recorded as follows;

- The prescription and programme is recorded on the Epidural or PCA Observations Chart
- The prescription and administration is recorded on the intra-operative section of the anaesthetic chart kardex by the anaesthetist
- The prescription is recorded on the post-operative section of the anaesthetic chart kardex

Record in the CDRB
It is the responsibility of the registered nurse or midwife who supplies a CD to an anaesthetist, for administration, to ensure that all sections of the CDRB are completed appropriately.

The following details should be recorded in the CDRB:

- Date and time of supply of a CD supplied. Times should be recorded using 24-hour clock notation.
- Patient's name and hospital number
- Amount supplied.
- Name, formulation and strength – should already be recorded on top of page.
- Name and signature of nurse/midwife and anaesthetist.
- **Balance of stock.**

- In the event **of a patient not** requiring a full dose i.e. wastage of CD it should be disposed of appropriately by the anaesthetist and witnessed by a registered nurse/midwife. The anaesthetist must record the amount wasted and both should sign the CDRB.

Pharmacy must be contacted immediately if, on opening the box, ampoules are found to be broken or any other discrepancy occurs.

8. Destruction on wards/departments

Only small amounts of CDs should be destroyed on wards and departments – for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or the dose is drawn up but not used. Destruction should be by a registered nurse, midwife, doctor on the ward or department and witnessed by a second competent professional such as a registered nurse, midwife, doctor or pharmacist.

Individual doses of controlled drugs which have been prepared but not administered should be destroyed by following the above procedure and the reason documented in the CDRB.

All destruction must be documented in the CDRB. Both persons should sign the CDRB stating the amount destroyed and the date of the destruction.

Anaesthetists are responsible for any CD supplied to them and registered nurses and midwives must not dispose of any syringes or infusions labelled as containing CDs at the end of a list. This is the anaesthetist's responsibility. A registered nurse or midwife must witness the destruction and both must record the witnessed destruction in the CDRB.

The witnessed destruction of a partially used epidural infusion or IV PCA infusion must be documented on the Epidural or IV PCA Observations Chart.

9. Method of Disposal

- Opened or partly used ampoules or broken ampoules: Empty contents into a sharps burn bin, which contains some absorbent material (e.g. paper towel) and liquid soap. Place empty ampoules also into the Sharps bin.
- Discontinued or partly used patient controlled analgesia (PCA), epidural preparations and solutions administered via a syringe driver: Empty into a burn bin, into the bottom of which some absorbent material (paper towel) and liquid soap has been placed. Two members of staff must record the volume wasted, print name and sign on the Epidural / IV PCA Observations Chart or syringe driver prescription chart.
- Used or partly used CD transdermal patches (e.g. Durogesic, Transtec, and Butrans): Fold patch firmly in two and place in the Burn Bin.
- Oral drugs dispensed for a patient who has refused administration: Record on the medicine kardex that the patient has refused the drug. Place in a burn bin, into the bottom of which has been placed liquid soap.

10. Returns

Unused CD stock, CD stock no longer required, CDs that are time-expired or otherwise unfit for use and patients' own CDs (see section 10) should be returned to pharmacy. Returns will only be processed during normal pharmacy opening hours on Monday to Friday. **The ward/ dept should contact pharmacy or the designated pharmacist to arrange for CDs to be returned.**

The pharmacist will call with the ward at the agreed date/time. The pharmacist and nurse or midwife in charge will be required to:

1. Complete the details of the CDs to be returned to pharmacy in the CD order book including the date, name, strength, formulation, quantity to be returned and the patient name, if patients' own CDs are being returned. In addition, the requisition must be endorsed '**controlled drugs to be returned to pharmacy'** and state the reason for return e.g. out of date. This should be signed by both the pharmacist and nurse/midwife.
2. Make an entry in the CDRB recording the date, reason for return, names and signatures of the pharmacist and the nurse/midwife in charge and the quantity removed and. The new stock balance should also be confirmed, signed and dated by these staff members.

The pharmacist will retain the first copy of the requisition and bring to pharmacy together with the drugs to be returned.

The nurse/midwife will contact pharmacy to advise that the pharmacist is leaving the ward with CD returns and will state the number of items being returned.

In exceptional circumstances, a ward may wish to return CDs directly to pharmacy. The ward must complete the details of the CDs to be returned to pharmacy in the CD order book including the drug name, strength, formulation and quantity to be returned. In addition, the requisition must be endorsed '**controlled drugs to be returned to pharmacy'**. The ward should contact pharmacy to advise that the CDs are to be returned to pharmacy by the nurse/midwife in charge. The nurse/midwife in charge must bring the CD order book, the CDRB and the drugs for return to pharmacy at the agreed time. All documentation of the return, as described above, must be completed.

11. Patients' own CDs

Patients' own CDs should not be stored on the ward but should be sent home with the patient's representative (family member or carer) as soon as possible after admission. The patient's representative should be given advice regarding the necessity for safe storage of the medicines and that other people must not use them**. If the CDs cannot be sent home immediately, they must be recorded in a separate part of the CDRB or a separate CDRB designated for that purpose.** The record should include the date, patient's name, hospital number, name, strength, formulation and quantity of CDs. The CDs should be sealed in an envelope and clearly marked with a patient identifier. The envelope should be placed in the CD cabinet and kept separate from ward stock. The ward CDRB must be completed if the CDs are subsequently returned to the patient or patient's representative.

Patients' own CDs should not be used for administration during in-patient stay.

Patients' own CDs must never be used to treat other patients.

If the CDs have been discontinued, and if the patient or the patient's representative agrees, the CDs should be returned to the pharmacy for safe destruction – following the procedure described in section 10.

12. Arrangements for CDs required outside pharmacy opening hours

Exchange or supply of CDs between wards is illegal and is strictly forbidden (Misuse of Drugs Act (NI) Regs 1986-89, Misuse of Drugs Act 1971). If a CD is required outside pharmacy opening hours, the senior nurse/nurse or midwife in charge should contact the pharmacist through the hospital switchboard.

13. Transfer of CDs with a patient

The circumstances are limited where a CD will move with a patient. This is due to the restriction in the Misuse of Drugs Regulations 2002 which prevents CDs being supplied from ward to ward. Patient controlled analgesia (IV PCA), epidural or administration via syringe driver or by transdermal patch are examples of occasions when a CD may need to move with the patient when only attached to the patient.

All information relating to the transfer of PCA, epidural or syringe driver (including signatures of those involved in the transfer) should be in line with transferring responsibility of a CD. The date and time (using 24 hour clock) of transfer, should be recorded on the PCA/ epidural monitoring chart or syringe driver prescription chart.

14. Discrepancies with stock balance

If there is a discrepancy in the stock balance of Schedule 2 CDs and other CDs that are recorded in the CDRB then this must be reported, investigated and resolved promptly. It is important to remember that a discrepancy may indicate diversion.

In the first instance check that:

- All CDs administered have been entered into the CDRB correctly.
- Arithmetic is correct, to ensure that balances have been calculated correctly.
- All requisitions received have been entered into the correct page of the CDRB.
- Items have not been accidentally put into the wrong place in the cabinet.

If the error or omission is traced then the registered nurse/midwife should make an entry in the CDRB, clearly stating the reason and the correct balance. This should be witnessed by a second registered health professional, both of whom must sign the CDRB.

Any volume discrepancies with oral liquid formulations of +/- 10% of expected volume must be recorded on Trust IR1 form.

If the discrepancy is not resolved by the above measures the ward/dept Sister / Nurse or Midwife in Charge and a designated / senior pharmacist must be informed without delay and an incident form completed. The nurse or midwife lead for the clinical area must also be informed.

The Pharmacy Services Manager will decide on the action required and will inform the police if appropriate.

15. Ward / Department CD stock checks

The stock balance of all CDs recorded in the CDRB must be checked at each change of shift with the minimum of a daily check. The CD check must be carried out by two registered nurses or midwives one of whom will be the nurse/midwife in charge or a nurse/midwife delegated by the nurse or midwife in charge. If the check occurs at the change of shift the two members of staff carrying out the check should be composed of one from the day staff and one from the night staff.

Confirm that the exact quantity of each CD recorded in the register agrees with quantity in cabinet. Always check from register to cabinet. Not the reverse. If a discrepancy is found it should be investigated without delay.

Packs with the tamper proof seal still intact should not be opened but counted as containing the amount specified on the box label. The check should confirm that the tamper evident seal is intact.

Each CD stock check **must** be recorded by both nurses/midwives (suggested proforma - Appendix d). These records must be retained at ward level for a period of 2 years after the last entry.

The ward/dept Sister / Nurse or Midwife in Charge should carry out a quarterly observational audit of practice and record this using the proforma in SOP Appendix e. A copy of the audit should be forwarded to pharmacy.

16. Three monthly CD checks by pharmacy

A pharmacist will arrange a suitable time with the ward/dept Sister / Nurse or Midwife in Charge for the 3 monthly check to be carried out. Alternatively, three monthly CD checks may be carried out as unannounced checks.

The pharmacist will perform a physical check of the CDs and inspect the stock level check sheets and CDRB in the presence of the ward/dept Sister / Nurse or Midwife in Charge. This gives the opportunity to discuss any queries that may arise about the record keeping and to discuss any action that needs to be undertaken in the future. The check will also include a spot check of entries and returns. It may be necessary to complete checks more frequently than at 3 monthly intervals. Any deviations from the trust policy will be recorded and the ward/dept Sister / Nurse or Midwife in Charge will agree a date for remedial action to be completed

The three monthly CD check documentation is provided in SOP Appendix e.

SOP Appendix a: Management of certain Schedule 1, 3 and 5 Controlled Drugs. Storage, ordering and record keeping requirements

The Misuse of Drugs Regulations 2001 categorise controlled drugs into schedules in accordance with activities such as prescribing, storage and record keeping. In BHSCT the management of schedule 1, 3 and 5 controlled drugs may exceed the Misuse of Drugs Regulations to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

	Cannabis (Sativex)	Morphine Sulphate oral liquid 10mg/5ml (Oramorph)	Temazepam tabs and liquid	Midazolam Injection	Midazolam Suspension	Phenobarbital Injection	Phenobarbital Tablets & suspension
Schedule	1	5	3	3	3	3	3
Requisition Book	CD Requisition book	CD Requisition book	CD Requisition book	CD Requisition book	CD Requisition book	CD Requisition book	CD Requisition book
Permitted on top-up?	No	No	No	No	No	No	No
Prescription requirements	Yes - CD	Yes - CD	Yes - CD	Yes - CD	Yes - CD	Yes - CD	Yes - CD
Ward storage	Lockable fridge	CD cabinet	CD cabinet	Drug cabinet	Drug cabinet	Drug cabinet	Drug cabinet
Ward register	Yes	Yes	Yes	No	No	No	No
Pharmacy storage	Lockable fridge	CD room / robot	CD room / robot	CD room / robot	CD room	CD room / robot	CD room / robot
Pharmacy register	Yes	No	No	No	No	No	No
Emergency cupboard	No	No	No	No	No	No	No
Returns	Follow procedure for return of Schedule 2 CDs			Return to pharmacy when no longer required. Store returns in pharmacy CD room pending processing / destruction.			

Belfast Health and Social Care Trust

SOP Appendix b
Controlled Drug Signature Register: Nurses/Midwives

The ward/dept Sister / Nurse or Midwife in Charge must approve staff who are authorised to order controlled drugs. The sheet will be subject to regular update.

Ward/Dept:	**Ward/Dept Sister / Nurse or Midwife in Charge:**

Date added	Forename (BLOCK CAPITALS)	Surname (BLOCK CAPITALS)	NMC number	Signature	Grade	Authorised by Ward/dept Sister/nurse or Midwife in charge (Signature)	Date removed

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Discharge Prescription for Controlled Drugs

SOP Appendix c

This prescription must be completed in ink and must be signed by the prescriber with their usual signature

Patient's name: _____ Hospital number: _____

Patient's home address: **(IN FULL)** _____

_____ Post code: _____

Patient's D.O.B.: _____ Hospital: _____ Ward/Dept: _____

Please supply: *It is normal practice to supply a maximum of 7 days of prescribed controlled drugs*

Drug name (Brand name)	**Form** (eg. tabs)	**Strength**	**Dose** (eg. Two BD)	**Total quantity**	**Pharmacy Use Only**
				Figures: ..... Words:	
				Figures: ..... Words:	
				Figures: ..... Words:	
				Figures: ..... Words:	
				Figures: ..... Words:	

Cross out any unused lines. Reference the controlled drugs on the main discharge prescription

Signature of prescriber: _____ Date: _____
(Prescription valid for 28 days from this date)

Prescriber name: (PRINT) _____ Bleep No: _____

Notes

1. If a dose is prescribed which can only be met by two different strengths, then the total quantity of both strengths must be specified.
2. Ensure that the controlled drug(s) ordered on this prescription are also referenced on the main discharge prescription form that is sent to the GP.

Please send prescription to pharmacy as early as possible in advance of discharge

For pharmacy use only		
Clinical check: (Initials & ID)	Dispensed by: (Initials & ID)	Final Check: (Initials & ID) Date: .....

Collected by / Received on ward by:	Supplied by		
Signature:	Signature: ..... User ID No:		
Printed name:	Date of supply:		
Role/Grade (e.g. S/Nurse):	Identification requested? Circle	Yes	No
	If 'No' above why? (eg. known)		
.....	Identification provided? Circle	Yes	No
Supply entered into pharmacy CD register			
Signature & User ID No:			

Belfast Health and Social Care Trust

SOP Appendix d
Record of CD stock level checks

Ward/Dept:		Month:		Year:	
Date	AM Check		PM Check (if applicable)		
	Checked By	Checked By	Checked By	Checked By	

Retain completed sheet for 2 years after the las

SOP Appendix e: Form CD2A

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:		**Date**	**/ /**
Time Taken:			

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	Y / N Y / N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	Y / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	Y / N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y / N	
Check and update list of authorised signatories	Y / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / N	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
				Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**Register Entry Correct**	**Pharmacy log completed**
				Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N

Ward IS/ IS NOT (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)	
Signature (Ward/dept sister/nurse or midwife in charge);	Signature (Pharmacist):
Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other	

Belfast Health and Social Care Trust

Trust Policy for approval by **Trust Policy Committee**

Dealing with discrepancies or concerns involving Controlled Drugs	
Summary	Controlled Drugs are subject to specific legislative controls as there is a potential for them to be abused or diverted, causing possible harm. The purpose of this policy is to establish appropriate arrangements for dealing with discrepancies or concerns involving the management of controlled drugs within BHSCT and to ensure the trust complies with recent significant legislative changes. This policy should be read in conjunction with the BHSCT Management of Controlled Drugs Policy and BHSCT Medicines Code.
Operational date	March 2011.
Review date	March 2014
Version Number	V1.0
Director Responsible	Dr AB Stevens
Lead Author	Eimear McCusker
Lead Author, Position	Head of Pharmacy and Medicines Management
Department / Service Group	Pharmacy, Cancer and Specialist Services
Contact details	[redacted]
Additional Author(s)	

Reference Number	SG 18/11
Supersedes	N/A

Version Record

Date	Version	Author	Comments
28/01/11	0.1	EMcCusker	Draft doc
16/02/11	0.2	SODonnell	Updated comments
16/03/11	0.3	PKing	Updated comments
27/04/11	1.0	ACarrington	Final comments

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

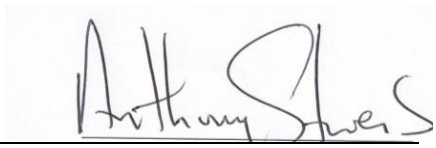
Standards and Guidelines Committee	Approval	21/04/2011	V0.3
Policy Committee	Ratify	16/05/2011	V0.4
Executive Team	Authorise	17/05/2011	V0.4
Appropriate Director	Sign Off	18/05/2011	V0.4

Local Approval Process

	Approval		

Dissemination

Areas :	



Director
Printed name: **A B Stevens**

Date: May 2011

Author
Printed Name: **Eimear McCusker**

Date: May 2011

1. Title:

Dealing with discrepancies or concerns involving controlled drugs

2. Introduction:

The Health Act 2006 and the Regulations require "Designated Bodies" to nominate or appoint an Accountable Officer to be responsible for a range of measures relating to the monitoring of the safe use and management of controlled drugs within the organisation and take appropriate action where necessary. Designated Bodies include the Regional Health and Social Care Board, Health and Social Care Trusts, Northern Ireland Ambulance Service Trust and Independent Hospitals.

The Accountable Officer within BHSCT is the Head of Pharmacy and Medicines Management.

Accountable Officers must establish, operate and review appropriate arrangements for the management and use of controlled drugs within their Designated Body or ensure that the Designated Body does so. They must also ensure that any person or body acting on behalf of, or providing services under arrangements made with their Designated Body, establishes, operates and reviews appropriate arrangements for the management and use of controlled drugs.

The Regulations place a statutory duty of co-operation to share information giving rise to concerns about the management or use of controlled drugs by any "relevant person".

As part of the arrangements for ensuring the sharing of information, Accountable Officers participate in a single network, covering Northern Ireland, a Local Intelligence Network (LIN), for sharing information regarding the management and use of controlled drugs.

Membership of the LIN is described in the Regulations and involves key agencies (regulation 18). The LIN facilitates timely and appropriate sharing of information, and enable agencies that have a concern about the activities of any member of staff or organisation to liaise at an early stage with other local agencies who may be affected or who have complimentary information.

Accountable Officers must provide the Chair of the LIN with a quarterly occurrence report (regulation 29). This report provides details of any concerns that the Designated Body may have identified regarding the management or use of controlled drugs or confirm that it has not identified any such concerns.

3. Purpose:

The purpose of this policy is to standardise dealing with discrepancies or concerns involving the management of controlled drugs within BHSCT.

N.B the legislation and this policy cover all schedules of controlled drugs - Refer to BHSCT Management of Controlled Drugs Policy

Managers/Team Leaders / ward and department Sister/Nurse in Charge are responsible for ensuring that their staff, especially new employees, locum staff and agency staff, have access to and adhere to this policy. It is the responsibility of all staff to familiarise themselves with this policy and associated procedures and adhere to same.

4. The Scope:

This policy covers the governance arrangements for the management of concerns relating to controlled drugs within BHSCT, including any occupiers of the site.

5. Objectives:

To ensure;

1. Appropriate arrangements are in place for managing concerns about incidents involving improper management or use of controlled drugs http://www.dhsspsni.gov.uk/managing-and-sharing-concerns.pdf
2. Appropriate action is taken to protect patients and/or the public in cases where concerns appear to be well-founded
3. Ensure arrangements are in place for sharing of appropriate information with other responsible bodies via the Local Intelligence Network (quarterly occurrence report)

6. Roles and Responsibilities:

- The Accountable Officer for controlled drugs – Head of Pharmacy and Medicines Management BHSCT
  - The AO is responsible for all aspects of the safe and secure management of CDs in the BHSCT. This includes ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents related to CDs.
  - To ensure that members of staff who are involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training to enable them to carry out their duties
  - Attendance at the Northern Ireland Local Intelligence Network (LIN) and to submit quarterly occurrence reports identify concerns and incidents relating to controlled drug management in BHSCT and annual Declaration and Self assessment

- All staff
  - It is the responsibility of all staff to report any concerns about incidents involving improper management or use of controlled drugs to the Trust Accountable Officer for controlled drugs and any specific concerns relating to staff must also be reported either to the line manager or in line with the Trust Whistleblowing Policy.

7. The definition and background of the policy:

The Chief Executive has overall responsibility for the safe and secure handling of medicines as part of the Controls Assurance Medicines Management Framework.
All staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in this policy.

8. Policy

This policy sets out strengthened governance arrangements for the management and use of controlled drugs within BHSCT

9. Policy statements:

- Concerns about incidents involving improper management or use of controlled drugs must be reported in line with this policy
- Healthcare professionals are not permitted to use stocks of medicines on wards, departments or facilities for their personal use.
- The trust has a statutory duty of collaboration to share information about potential controlled drug offences and potential or actual system failures.
- The Accountable Officer must provide the Chair of LIN with a quarterly occurrence report for the trust detailing such concerns

10. Implementation / Resource requirements:

Education and Training on the implementation of this policy, the Controlled Drugs Policy and BHSCT Medicines Code

Regulation 7 requires a designated body to provide its Accountable Officer with the funds and resources to carry out their responsibilities.

11. Source(s) / Evidence Base:

- Safer Management of Controlled Drugs. A guide to good practice in secondary care (Northern Ireland), DHSSPS August 2009
- Misuse of Drugs (Safe Custody) Regulations 1973
- Medicines Act 1968
- Misuse of Drugs Act 1971
- Misuse of Drugs Regulations 2001 (MDR) and Misuse of Drugs Regulations Northern Ireland (NI) 2002
- Prescription Only Medicines (Human Use) Order 1997
- Controls Assurance Medicines Management Framework DHSSPSNI (2008)
- Health Act 2006
- NMC Standards for Medicines Management August 2008
- Use and Control of Medicines DHPSS 2008

Related BHSCT Policies

- BHSCT Medicines Code (December 2010)
- BHSCT Controlled Drugs Policy 2011
- Non-medical Prescribing Policy (December 2008)
- Use of Abbreviations Policy 2008

12. Consultation Process:

Pharmacy Executive Team
Central Nursing
Medical Director
Drugs and Therapeutics
Standards and Guidelines

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.

x☐ Screening completed ☐ Full impact assessment to be carried out.
No action required.

Controlled Drugs – Governance arrangements

1.0 Systems for the Safe and Secure handling of controlled drugs

The Belfast Trust management of controlled drugs policy covers many aspects of the safe and secure handling of controlled drugs. In addition more detail of the pharmacy processes relating to controlled drugs are covered by site pharmacy procedures. Together the processes cover all aspects of the controlled drug journey from procurement and supply through to administration and disposal.
The Accountable Officer (AC) for Belfast Trust is the Head of Pharmacy and Medicines Management.
Designated officers are the Deputy Heads of Pharmacy:
Pharmacy Services Manager (RGH and Mater),
Pharmacy Services Manager (BCH, Musgrave, Knockbracken and Muckamore) and
Pharmacy Services Manager (Production and Procurement)

2.0 Dealing with discrepancies and concerns regarding controlled drugs

2.1 Investigating and reporting controlled drug incidents

2.1.1 Incidents relating to discrepancies

This refers to situations where the quantity of the controlled drug in stock (on a ward or in pharmacy) is different to the level recorded in the controlled drug register or, in the case of pharmacy, also different to that recorded on the JAC computerised stock system.

- It is important to be aware that a discrepancy can indicate misuse. All suspected controlled drug discrepancies must be investigated.
- Any unresolved discrepancies during and outside working hours must be reported in line with appendix 1 (Reporting Unresolved Discrepancies During Working Hours) and appendix 2 (Reporting Unresolved Discrepancies Outside Working Hours).
- An unresolved discrepancy must be reported to the Head of Pharmacy or a Deputy Head of Pharmacy within one working day. All controlled drug related incidents and near misses must be reported in line with the Trust Adverse Incident Reporting and management policy

2.1.2 Other incidents (not relating to discrepancies)

All controlled drug related incidents and near misses must be reported in line with the Trust Adverse Incident Reporting and management policy.

When the Trust Adverse Incident Reporting and management policy is followed, the Accountable Officer for controlled drugs (Head of Pharmacy and Medicines Management) is made aware of all red and orange incidents involving controlled drugs. Refer to appendix 3 (CD Accountable Officer process for dealing with suspected or confirmed unlawful activity) for details of the subsequent process which the Accountable Officer for controlled drugs will follow in the event of being notified of any issues relating to suspected or confirmed unlawful activity.

2.2 Raising and dealing with concerns relating to controlled drugs

- Concerns may occur which do not involve specific incidents or near misses but include healthcare matters, such as suspected mistreatment of patients and / or issues relating to the quality of care given, concerns about professional / clinical practice and concerns relating to the competence of staff.
- Concerns regarding increased or abnormal usage of controlled drugs may also be identified following a review of usage of drugs liable to misuse within that area.
- Any concerns must be reported to the Trust Accountable Officer for controlled drugs and any specific concerns relating to staff must also be reported either to the line manager or in line with the Trust Whistleblowing Policy.
- Refer to appendix 3 (CD Accountable Officer Process for Dealing with Suspected or Confirmed Unlawful Activity) for guidance.

2.3 Incident reviews

Incident reviews will be undertaken by individuals nominated by the Designated Officer or Accountable Officer for controlled drugs and a professional Lead for the area. Depending on the nature of the incident / near miss, it may be necessary to include a member of the police force. The Accountable Officer/Designated Officer for controlled drugs should contact the Police in order to determine if this is necessary and for advice regarding the preservation of evidence collected during an investigation which may be required at a later stage for proceedings instituted by police.
The incident review panel is responsible for investigating the incident and recommending actions. In order to ensure that there is clear separation between the investigation and decision making process, the Accountable Officer for controlled drugs will not be part of the incident review panel but will review the report and suggested actions as a result of the panel review and make the final decision regarding the outcome of the review. Findings and any final action taken, as decided by the Accountable Officer for controlled drugs, will be clearly documented as part of the formal incident review paperwork. The Accountable Officer for controlled drugs must inform the Local Intelligence Network (LIN) of all incident reviews so that trends may be monitored.

Following the implementation of actions from an incident review, the Accountable Officer / Designated Officer for controlled drugs may chose to conduct informal / formal inspections. If this is the case, they must clearly document the findings from the inspection.

3.0 Information Sharing

In line with The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 there is a statutory duty of collaboration on healthcare organisations, police forces, social services authorities and the relevant inspection and regulatory bodies. This is to enable information to be shared about potential controlled drug offences and potential or actual systems failures. The Accountable Officer for controlled drugs will ensure all information is shared, as required.

A combined Local Intelligence Network (LIN) for Northern Ireland has been established.

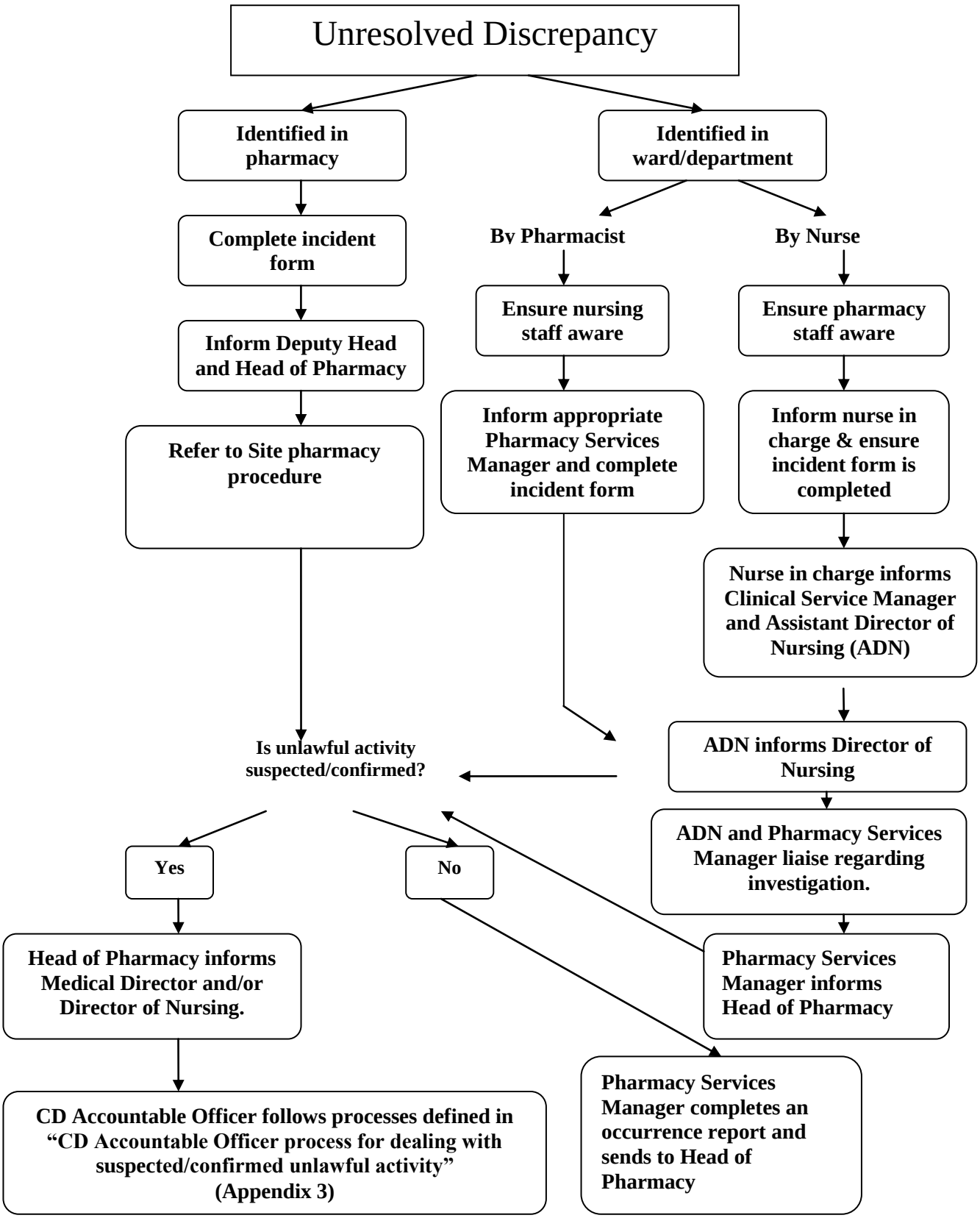
4.0 Closure of cases

Cases considered by the Accountable Officer should be recorded with a clear account of the findings and actions taken. This includes the outcome of any proceedings by the police, civil courts, regulatory body, disciplinary proceedings as appropriate.

Appendix 1:

Reporting **unresolved** discrepancies during working hours

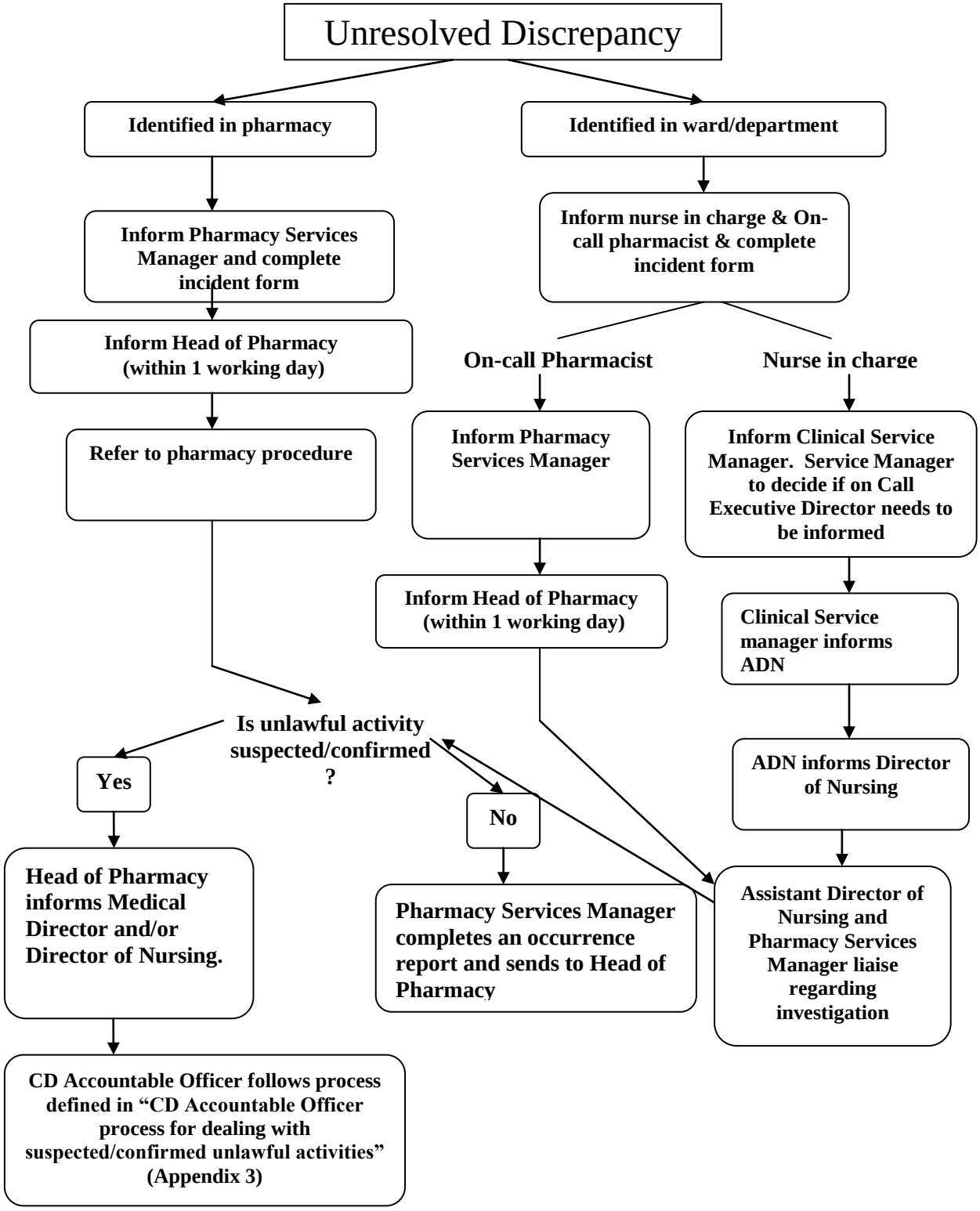
When a discrepancy is identified, an investigation must be undertaken. If the discrepancy remains unresolved, the actions outline below must be followed:



Appendix 2:

Reporting **unresolved** discrepancies outside working hours

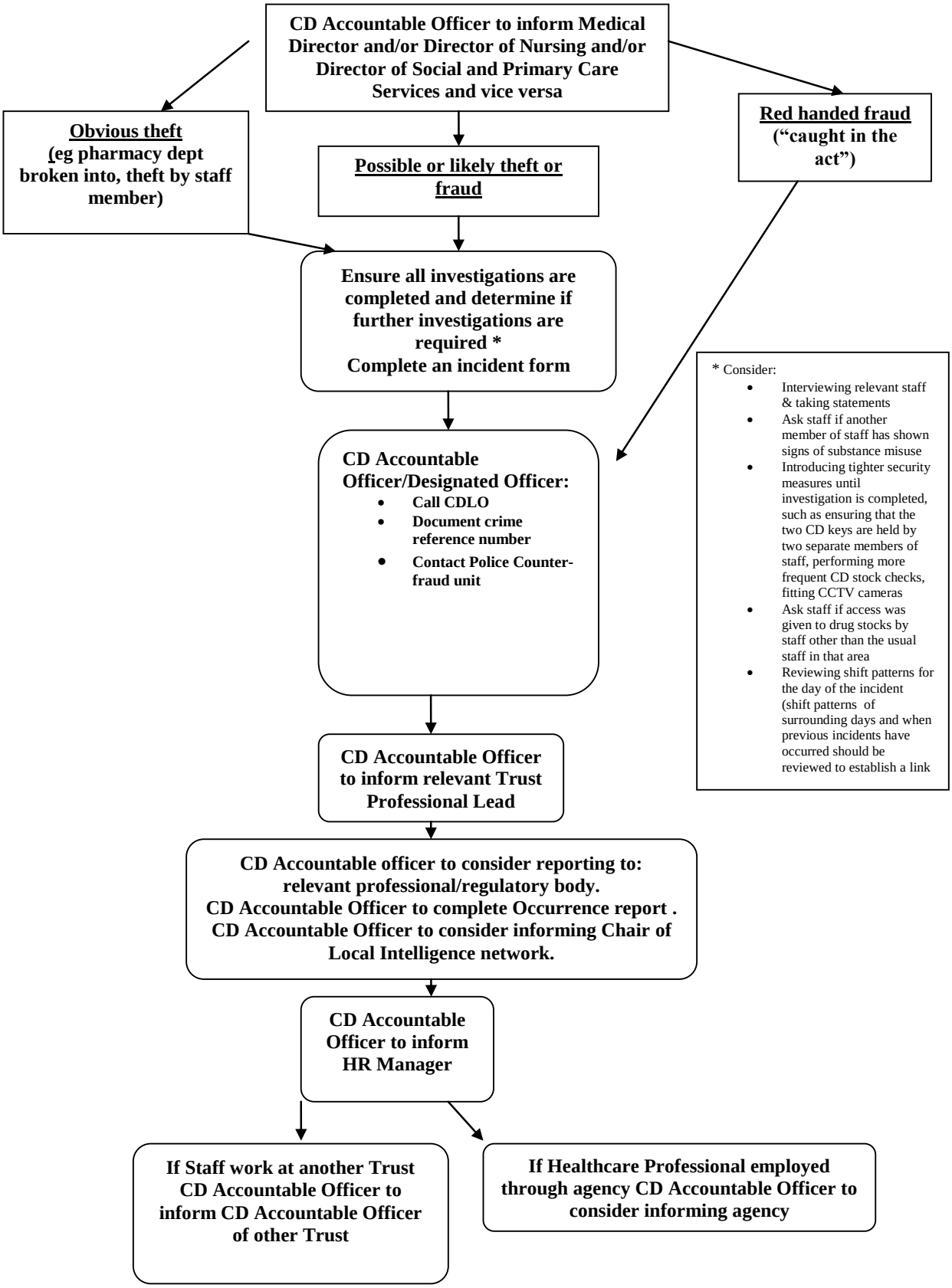
When a discrepancy is identified, an investigation must be undertaken in line with the Trust Medicine Policy. If the discrepancy remains unresolved, the actions outlined below must be followed:



Appendix 3:

CD Accountable Officer process for dealing with suspected or confirmed unlawful activity

This process must be followed in addition to the Trust Adverse Incident Reporting and Management policy



Belfast Health and Social Care Trust

Reference No: SG 01/11

Title:	Controlled Drugs Policy – Inpatient areas		
Author(s)	Julia Tolan, Deputy Head of Pharmacy, Pharmacy Services Manager (BCH, Musgrave, KBN) [redacted] Aideen O'Kane, Lead Pharmacist, Controlled Drugs [redacted]		
Ownership:	Dr Tony Stevens, Medical Director Ms Brenda Creaney, Director of Nursing and User Experience Mrs Jennifer Welsh, Director of Cancer and Specialist Services		
Approval by:	Drugs and Therapeutics Standards and Guidelines Policy Committee Executive Team Meeting	**Approval date:**	5/4/13 18/4/13 20/5/13 22/5/13
Operational Date:	June 2013	**Next Review:**	June 2016
Version No.	2 **Supercedes** V1 February 2011-2013		
Key Words	Controlled, Controlled drugs, CD, accountable officer, Medicines code		
Links to other policies	BHSCT Controlled Drug Procedures Dealing with discrepancies or concerns involving controlled drugs (March 2001) BHSCT Medicines Code (February 2011) Supply of Pethidine to Community Midwives for a home birth BHSCT Non-Medical prescribing Policy		

Date	Version	Author	Comments
04/01/10	0.1	J Tolan	Initial Draft
25/7/10	0.2	J Tolan	BHSCT draft. Inclusion of CD template prescription (Steven McNeill & Orla Daly)
06/09/10	0.3	J Tolan	Reference to strong potassium infusion removed from policy appendix 2
31/10/10	0.4	J Tolan	Revisions following review by central nursing and Dr Susan Atkinson
24/11/10	0.5	J Tolan	Final comments from central Nursing (Bernadette Gribben) Final comments from Dr Julian Johnston (Standards and Guidelines BHSCT)
10/12/10	0.6	J Tolan	Addition of dentist as prescriber Addition of requirement for risk assessment if two practitioners not involved in administration of CD. Addition of cannabis (Sativex™)

14/12/10	0.7	J Tolan JRJohnston	Only format changes
14/12/10	0.8	J Tolan O MacLeod	Final BHSCT submitted for approval Final revisions
			Approved – for dissemination
10/1/2011	0.9	J Tolan	Updated Discharge prescription form as pdf.
15/2/2011	1.0	J Tolan	Addition of Midwives exemptions
24/12/12	1.1	JTolan A O'Kane	Review and Update of Version 1.0
08/02/13	1.2	JTolan	Updated with comments from Eimear McCusker, Aideen O'Kane, Steven McNeill
14/2/13	1.3	JTolan	Appendices updated by Aideen O'Kane
20/03/13	1.4	JTolan	CDSOPA appendix g reviewed and updated by Aideen O'Kane following feedback from CD workshop
21/03/13	1.5	JTolan	Separate the Policy from Standard Operating Procedures (SOPs) Amendments following policy review by pharmacy and nursing workshop
28/03/13	1.6	JTolan	Inclusion of ADNs in roles/ responsibilities
12/4/13	1.7	JTolan	Amendment to cannabis (sativex) to part 1 of Schedule 4 but retained as BHSCT category A. Inclusion of the associated updated legislation in the list of references (Updated in both Policy and Procedures)
23/4/13	1.8	JTolan	Procedures document: Correction to stated review dates of SOPs, relocation of midazolam advice on Pg 50 to Pg47
23/6/13	1.9	JTolan	Updated with comments from Dr Robinson and Janice Flannagan at S&G.
Dec 15	1.10		Updated to include 2 appendices

Contents

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care. However, as a result of the actions of Harold Shipman, and the recommendations arising from the Shipman Inquiry, significant changes have been made in both governance and legislation surrounding the use and management of controlled drugs.

Controlled drugs (CDs) are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm.

The Misuse of Drugs Regulations 2001 define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities and lay down the conditions under which these activities may be carried out. Further information is provided in section 4.0.

The Health Act 2006 provided for regulations to be made relating to strengthened governance and monitoring arrangements for CDs. The Health Act 2006 is primary legislation and applies to the whole of the UK. The Regulations developed under the Health Act may differ to some extent in the different administrations. The Northern Ireland legislation, The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, came into operation on 1st October 2009.

The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2012 provide that Nurse and 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 is not permitted, except for the purpose of treating organic disease or injury.) Refer to the BHSCT non-medical prescribing policy for further information.

All healthcare organisations are accountable, through the Accountable Officer, for ensuring the safe management of CDs. **The Accountable Officer (AO) for controlled drugs for the BHSCT is the Head of Pharmacy and Medicines Management.**

1.2 Purpose

The purpose of this policy is to ensure the safe and effective use and management of controlled drugs in hospital in-patient sites within BHSCT and should be read in conjunction with;

BHSCT Controlled Drug Procedures http://intranet.belfasttrust.local/policies/Documents/Controlled%20Drugs%20Procedures%20Inpatient%20Areas%20BHSCT.pdf	**SG 01/11**
Dealing with discrepancies or concerns involving controlled drugs (March 2011)	**SG 18/11**
BHSCT Medicines Code and Policy	SG 09/11
Supply of Pethidine to Community Midwives for a home birth	SG 180/11
BHSCT Non-Medical Prescribing Policy	SG 014/09

This policy is for all staff working within the BHSCT and aims, through the associated Controlled Drug Procedures document, to provide clear instructions for storing, supplying, transporting, prescribing, administering, recording, monitoring and disposing safely of controlled drugs in accordance with legislation, professional standards and best practice standards including;

- Misuse of Drugs Act 1971
- Misuse of Drugs Regulations (NI) 2002
- Safer Management of Controlled Drugs, A guide to Good Practice in Secondary Care (Northern Ireland) updated August 2012
- NMC Standards Medicines Management, August 2008

1.3 Objectives

To ensure;

1.3.1 CDs are used and managed safely and securely whilst ensuring patients have timely access to the medicines prescribed for them.

1.3.2 All staff involved in the use and management of CDs are aware of their roles and responsibilities in relation to medicines management.

2.0 SCOPE OF THE POLICY

2.1 This policy applies to all BHSCT staff, including medical, dental, nursing and midwifery and pharmacy staff, involved in the use and / or management of controlled drugs and to all staff contracted by the Trust who

may be involved in the transport of controlled drugs or those trained and authorised to witness destruction of pharmacy stock.

2.2 The policy is primarily intended for BHSCT hospital in-patient facilities however the principles may be adopted by community facilities when appropriate.

2.3 The policy is not intended specifically to address clinical trials involving CDs however the principles may be adopted in addition to legislation governing clinical trials.

3.0 ROLES/RESPONSIBILITIES

3.1 Chief Executive Officer

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

3.2 The Accountable Officer – Controlled Drugs

The BHSCT Accountable Officer (AO) for controlled drugs is the Head of Pharmacy and Medicines Management. The AO is responsible for all aspects of the safe and secure management of CDs in the BHSCT and is accountable to the Chief Executive in this regard. This includes;

- ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents related to CDs and reports to the BHSCT Medicines Management Committee in this regard
- to ensure that members of staff who are involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training to enable them to carry out their duties
- attendance at the Northern Ireland Local Intelligence Network (LIN) and to submit quarterly occurrence reports identify concerns and incidents relating to controlled drug management in BHSCT and annual Declaration and Self assessment

3.3 All staff

All staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in this policy, associated Standard Operating Procedures (SOPs) and the BHSCT policy for dealing with discrepancies or concerns involving controlled drugs.

3.4 Nursing and midwifery staff

3.4.1 All nursing and midwifery staff;

- Adherence to the BHSCT Policy for Management of Controlled drugs and the Standard Operating Procedures (SOPs) contained within the BHSCT Controlled Drugs Procedures document.

- Adherence to professionals standards as outlined in NMC Standards for Medicines Management

3.4.2 The registered nurse or midwife, **on duty and in charge,** is responsible;

- for the CD key which should be held on their person
- for keeping the Controlled Drug Record Book (CDRB) up to date, accurate, in good order and compliant with the Trust CD SOPs.
- for ensuring the stock balance of all CDs entered in the CDRB are checked and reconciled in accordance with the relevant Trust Controlled Drug SOP.

3.4.3 The ward sister/charge nurse, as well as team leads and nurse or midwife in charge of a ward or department is responsible for;

- **the safe and appropriate management of controlled drugs in that area.**
- ensuring that staff comply with the Trust systems and that procedures are in place for the management of CDs within their area of responsibility.
- ensuring stock levels of CD preparations held in wards, departments and facilities match what is routinely used in that clinical area
- ensuring that a robust audit trail exists for patients own CDs brought into hospital on admission or supplied at discharge
- ensure compliance with pharmacy quarterly CD check and where actions are identified, ensure implementation.
- ensuring that their staff, especially new employees, locum staff and agency staff, have access to and adhere to this policy and associated procedures.
- the completion of quarterly observational audit of practice and actions required to achieve and maintain compliance

3.4.4 Associate Directors of Nursing (ADNs) and Associate Director of Midwifery (ADM)

Support Co-Directors in monitoring and ensuring compliance at quarterly CD checks

3.5 Prescribers (medical, dental and non-medical prescribers)

Responsibilities of Trust prescribers (medical, dental and non-medical prescribers) are:

- Adherence to the BHSCT Policy for Management of Controlled drugs and the associated Controlled Drug Procedures.
- Compliance with CD prescription writing requirements as described in the British National Formulary and the BHSCT SOPs.

- To avoid creating dependence by introducing drugs to patients without sufficient reason and to avoid being used as an unwitting source of supply for addicts.
- Medical staff, including FY1s, are only permitted to prescribe medicines, including CDs, as part of their required duties in their post and should not prescribe for private patients or their own use.
- Non-medical independent prescribers - Nurse and Pharmacist independent prescribers. To prescribe within their competence, administer, or direct anyone to administer a limited range of controlled drugs solely for specified medical conditions (see latest edition of the British National Formulary). See also BHSCT non-medical prescribing policy
- Supplementary prescribers. To act under and in accordance with the terms of an agreed individual clinical management plan (CMP). To prescribe and administer and/or supply or direct any person to administer any controlled drug provided that the controlled drug is included in the CMP.

3.6 Pharmacy Staff

- The Head of Pharmacy and Medicines Management through the Pharmacy Services Managers and the Pharmacy Procurement and Production lead is responsible for the safe and appropriate management of controlled drugs in BHSCT pharmacy sites
- Pharmacy department Standard Operating Procedures are developed and maintained and cover each of the aspects of the safe management of controlled drugs including ordering, receipt, safe custody, record-keeping, auditing, issuing of stock, dispensing prescriptions, transporting of supplies, and destruction of unwanted drugs. Pharmacy SOPs should be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived. SOPs should be approved by the AO or by the person to whom he has delegated this task.
- All relevant pharmacy staff must be trained in the pharmacy department SOPs and must adhere to the SOPs.
- Pharmacy stocks of controlled drugs must be checked and reconciled each month by a competent person and recorded indelibly in the Pharmacy CD register(s).

3.7 CD messengers (e.g. nursing auxiliaries, ward housekeepers, student nurses or student midwives, porters or drivers)

The person who conveys the controlled drug acts as a messenger, that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container.

Responsibilities of the CD messenger include;

- Ensure the destination is known, be aware of safe storage and security, the importance of handing over the intact and sealed container to an authorised person and obtaining a signature for delivery
- Have a valid ID badge (e.g. BHSCT photographic ID, valid university ID, taxi photographic ID)

3.8 Designated Governance leads

Designated governance leads trained and authorised by DHSSPSNI are responsible for witnessing the destruction of pharmacy-held stock of obsolete, expired or unwanted Schedule 2 controlled drugs and associated record keeping in accordance with pharmacy SOP.

3.9 Co-Directors

Co-Directors are responsible for ensuring compliance with quarterly CD checks and that any actions / recommendations from quarterly CD checks are completed within 4 weeks of completion of the audit.

4.0 The definition and background of the policy

4.1 Definitions

Controlled Drugs: Controlled drugs are 'dangerous or otherwise harmful drugs' as controlled by the Misuse of Drugs Act 1971. The Misuse of Drugs Regulations 2001 define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities and lay down the conditions under which these activities may be carried out. Controlled drugs are divided into five schedules each specifying the minimum requirements governing such activities as import, export, production, supply, possession, prescribing, storage and record keeping which apply to them. Table 1 provides examples of controlled drug by schedule.

Table 1: Examples of Controlled drugs by Schedule

Schedule	Description of Schedule as per Misuse of Drugs Regulations 2001
1	Drugs such as cannabis and lysergide. Possession and supply are prohibited except in accordance with Home Office authority.

2	Drugs such as diamorphine, morphine, remifentanil, pethidine, secobarbital, glutethimide, amfetamine, and cocaine. Schedule 2 CDs are subject to the full controlled drug requirements relating to prescriptions, safe custody (except for secobarbital), the need to keep registers, etc. (unless exempted in Schedule 5).
3	Includes the barbiturates (except secobarbital), buprenorphine, diethylpropion, mazindol, meprobamate, **midazolam**, pentazocine, phentermine, and temazepam. They are subject to the special prescription requirements (except for temazepam) but not to the safe custody requirements (except for buprenorphine, diethylpropion, and temazepam) nor to the need to keep registers (although there are requirements for the retention of invoices for 2 years).
4	Includes in Part I benzodiazepines (except temazepam and midazolam, which are in Schedule 3) and zolpidem, which are subject to minimal control. Part II includes androgenic and anabolic steroids, clenbuterol, chorionic gonadotrophin (HCG), non-human chorionic gonadotrophin, somatotropin, somatrem, and somatropin. Controlled drug prescription requirements do not apply and Schedule 4 Controlled Drugs are not subject to safe custody requirements.
5	Includes those preparations which, because of their strength, are exempt from virtually all Controlled Drug requirements other than retention of invoices for two years e.g. co-codamol 8/500

A summary of the BHSCT categorisation of controlled drugs and their management and examples of Controlled Drugs held in stock in BHSCT hospital sites are included in Appendix 1 & 2.

Controlled Drug Standard Operating Procedures (SOPs) are contained within BHSCT Controlled Drug Procedures Document.

The BHSCT management of controlled drugs in relation to prescribing, storage and record keeping may exceed the Misuse of Drugs Regulations or non-CDs may be managed in the same way as CDs. This is to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

4.2 Policy Statement(s)

4.2.1 All CDs in BHSCT must be used / managed in accordance with this policy, the Trust Controlled Drug Procedures and the BHSCT Medicines Code whilst ensuring patients have timely access to the medicines prescribed for them.

4.2.2 The BHSCT categorises controlled drugs, including high risk medicines, into three categories with guidance in handling, storage, returns procedures etc provided for each category.

4.2.3 The prescribing, ordering and usage patterns for controlled drugs will be monitored in accordance with the Health Act 2006 and under the Controlled Drugs (Supervision of management and Use) Regulations 2006.

4.2.4 Standard Operating Procedures (SOPs) cover the management of the BHSCT categories of controlled drugs within hospital in-patient facilities and ensure compliance with the current legal requirements for controlled drugs and best practice guidance for high risk medicines. Any local deviations from the SOPs must be documented and approved by a Pharmacy Services Manager

4.2.5 Each ward or department which may use or store controlled drugs must have a printed and signed copy of each SOP available on the ward.

4.2.5 The BHSCT management of controlled drugs in relation to prescribing, storage and record keeping may exceed the Misuse of Drugs Regulations. This is to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

4.2.6 Certain high risk medicines are ordered, stored or recorded as controlled drugs to ensure a higher level governance and risk management.

4.2.7 Healthcare professionals authorised to prescribe, administer or manage controlled drugs must do so in accordance with professional standards of practice, relevant legislation, this Controlled Drugs Policy and associated Standard Operating Procedures

4.2.8 All medicines including controlled drugs available in BHSCT are for use only for patients within BHSCT.

Healthcare professionals are not permitted to use stocks of medicines on wards, departments or facilities for their personal use.

4.2.9 A clear audit trail exists for the movement and use of all CDs. At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties

4.2.10 Controlled drugs (ALL BHSCT CD categories) **MUST NOT** be supplied from one ward/dept to another ward/dept. A controlled drug may be transferred only (when attached to a patient) when a patient receiving a controlled drug by means of a syringe, infusion, epidural or transdermal patch is transferred to another ward/dept. Patients own CDs (admission or discharge supplies) may be transferred with a patient to another ward/dept.

4.2.11 Controlled drugs **MUST NOT** be administered following only a verbal order even if in the presence of a doctor.

4.2.12 Processes are in place to protect the security of the stock of CDs held in the ward or department and to ensure that stocks of CDs correspond with the details shown in the controlled drug record book.

4.2.13 There should be a separate CDRB for each CD cabinet where the CD cabinets are in separate ward/dept or separate rooms within a ward/dept.

4.2.14 Access to CDs is restricted to appropriate, designated and legally authorised personnel.

4.2.15 The use of CDs is audited and action taken as necessary

4.3 Policy

4.3.1 The BHSCT categorises controlled drugs into three categories with guidance in handling, storage, returns procedures etc provided for each category. Refer to Appendix 1 and 2

4.3.2 Standard Operating Procedures cover the management of controlled drugs in each category and are contained within the BHSCT Controlled Drug Procedures document. SOPs;

4.3.2.1 CD Standard Operating Procedure A (CDSOPA): Management of Schedule 2 and certain schedule 1, 3 and 5 Controlled Drugs and controlled high risk medicines

4.3.2.2 CD Standard Operating Procedure B (CDSOPB): Management of Schedule 3 CDs (excluding Temazepam, diethylpropion, buprenorphine and Flunitrazepam)

4.3.2.3 CD Standard Operating Procedure C (CDSOPC): Management of Schedule 4 and 5 CDs excluding those specified within CDSOPA

4.3.3 The Standard Operating Procedures cover, either in detail or summary format, the following activities:

Description
Storage of Controlled Drugs
Key holding and access to CDs
CD Stationery
Prescribing of Controlled Drugs
Ordering CDs for ward/dept stock
Collection / transportation and receipt of ward stock CDs onto a ward or department
CD Record Keeping
Administration of CDs (except in theatres1)
Prescribing, administration, destruction and record keeping of Controlled Drugs in theatres and recovery
Destruction of Controlled Drugs on wards/departments including theatre areas
Returns
Patients own Controlled drugs
Transfer of CDs with a patient
Discrepancies with stock balance
Ward / Department CD stock checks
Three monthly (quarterly) CD checks by pharmacy staff

5.0 IMPLEMENTATION AND RESOURCE REQUIREMENTS

5.1 Dissemination

This policy is relevant to:

- Prescribers (Medical, dental and non-medical prescribers)

[1] Including areas where anaesthesia involving the administration of controlled drugs is practiced

- Nursing and midwifery staff
- Pharmacy Staff
- CD Messengers (nursing auxiliaries, student nurses or student midwives, porters or drivers)
- Designated directorate Governance Leads with responsibility for destruction of CDS

The Lead author should be notified if there are significant barriers to implementation of this policy.

5.2 Resources

Implementation will include a series of training events and local workshops lead by the Lead Pharmacist for Controlled Drugs and the Co-Director Nursing: Governance, Standards and performance

5.3 Exceptions

Refer to section 2.0

6.0 MONITORING

Quarterly audits on adherence to the Controlled Drug Policy and procedures therein are undertaken in all locations where controlled drugs are stored and used. Audit results are collated and disseminated by Co-Directors requiring completion of audit findings / recommendations within 4 weeks of the audit.

Key performance Indicator: Each ward / department must maintain full compliance with the CD Policy and procedures therein as measured at quarterly CD audits

The prescribing, ordering and usage patterns for controlled drugs will be monitored in accordance with the Health Act 2006 and under the Controlled Drugs (Supervision of management and Use) Regulations 2006.

7.0 EVIDENCE BASE / REFERENCE

- Safer Management of Controlled Drugs. A guide to good practice in secondary care (Northern Ireland), DHSSPS August 2009 updated August 2012
- Medicines Act 1968
- Misuse of Drugs Act 1971
- Misuse of Drugs (Safe Custody) Regulations 1973
- Misuse of Drugs Regulations 2001 (MDR) and Misuse of Drugs Regulations Northern Ireland (NI) 2002

- The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 No 225'
- The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2012
- Prescription Only Medicines (Human Use) Order 1997
- Controls Assurance Medicines Management Framework DHSSPSNI (2008)
- Health Act 2006
- NMC Standards for Medicines Management August 2008
- Use And Control Of Medicines DHPSS 2008
- The Misuse Of Drugs (Amendment) Regulations (Northern Ireland) 2013

8.0 CONSULTATION PROCESS

Review by;
Head of Pharmacy and Medicines Management
Co-Director for Nursing: Governance, Standards and performance
Drugs and Therapeutics Committee
Workshop including pharmacy and nursing staff and including central nursing.

9.0 APPENDICES / ATTACHMENTS

Appendix	Description
1	BHSCT categories of controlled drugs including controlled high risk medicines
2	Examples of controlled drugs in stock in BHSCT (Dec-12) and controlled high risk medicines by Schedule and by BHSCT category

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. ☒

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

_____ Date: ____June 2013_____
Author

_____ Date: _____June 2013_____
Director

Appendix 1: BHSCT categories of controlled drugs including controlled high risk medicines

BHSCT CD category (SOP ref#)	CD category A CDSOPA -Refer to BHSCT CD Procedures	CD category B CDSOPB - Refer to BHSCT CD Procedures	CD category C CDSOPC - Refer to BHSCT CD Procedures
Schedule	ALL Schedule 2 CDs Specific Schedule 1, 3 and 5 CDs Certain controlled high risk medicines	Schedule 3 CDs (except Temazepam, diethylpropion and buprenorphine. Flunitrazepam)	Schedule 4 and 5 CDs excluding those specified within CDSOPA
Drugs by schedule **(Refer also to Appendix 2, CDs held in stock in BHSCT Dec12)**	**Schedule 2**: ALL e.g. morphine, oxycodone, pethidine, diamorphine, nabilone, methylphenindate, methadone, fentanyl, alfentanil, hydromorphine, remifentanil **Schedule 3**: temazepam, flunitrazepam, buprenorphine, diethylpropion **Schedule 4**: Cannabis (Sativex) **Schedule 5**: Morphine sulphate oral liquid 10mg/5ml (Oramorph) **Controlled High Risk medicines;** 1. Strong Potassium Chloride 15% injection 2. Addiphos injection (30mmol potassium / 20ml) 3. Potassium Dihydrogen Phosphate (1mmol potassium, 1mmol Phosphate)	**Schedule 3**: Includes the barbiturates (amylobarbitone, phenobarbital), mazindol, meprobamate, **midazolam**, pentazocine, phentermine	**Schedule 4 (part 1):** Examples include diazepam, oxazepam, lorazepam, chlordiazepoxide, ketamine, flurazepam, nitrazepam, zolpidem **Schedule 4 (part 2):** androgenic and anabolic steroids **Schedule 5**: co-codamol 8/500, co-codamol 30/500, codeine phosphate tabs
Requisition Book	**CD order/returns book**	**CD order/returns book**	Pharmacy requisition book (investigate requisitions if on top-up)
Permitted on top-up?	No	No	Yes
Prescription writing requirements	Yes	Yes	No
Validity of prescription	28 days (6 months for controlled high risk medicines)	28 days	28 days (6 months for schedule 5 CDs)
Ward storage /Safe Custody (storage) – including PODs and returns	**CD cabinet** Cannabis: **Separate** lockable fridge	Ward medicines cupboard/cabinet	Ward medicines cupboard/cabinet
Ward register	Yes	No	No
Pharmacy storage	Schedule2 & specified high risk medicines: CD room Cannabis: **Separate** lockable fridge Sch 3 & 5: CD room / robot	CD room / robot	Robot
Pharmacy register	Yes (except Temazepam, Flunitrazepam, buprenorphine, diethylpropion, specified high risk medicines)	No	No
Retention of invoices for 2 years	Yes	Yes	Yes
Permitted in Emergency cupboard	No	No	Yes
Returns	Must be returned by pharmacist / nurse or midwife in charge directly to pharmacy using Procedure in CDSOP01	Must be returned by pharmacist / nurse or midwife in charge directly to pharmacy using Procedure in CDSOP01	Return unused stock to pharmacy when no longer required

Appendix 2: Examples of controlled drugs in stock in BHSCT (Dec-12) and controlled high risk medicines by Schedule and by BHSCT category

Schedule 1	Schedule 2	Schedule 3	Schedule 4 (part 1)	Schedule 4 (part 11)	Schedule 5	High Risk Medicines *
Cocaine	Alfentanil	Amylobarbitone	Cannabis (Sativex)	Chorionic gonadotrophin (HCG)	Codeine[2]	Addiphos™ inj
	Codeine inj[1]	Butobarbital (butobarbitone)	Alprazolam	Danazol	Codeine linctus	Potassium Chloride 15% inj
	Dexamfetamine	Buprenorphine	Chlordiazepoxide	Nandrolone	Dihydrocodeine[2]	Potassium Dihydrogen Phosphate (1mmol Potassium, 1mmol phosphate) inj
	Dextromoramide	Flunitrazepam	Clobazam	Oxandrolone	Pholcodine[2]	
	Diamorphine	Mazindol	Clonazepam	Oxymetholone	Morphine Sulphate 10mg/5ml oral solution Oramorph™	
	Dihydrocodeine inj[1]	Meprobamate	Diazepam	Testosterone		
	Dihydromorphine	Midazolam	Flurazepam	Somatropin		
	Fentanyl	Pentazocine	Ketamine	Stanozolol		
	Hydromorphine	Phenobarbital (Phenobarbitone)	Loprazolam	DHEA (dehydoepiandrosteron)		
	Morphine	Temazepam	Lorazepam			
	Methadone		Lormetazepam			
	Methylphenidate		Nitrazepam			
	Nabilone		Oxazepam			
	Oxycodone					
	Papaveretum[3]					
	Pethidine					
	Pholcodine[1]					
	Remifentanil					
	Secobarbital (quinalbarbitone)					

BHSCT – CD category A

BHSCT – CD category B

BHSCT – CD category C

Notes

1. Falls within paragraph 6 of Part 1 of Schedule 2 MDA 1971 if in a preparation designed for administration by injection
2. Falls within Schedule 5 if in a preparation either alone or with one or more of the drugs referring to this note not being a preparation designed for administration by injection, when compounded with one or more active or inert ingredients and containing a total of not more than 100mg of the substances (calculated as base) per dosage unit or with a total of not more than 2.5% (calculated as bas) in undivided preparations.
3. Falls within Schedule 2 but Schedule 5: (a) if in any preparation from which the opium cannot be readily recovered in amounts which constitute a risk to health and with maximum strength 0.2%, (b) if in a powder containing opium 10%, 10% ipecacuanha root and 80% of another powdered ingredient (not a controlled drug),(c) if for non-parenteral use in unit preparations diluted to at least one part million (6x) in response to a specific request or (d) if for non-parenteral use in unit preparations diluted to at least one part in a million million (6c)

* Non-CDs - denotes high risk drugs which are legal category POM but are managed as controlled drugs as per BHSCT policy

Appendix 3: Operating Department Practitioners (ODPs)

1 Introduction

Operating Department Practitioners (ODPs) are defined in the Misuse of Drug Regulations Northern Ireland 2002 as a person who is registered under the Health Professional Order 2001. In 2007 legislation was amended to enable ODPs to have similar authority to the senior registered nurse in charge in relation to controlled drug management. (The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007).
The following section will outline specific roles and responsibilities of ODPs working within BHSCT theatre and recovery areas.

Upon registration with the Health and Care Professions Council (HCPC) ODPs are able to assist with the delivery of care in anaesthesia, surgery and recovery settings.

Within BHSCT the Lead Theatre Nurse of the relevant theatre department will be responsible for the management and development of ODPs.

2 Roles and responsibilities of Ward Sister / Charge Nurse (theatre, Day procedure units and recovery areas)

The Ward Sister/Charge Nurse of a theatre/Day Procedure Unit/recovery area has **overall responsibility and accountability** for management of controlled drugs within theatre and recovery areas. The Ward Sister/ Charge Nurse:

- must ensure that any ODPs working within their theatre or recovery area are registered with the Health and Care Professions Council (HCPC)
- must ensure that ODPs have access to and adhere to the BHSCT controlled drugs policy and associated procedures
- must ensure that ODPs have access to and adhere to the BHSCT (Acute)Medicines Code Policy
  should complete quarterly observational audits of controlled drug practice as outlined in the BHSCT CD policy, this should include both registered nurses/midwifes and ODPs

3 Operating Department Practitioners

ODPs working within BHSCT

- Must be registered with the HCPC
- Must adhere to HCPC Standards of Proficiency for Operating Department Practitioners:
- http://www.hcpc-uk.org/assets/documents/10000514Standards_of_Proficiency_ODP.pdf
- Must complete all necessary mandatory training requirements
  Must ensure that their practice remains up to date in line with professional guidance and standards including CPD requirements; have awareness of the College of Operating Practitioners Scope of Practice

- Must adhere to the BHSCT Medicines Code
- Must ensure that they adhere to the BHSCT controlled drugs policy
- Must have access to and adhere to the Standard Operating Procedures CDSOPA 1 -16 as laid out in the CD Procedures Document
- Must adhere to the information described in the sections below

4 Roles and responsibilities of ODPs in practice

The registered Operating Department Practitioner on duty may be assigned responsibility for **the safe and appropriate management of controlled drugs in that area including**

- The controlled drug key, which should be held on their person
- Keeping the Controlled Drug Record Book (CDRB) up to date, accurate, in good order and compliant with the trust controlled drug standard operating procedures (SOPs)
- Ordering controlled drugs on trust approved controlled drug stationery
- Ensuring the stock balance of all controlled drugs entered in the CDRB are checked and reconciled each time a CD is required and at each change of shift in accordance with trust CD procedures
- Ensuring stock levels of controlled drug preparations held in wards, and theatres match what is routinely used in that clinical area

5 Specific roles and responsibilities of the registered ODP

Registered ODPs Must read and sign the following policies:

- BHSCT Medicines Code – Acute
- BHSCT CD Policy – Inpatient Areas
- BHSCT CD Procedures – Inpatient Areas
- BHSCT Dealing with discrepancies or concerns involving controlled drugs

5.1 Controlled Drug Key(s)

The responsibilities of the Registered ODP in relation to the controlled drug key include:

- The key of the CD cabinet must be carried on the person of the registered ODP
- At shift change it must be handed over personally to the in-coming registered nurse/midwife/ODP on duty and in charge
- The CD key **must not** be handed to medical staff/unauthorised staff
- If the registered ODP has been delegated to hold the CD key they must know its whereabouts at all times
- The CD key should be returned to the registered ODP in charge immediately after its use by another registered nurse or midwife
- The ODP in charge of theatre may be responsible for co-ordination of key holding to registered staff within theatre areas

5.2 Controlled Drug Stationery

Registered ODPs should be aware that;

- Only approved BHSCT CD stationery should be in use
- CD stationery must be stored securely in a locked cabinet or drawer

when not in use

5.3 Ordering Controlled Drugs

Registered ODPs should be aware that;

- Each theatre or recovery ward must hold a stock list with minimum stock levels
- Only CDs on the stock list should be routinely requisitioned
- They must be approved as an authorised signatory by the ward sister/charge nurse
- Orders for controlled drugs must be signed by an authorised signatory

5.4 Collection and Receipt of Controlled Drugs

Registered ODPs should be aware that;

- At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of signatures of both parties
- If a registered ODP collects CDs from pharmacy they will be required to the sign the requisition – it is good practice that the person collecting the CDs is not the same person who ordered the CDs
- They will be asked to provide Trust identification on request
- When CDs arrive at ward level they must be checked by the registered nurse/ODP in charge to ensure the correct drug and quantity has been received.
- The registered nurse/ODP receiving the controlled drugs must complete the relevant copy of the requisition and return it to the supplying pharmacy department
- If the controlled drugs are schedule 2 (category A) they must be stored in the CD cabinet
- A record of receipt must be made in the relevant CDRB
- All sections on the CDRB must be completed and countersigned by a witness
- CDRB entries require
  - ✓ Date received
  - ✓ Amount received
  - ✓ Name of pharmacy and serial number of requisition
  - ✓ Name and signatures of persons taking receipt
  - ✓ Stock balance
  - ✓ Confirmation that stock balance is correct – date and signature

5.5 Issue of controlled drugs in theatres

ODPs must be aware that:

- That the supply of a CD to an anaesthetist must be witnessed by a registered ODP/nurse/midwife
- The anaesthetist is responsible for the administration of a CD to a patient in the presence of a registered nurse/ODP but not necessarily witnessed by a registered nurse/midwife/ODP
- The destruction of any surplus drug must be safely disposed of and witnessed by a registered nurse/midwife/ODP before the anaesthetist leaves theatre

- The anaesthetist and registered nurse/midwife/ODP must record the destruction of the CD in the CDRB

5.6 Administration of controlled drugs*
(*administration of medication dependent on completion of trust approved administration of medicine programmes)

ODPS must be aware that:

- CDs must **NOT** be administered on the basis of a verbal order even if the order is given by or in the presence of the doctor
- Two practitioners must be involved in the administration of a controlled drug *(except where the administration is being done by an anaesthetist)*
- Both practitioners must be present during the whole administration and must witness
  - The preparation of the CD
  - The CD being administered to the patient
  - The destruction of any surplus drug
- It is the responsibility of the practitioner, who supplied the CD to a doctor for administration or who administered the CD, to ensure that all sections of the CDRB is completed correctly

5.7 Management of Epidural/ IV PCA Infusions commenced in theatre

If the registered ODP has completed the necessary epidural/IV PCA infusion training they should follow the procedure outlined in CDSOP9 (A)
(dependent on eligibility/completion of trust approved training programmes)

5.8 Disposal of controlled drugs

ODPS must be aware that:

- Only small amounts of CDs should be destroyed on wards and in theatres e.g. the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up
- Destruction of a CD should be by a registered nurse/midwife/ODP/doctor
- Destruction of a CD must be witnessed by a second professional such as registered nurse, midwife, ODP, doctor or pharmacist
- Destruction details must be documented in the CDRB
- Anaesthetists are responsible for destruction of CDs issued to them but that the disposal must be witnessed by a registered nurse, midwife or ODP
- Date expired CDs must not be destroyed at ward level – they must be returned to pharmacy

5.9 Controlled Drugs returns to pharmacy

ODPs must be aware that:

- To return a CD they must contact the pharmacy/designated pharmacist to arrange a time for the CDs to be returned
- They must complete the details of the CDs being returned on the relevant CD order/returns book including, name of drug, strength, quantity and reason for return

- If the CD is a schedule 2 CD a corresponding entry must be made in the CDRB and the running balance updated, the pharmacist must also sign and print their details in the CDRB
- The CDs must be placed in an envopak
- They must phone pharmacy to inform them of the name of pharmacist carrying the CDs and the number of CDs in the envopak

5.10 Stock checks of controlled drugs

ODPs must be aware that:

- The stock balance of all CDs recorded in the CDRB must be checked at each change of shift with the minimum of a twice daily check
- The CD stock check must be carried out by two registered staff (nurse/ODP) one of whom will be the nurse/ODP in charge
- If the stock check occurs at the change of shift the two members of staff carrying out the stock check will be a member from each shift,i.e. one member is from in-coming shift and the other member is from the out-going shift
- The CD stock check undertaken at shift changes represents the transfer of responsibility for controlled drugs.
- The CD check must involved checking the exact quantity of each CD recorded in the CDRB against the quantity in the cabinet
- The CD checks must be recorded in the CDRB
- Expired stock must be effectively quarantined pending return to pharmacy

5.11 Controlled drug quarterly audits

ODPs must be aware that:

- All departments/wards must have a quarterly controlled drug audit
- The CD audit is arranged with the ward sister/charge nurse – they may wish to delegate the audit to a registered nurse/midwife/ODP
- The CD audit may be completed by a pharmacist and a registered nurse/ODP
- The standard audit form must be used – see appendix g of CD Procedures
- A record of the CD check must be documented in the CDRB by the registered nurse/ODP and the pharmacist
- A copy of the completed CD audit form must be left for the ward sister/charge nurse's attention

References

1. Standards of Proficiency – Operating Department Practitioners, Health and Care Professions Council 2014
2. Continuous Professional Development – Health and Care Professions Council http://www.hcpc-uk.org/registrants/cpd/
3. Safer Management of Controlled Drugs in Secondary Care 2012
4. The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007

Appendix 4: CDSOPA -BHSCT Ward/Department Quarterly CD Check Audit

Date		Time taken	A CD audit will be completed for each ward / department every three months by a pharmacist. A copy of the completed audit will be given to the Ward Sister/ Charge Nurse, Pharmacy Services Manager and the appropriate Co-director. **All remedial actions must be completed within 4 weeks**
Ward/Dept			
Audit completed by	Sign	Print	
Role			
Witnessed by	Sign	Print	
Role			

Policy Ref	**Audit Standard**	**Y/ N**	**Problem Identified** (inc page numbers and dates) **& action(s) required**
1.1.1	No unauthorised items stored in CD cabinet		
1.1.3. &3.1	Regulation CD cabinet in use, all CDs and CD stationery stored securely		
2.0	Keys are held by the appropriate person and are separate from main drug keys		
5.2.3	Authorised signatories list is up-to-date (Copy to pharmacy)		
7.0	Running balance maintained, signed and dated		
7.0	Receipts are recorded correctly, name of supplying pharmacy stated		
8.0	All administration / destruction details recorded accurately (including signature and printed name)		
12.5	Patients' Own CDs & discharge CD scripts are documented correctly in CD POD register		
15.1	Twice daily stock checks occur, are signed by two registered nurses; recorded in register		
16.3	Quantity in stock tallies with balance in CDRB & CD POD register		
16.5	A record of stock check has been made in CDRB		
16.7	No unexplained exceptional usage or peculiar patterns of usage of CDs		
16.0	A bung is present in CD liquids dispensed by BHSCT pharmacy departments for ward stock		

Spot checks:

Date of issue	**Requisition No.**	**Item**	**Quantity issued**	**CDRB correct**	**Authorised signatory**
Date of return	**Requisition No.**	**Item**	**Quantity returned**	**CDRB correct**	**Pharmacy log completed**

Ward / Dept compliant with BHSCT CD Procedures	**Yes**	**No**
IR 1 form completed if required	**Yes**	**No**
	IR1#	
Copy to Ward Sister/ Charge Nurse (Insert Name)		
Pharmacy Services Manager (Sign & Date)		

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Reference No: SG 18/11

Title:	**Dealing with discrepancies or concerns involving controlled drugs**		
Author(s)	Eimear McCusker Accountable Officer, Head of Pharmacy and Medicines Management [redacted] Aideen O'Kane Lead Pharmacist Controlled Drugs [redacted]		
Ownership:	Dr Cathy Jack, Medical Director		
Approval by:	Drugs and Therapeutics Standards and Guidelines Policy Committee Executive Team Meeting	**Approval date:**	10/08/2015 13/08/2015 07/10/2015 14/10/2015
Operational Date:	October 2015	**Next Review:**	October 2018
Version No.	V2	**Supercedes**	V1 –March 2011- 2014
Key words:	Controlled Drugs, CD, discrepancies, concerns, accountable officer, incident		
Links to other policies	BHSCT Controlled Drug Policy - 2013 BHSCT Controlled Drug Procedures - 2013 BHSCT Community Controlled Drugs policy - 2015 (draft)		

Date	Version	Author	Comments
28/01/11	0.1	E McCusker	Initial Draft
16/02/11	0.2	S O'Donnell	Updated comments
16/03/11	0.3	P King	Updated comments
27/04/11	1.0	A Carrington	Final comments
17/06/15	1.1	A O'Kane	Update of policy V1.0

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

Controlled drugs are subject to special legislative controls because there is potential for them to be abused or diverted causing possible harm. The Health Act (2006) introduced regulations to strengthen governance and monitoring arrangements for controlled drugs. The principles of The Health Act were further defined in Northern Ireland by, The Controlled Drugs (Supervision of Management and Use) Regulations 2009.

All healthcare organisations or designated bodies are accountable through the Accountable Officer for ensuring the safe management of controlled drugs. Designated bodies include Health and Social Care Trusts, Northern Ireland Ambulance Service Trust, Health and Social Care Board, Independent Hospitals.

The Accountable Officer is responsible for all aspects of the safe and secure management of controlled drugs in their organisation. This includes ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigation of concerns and incidents relating to controlled drugs.

The Accountable Officer within BSHCT is the Head of Pharmacy and Medicines Management.

Accountable Officers must establish, operate and review appropriate arrangements for the management and use of controlled drugs within their Designated Body or ensure that the Designated Body does so. They must also ensure that any person or body acting on behalf of, or providing services under arrangements made with their Designated body, established, operated and reviews appropriates arrangements for the management and use of controlled drugs.

The Accountable Officer must establish and operate appropriate arrangements for;

- assessing concerns expressed about incidents that involved or may have involved the improper management or use of controlled drugs
- investigating such concerns

The Accountable officer has a statutory duty to share information giving rise to concerns about the management or use of controlled drugs by any “relevant person” As part of the arrangements for ensuring the sharing of information regarding the management and use of controlled drugs, Accountable Officers participate in a single network, covering Northern Ireland known as the Local Intelligence Network (LIN).

Membership of LIN is described in Regulation 18 of The Controlled Drugs (Supervision of Management and Use) Regulations (2009). LIN facilitates the timely and appropriate sharing of information and enables agencies that have a concern about the activities of any staff or organisation to liaise at an early

stage with other local agencies who may be affected or who have complimentary information.

Accountable Offices must provide the Chair of LIN with a quarterly occurrence report. The report may contain the following information;

- details of any concerns regarding the management or use of controlled drugs
- confirmation that there are no concerns to report regarding management or use of controlled drugs

1.2 Purpose

The purpose of this policy to define the process and procedures for dealing with discrepancies or concerns involving the management of controlled drugs within BHSCT. This policy outlines the governance arrangements for the management and use of controlled drugs within BSHCT.

This policy should be read in conjunction with;

BHSCT Controlled Drug Policy – In-patient areas	SG 01/11
BSHCT Controlled Drug Procedures – In-patient areas	SG 01/11
BHSCT Community Controlled Drugs Policy	SG 23/15
BHSCT Medicines Code	SG 09/11
BHSCT Community Medicines Code	SG 06/13

1.3 Objectives

To ensure;

- Appropriate arrangements are in place for managing concerns about incidents involving improper management or use of controlled drugs
- Appropriate action is taken to protect patients and/or the public in cases where concerns appear to be well-founded
- Arrangements are in place for sharing of appropriate information with other responsible bodies via the Local intelligence Networ

2.0 SCOPE OF THE POLICY

The Dealing with discrepancies or concerns involving controlled drugs policy applies to;

2.1 All trust employed staff who provide BHSCT services within all settings incorporating controlled drug management, .e.g. in-patient, community, care home and domiciliary care settings.

2.2 Services which may be provided to BHSCT facilities or non-BHSCT facilities which are regulated by the Regulations and Quality Improvement Authority (RQIA), or in the patient's home.

2.3 The Dealing with discrepancies or concerns involving controlled drugs policy covers all schedules of controlled drugs.

3.0 ROLES/RESPONSIBILITIES

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

3.2 Accountable Officer
Accountable Officer responsibilities are defined in Regulations 8-18 of The Controlled Drugs (Supervision of Management and Use) Regulations 2009. They include;

BHSCT Accountable Officer is The Head of Pharmacy and Medicines Management

3.3 All staff
All staff are accountable for properly discharging their duties and responsibilities in relation to controlled drugs as detailed in this policy. It is the responsibility of all staff to report any concerns about incidents involving improper management or use of controlled drugs to BHSCT Accountable Officer and any specific concerns relating to staff must also be reported either to the line manager or in line with BHSCT Whistle blowing Policy (TP022/08)

4.0 KEY POLICY PRINCIPLES

4.1 Definitions

Controlled Drugs: Controlled Drugs are "dangerous or otherwise harmful drugs" which are subject to strict legal controls to prevent them being misused; being obtained illegally; or causing harm. The Misuse of Drugs

Regulations includes five schedules that classifies all medicines and the associated legal controls.

Local Intelligence Network (LIN): A Local Intelligence Network (LIN) for Northern Ireland was established as per the legislative requirements of the Controlled Drugs (Supervision of management and Use) Regulations (Northern Ireland) 2009. This legislation imposed a statutory duty of collaboration on healthcare organisations, police forces, social services authorities and the relevant inspection and regulatory bodies. This enables information to be shared about potential controlled drug offences and potential or actual system failures.

4.2 Policy Principles

4.2.1 The Controlled Drugs (Supervision of Management and Use) Regulations 2009 applies to all schedules of controlled drugs.

4.2.2 This policy applies to all schedules of controlled drugs – Refer to BHSCT Controlled Drugs Policy for further definition of controlled drug schedules

4.2.3 Concerns about incidents involving improper management or use of controlled drugs must be reported in line with this policy.

4.2.4 Healthcare professionals **are not permitted to** use stocks of medicines (including controlled drugs) on wards, departments or facilities for their personal use

4.2.5 BHSCT has a statutory duty of collaboration to share information about potential controlled drug offences and potential or actual system failures.

4.2.6 The Accountable Officer must provide the Chair of LIN with a quarterly occurrence report for the trust detailing concerns

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This policy is relevant to all trust employed staff that provide services within in-patient and community settings and facilities

- Prescribers (medical, dental and non-medical prescribers)
- Nursing and Midwifery staff
- Pharmacy staff
- Other healthcare staff
- Nursing and residential care home staff
- Domiciliary care staff
- Designated governance leads

The lead author should be notified if there are significant barriers to implementation of this policy.

5.2 Resources

Regulation 7 of The Controlled Drugs (Supervision of Management and Use) Regulations 2009 requires a designated body to provide its Accountable Officer with funds and other resources necessary to enable them to carry out their responsibilities as Accountable Officer.

The Dealing with discrepancies or concerns involving controlled drugs policy will be disseminated through the relevant service groups.

Awareness of the policy will be raised at the Update of Administration of Medicines and Nurse Induction programs.

The policy will be accessible via the intranet.

5.3 Exceptions

Applicable to all BHSCT staff and non-BHSCT staff contracted to provide services for BSHCT involving controlled drugs.

6.0 MONITORING

All errors and near misses involving controlled drugs will be reported in line with local reporting procedures and will include notification to Accountable Officer/Designated Officer or other as nominated.

7.0 EVIDENCE BASE / REFERENCES

1. BHSCT Medicines Code 2011
2. BHSCT Community Medicines Code 2013
3. BHSCT Controlled Drugs Policy – Inpatient Areas 2013
4. BHSCT Controlled Drugs Procedures – Inpatient Areas 2013
5. BHSCT Non-Medical Prescribing Policy 2013
6. BHSCT Community Controlled Drugs Policy 2015 (Draft)
7. DHSSPSNI Safer Management of Controlled Drugs: A guide to good practice in Secondary Care (Northern Ireland) 2012
8. DHSSPSNI Safer Management of Controlled Drugs: A guide to good practice in Primary Care (Northern Ireland) 2013
9. DHSSPSNI The Controlled Drugs (Supervision of Management and Use) Regulations (NI) 2009
10. DHSSPSNI Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Northern Ireland 2009

11. DHSSPSNI Managing and Sharing Concerns 2013
12. DHSSPSNI Safer Management of Controlled Drugs: A guide to strengthened governance arrangements in Northern Ireland 2013 (version 3)
13. DHSSPSNI The Misuse of Drugs Regulations (Northern Ireland) 2002
14. DHSSPSNI Misuse of Drugs (Safe Custody) Regulations 1973
15. NMC Standards for Medicines Management 2010
16. DOH Misuse of Drugs Act 1971
17. DOH The Health Act 2006
18. DOH The Human Medicines Regulations 2012

8.0 CONSULTATION PROCESS

D&T, Standards and Guidelines

9.0 APPENDICES / ATTACHMENTS

Appendix 1 - Controlled Drugs – Governance arrangements
Appendix 2 - Reporting **unresolved** discrepancies during working hours
Appendix 3 - Reporting **unresolved** discrepancies outside working hours
Appendix 4 - CD Accountable Officer process for dealing with suspected or confirmed unlawful activity

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. ☐

SIGNATORIES

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

Eimear McCusker

_____ Date: _____October 2015_____

Author

Cathy Jack

_____ Date: _____October 2015_____

Director

Appendix 1 Controlled Drugs – Governance arrangements

1.0 Systems for the Safe and Secure handling of controlled drugs

The Belfast Trust management of controlled drugs policy covers many aspects of the safe and secure handling of controlled drugs. In addition more detail of the pharmacy processes relating to controlled drugs are covered by site pharmacy procedures. Together the processes cover all aspects of the controlled drug journey from procurement and supply through to administration and disposal.

The Accountable Officer (AO) for Belfast Trust is the Head of Pharmacy and Medicines Management.
Designated officers are the Deputy Heads of Pharmacy;

- Pharmacy Services Manager Royal Group of Hospitals and Mater
- Pharmacy Services Manager BCH, Musgrave, Knockbracken and Muckamore
- Pharmacy Services Manager – Production and Procurement

2.0 Dealing with discrepancies and concerns regarding controlled drugs

2.1 Investigating and reporting controlled drug incidents

2.1.1 Incidents relating to discrepancies

This refers to situations where the quantity of the controlled drug in stock (on a ward or in pharmacy) is different to the level recorded in the controlled drug register or, in the case of pharmacy, also different to that recorded on the JAC computerised stock system.

- It is important to be aware that a discrepancy can indicate misuse. All suspected controlled drug discrepancies must be investigated
- Any unresolved discrepancies during and outside working hours must be reported in line with appendix 1 (Reporting Unresolved Discrepancies During Working Hours) and appendix 2 (Reporting Unresolved Discrepancies Outside Working Hours)
- An unresolved discrepancy must be reported to the Head of Pharmacy or a Deputy Head of Pharmacy within one working day. All controlled drug related incidents and near misses must be reported in line with the Trust Adverse Incident Reporting and management policy

2.1.2 Other incidents (not relating to discrepancies)

All controlled drug related incidents and near misses must be reported in

line with the Trust Adverse Incident Reporting and management policy.

When the Trust Adverse Incident Reporting and management policy is followed, the Accountable Officer for controlled drugs (Head of Pharmacy and Medicines Management) is made aware of all red and orange incidents involving controlled drugs. Refer to appendix 3 (CD Accountable Officer process for dealing with suspected or confirmed unlawful activity) for details of the subsequent process which the Accountable Officer for controlled drugs will follow in the event of being notified of any issues relating to suspected or confirmed unlawful activity.

2.2 Raising and dealing with concerns relating to controlled drugs

- Concerns may occur which do not involve specific incidents or near misses but include healthcare matters, such as suspected mistreatment of patients and / or issues relating to the quality of care given, concerns about professional / clinical practice and concerns relating to the competence of staff.

- Concerns regarding increased or abnormal usage of controlled drugs may also be identified following a review of usage of drugs liable to misuse within that area.

- Any concerns must be reported to the Trust Accountable Officer for controlled drugs and any specific concerns relating to staff must also be reported either to the line manager or in line with the Trust Whistle blowing Policy.

- Refer to appendix 3 (CD Accountable Officer Process for Dealing with Suspected or Confirmed Unlawful Activity) for guidance.

2.3 Incident reviews

Incident reviews will be undertaken by individuals nominated by the Designated Officer or Accountable Officer for controlled drugs and a professional Lead for the area. Depending on the nature of the incident / near miss, it may be necessary to include a member of the police force. The Accountable Officer/Designated Officer for controlled drugs should contact the Police in order to determine if this is necessary and for advice regarding the preservation of evidence collected during an investigation which may be required at a later stage for proceedings instituted by police.

The incident review panel is responsible for investigating the incident and recommending actions. In order to ensure that there is clear separation between the investigation and decision making process, the Accountable Officer for controlled drugs will not be part of the incident review panel but will review the report and suggested actions as a result of the panel review and make the final decision regarding the outcome of the review. Findings and any final action taken, as decided by the Accountable Officer for controlled drugs, will be clearly

documented as part of the formal incident review paperwork. The Accountable Officer for controlled drugs must inform the Local Intelligence Network (LIN) of all incident reviews so that trends may be monitored.

Following the implementation of actions from an incident review, the Accountable Officer / Designated Officer for controlled drugs may chose to conduct informal / formal inspections. If this is the case, they must clearly document the findings from the inspection.

3.0 Information Sharing

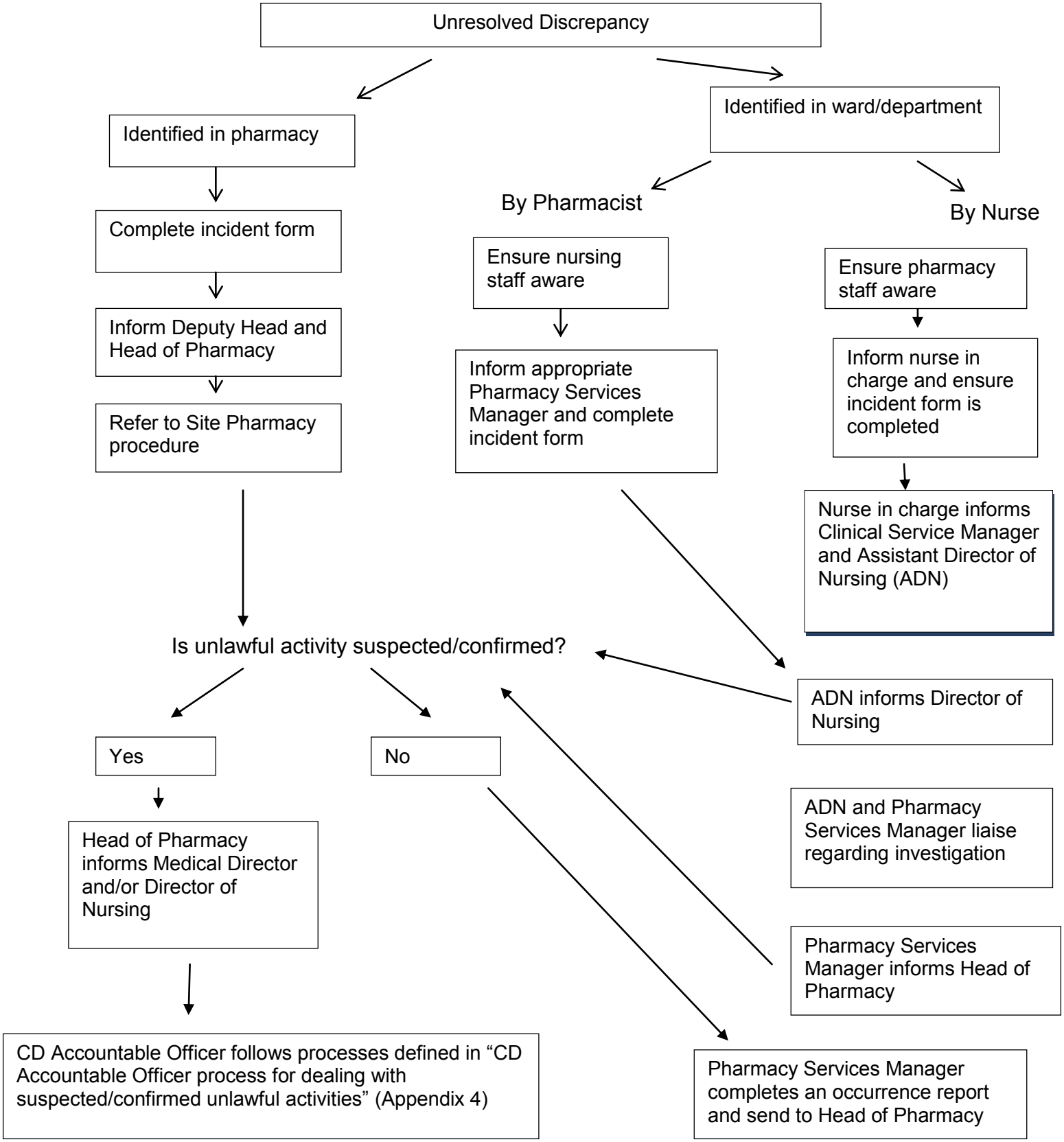
In line with The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 there is a statutory duty of collaboration on healthcare organisations, police forces, social services authorities and the relevant inspection and regulatory bodies. This is to enable information to be shared about potential controlled drug offences and potential or actual systems failures. The Accountable Officer for controlled drugs will ensure all information is shared, as required.
A combined Local Intelligence Network (LIN) for Northern Ireland has been established.

4.0 Closure of cases

Cases considered by the Accountable Officer should be recorded with a clear account of the findings and actions taken. This includes the outcome of any proceedings by the police, civil courts, regulatory body, and disciplinary proceedings as appropriate.

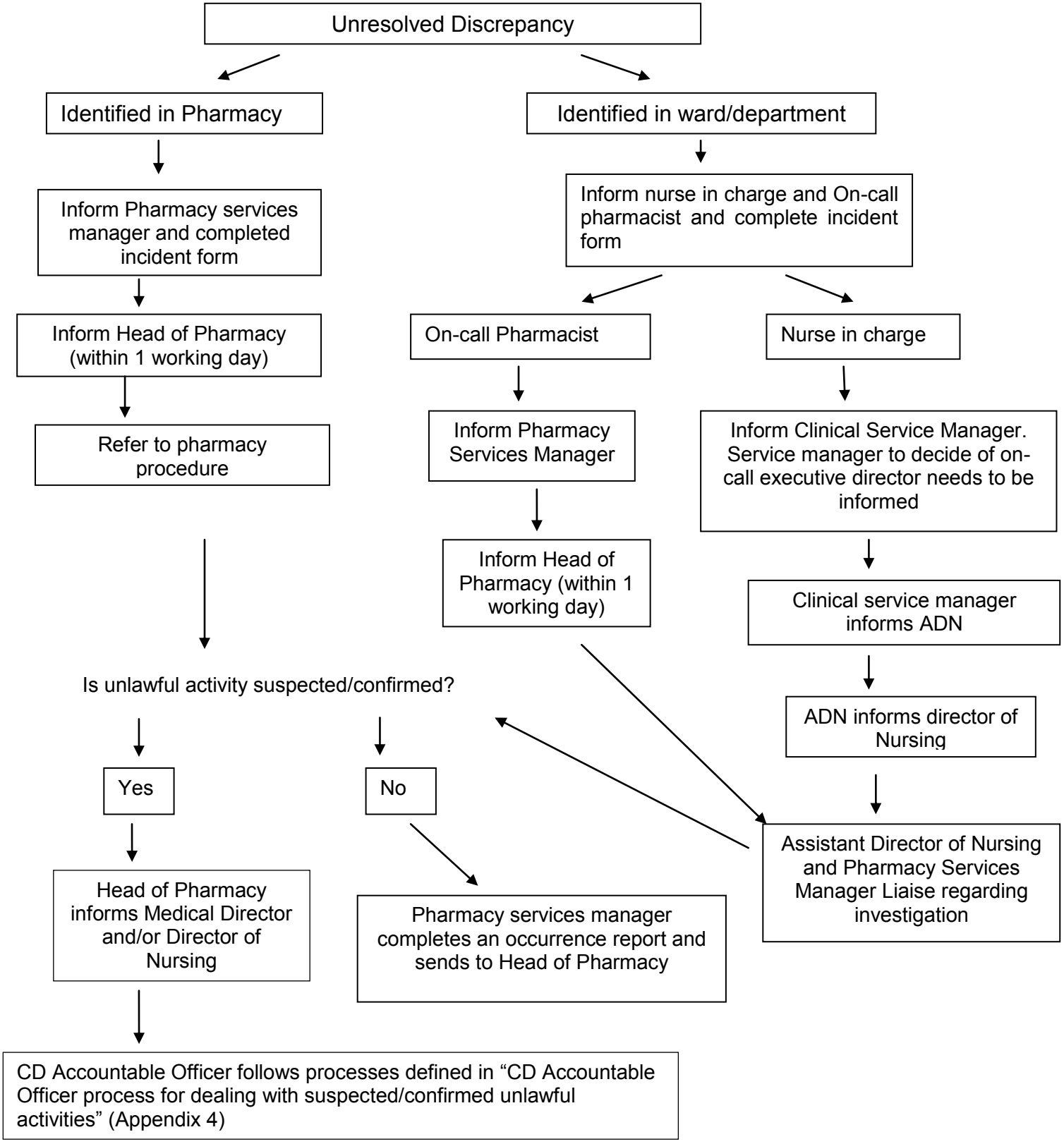
Appendix 2: Reporting **unresolved** discrepancies during working hours

When a discrepancy is identified, an investigation must be undertaken. If the discrepancy remains unresolved, the actions outline below must followed:



Appendix 3: Reporting **unresolved** discrepancies outside working hours

When a discrepancy is identified, an investigation must be undertaken in line with the Trust Medicine Code policy. If the discrepancy remains unresolved, the actions outlined below must be followed:



Appendix 4: CD Accountable Officer process for dealing with suspected or confirmed unlawful activity

This process must be followed in addition to the trust Adverse Incident Reporting and Management Policy

CD Accountable Officer to inform Medical director and/or Director of Nursing and/or Director of Social and Primary Care Services and vice versa

Obvious theft
(e.g. pharmacy dept broken into, theft by staff member)

Possible or likely theft of fraud

Red handed fraud
("caught in the act")

Ensure all investigations are completed and determine if further investigations are required*
Complete an incident form

CD Accountable Officer/Designated Officer
- Call CDLO
- Document crime reference number
- Contact Police Counter-fraud unit

CD Accountable Officer to inform relevant Trust Professional Lead

CD Accountable Officer to consider reporting to: relevant professional/regulatory body.
CD Accountable Officer to complete Occurrence report.
CD Accountable Officer to consider informing Chair of Local Intelligence Network

CD Accountable Officer to inform HR Manager

If staff work at another trust CD accountable officer to inform CD Accountable Officer of other Trust

If Healthcare Professional employed through agency, CD Accountable Officer to consider informing agency

*Consider
- Interviewing relevant staff & taking statements
- Ask staff if another member of staff has shown signs of substance misuse
- Introducing tighter security measures until investigation is completed, such as ensuring that the two CD keys are held by two separate members of staff, performing more frequent CD stock checks, fitting CCTV cameras
- Ask staff if access was given to drug stocks by staff other than the usual staff in that area
- Reviewing shift patterns for the day of the incident(shift patterns of surrounding days and when previous incidents have occurred should be reviewed to establish a link

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Reference No: SG 64/16

Title:	**Clinical monitoring of patients who have been prescribed controlled drugs**		
Author(s)	Aideen O'Kane, Lead Pharmacist Controlled Drugs. Eimear McCusker, Head of Pharmacy and Medicines Management.		
Ownership:	Jennifer Welsh, Director of Surgery and Specialist Services.		
Approval by:	Drugs and Therapeutics Standards and Guidelines Policy Committee Executive team Meeting	**Approval date:**	30/09/2016 28/09/2016 05/10/2016 19/10/2016
Operational Date:	November 2016	**Next Review:**	November 2021
Version No.	V1	**Supercedes**	
Key words:	Controlled drug, opioids, CD, clinical monitoring, prescribing, administration		
Links to other policies	BHSCT Controlled Drugs Policy – in-patient areas – 2013 BHSCT Controlled Drug Procedures: in-patient areas 2013 BHSCT Community Controlled Drugs Policy - 2015 See Appendix 2 for details of BHSCT policies, guidelines and guidance referencing controlled drugs		

Date	Version	Author	Comments
25/04/2016	0.1	A O'Kane	Initial Draft
08/06/2016	0.2	A O'Kane	Comments from E McCusker
23/09/2016	0.3	A O'Kane	Comments from D&T Committee – reference to NICE Guideline NG 46 Controlled drugs: safe use and management
23/09/2016	0.4	A O'Kane	Comments from J Tolan – clarification of pharmacy staff responsibilities

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

The purpose of the Clinical Monitoring of Controlled Drugs policy is to ensure there is appropriate monitoring and documentation of the use of controlled drugs within BHSCT.

Controlled Drugs (CDs) are subject to special legislative controls because there is potential for them to be abused or diverted causing possible harm. There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care.

The use of controlled drugs in medicine is permitted by the Misuse of Drugs Regulations: the current version came into operation in 2002 and is periodically revised and amended. The Misuse of Drug Regulations categorises controlled drugs into schedules, which dictate how their use should be regulated. The schedules balance therapeutic use with potential for harm through misuse or abuse.

Following the Shipman Inquiry there have been significant changes in both governance and legislation surrounding the use and management of controlled drugs. The 2006 Health Act introduced regulations to strengthen governance and monitoring arrangements for CDs. The regulations in Northern Ireland are known as The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. The regulations outline the statutory requirements of all healthcare organisations to appoint an Accountable Officer. The Accountable Officer must provide a forum for sharing of concerns, and be a member of the Local Intelligence Network. The regulations also created a power of entry and inspection by certain authorised persons to inspect stocks and records of controlled drugs.

The Accountable Officer for BHSCT is the Head of Pharmacy and Medicines Management.

Regulation 9 of the legislation states that the Accountable Officer must ensure there are standard operating procedures for the management and use of controlled drugs to include:

- Access
- Safe storage
- Security in relation to storage and transportation
- Record keeping
- Disposal of CDs
- Reporting and management of errors and incidents

In 2015 an amendment was made to Regulation 9 to include the requirement to have standard operating procedures for

- Prescribing, supply and administration of controlled drugs
- Clinical monitoring of patients prescribed controlled drugs

(See BHSCT Controlled Drug Procedures (SG01/11) for standard operating procedures of prescribing, supply and administration of controlled drugs).

In 2016 NICE published NG 46 Controlled drugs: safe use and management, the guideline offers best practice advice on the safe use and management of controlled drugs. The standard operating procedures within this policy reflect the practice advice in the NICE guideline.

1.2 Purpose

The purpose of the policy is to define the process and procedures for clinical monitoring of patients prescribed controlled drugs within BHSCT.

This policy outlines the legislative requirements of Regulation 9 of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 updated 2015.

This policy should be read in conjunction with;

BHSCT Controlled drugs policy: in-patient areas	SG 01/11
BHSCT Controlled drug procedures: in –patient areas	SG 01/11
BHSCT Community controlled drugs policy	SG 23/15
Any policy referencing controlled drugs see appendix 2	

1.3 Objectives

To ensure:

- To clearly identify the responsibilities of BHSCT and BHSCT registered staff
- Standard operating procedures are in place for clinical monitoring of patients prescribed controlled drugs
- To ensure standard operating procedures are in line with NICE Guideline NG 46 Controlled drugs: safe use and management

2.0 SCOPE OF THE POLICY

The clinical monitoring of patients who have been prescribed controlled drugs policy applies to;

2.1 Staff within BHSCT who have a role in prescribing controlled drugs (medical and non-medical prescribers) throughout in-patient, out-patient and community facilities including GP Out of hour's facilities.

2.2 Registered staff in BHSCT who have a role in administering controlled drugs

(registered nursing staff, registered operating department practitioners, and registered Allied Health Professionals), within in-patient, out-patient and community registered facilities as well as patient's homes.

2.3 BHSCT Pharmacy staff who have role in reviewing, monitoring, clinical checking prescriptions for controlled drugs at ward level and completing a professional screen on controlled drug prescriptions in pharmacy departments.

2.4 The policy does not apply to the ordering and supply processes of controlled drugs via controlled drug requisition, supplementary orders, or ward top-up supply to in-patient areas.

3.0 ROLES/RESPONSIBILITIES

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

3.2 Accountable Officer
The Accountable Officer (AO) for BHSCT is the Head of Pharmacy and Medicines Management. The AO is responsible for the safe and secure management and use of controlled drugs, this encompasses:

- Ensuring safe systems are in place for the management and use of controlled drugs
- Ensuring standard operating procedures in relation to controlled drug management are in use
- Monitoring and auditing the management systems
- Investigating concerns and incidents relating to controlled drugs

3.3 Prescribers (medical, dental and non-medical prescribers)
Prescribers must adhere to the standard operating procedure on clinical monitoring of patients prescribed controlled drugs – section 1

3.4 Nursing and Midwifery staff
Registered nursing and midwifery staff who administer controlled drugs must adhere to the standard operating procedure on clinical monitoring of patients prescribed controlled drugs – section 2

3.5 Pharmacy staff

3.5.1 Pharmacy staff who monitor and review controlled drug kardexes and prescriptions at ward level must adhere to the standard operating procedure on clinical monitoring of patients prescribed controlled drugs – section 3

3.5.2 Pharmacy staff who provide a professional screen of controlled drug prescriptions must adhere to the standard operating procedure on clinical monitoring of patients prescribed controlled drugs – section 4

3.6 Registered Operating Department Practitioners (ODPs) and registered Allied Health Professionals (AHPs)
Registered ODPs and AHPS who administer controlled drugs must adhere to the standard operating procedure on clinical monitoring of patients prescribed controlled drugs – section 2

4.0 KEY POLICY PRINCIPLES

4.1 Definitions

Controlled Drugs: Controlled Drugs are "dangerous or otherwise harmful drugs" which are subject to strict legal controls to prevent them being misused; being obtained illegally; or causing harm. The Misuse of Drugs Regulations includes five schedules that classifies all medicines and the associated legal controls.

Local Intelligence Network (LIN): A Local Intelligence Network (LIN) for Northern Ireland was established as per the legislative requirements of the Controlled Drugs (Supervision of management and Use) Regulations (Northern Ireland) 2009. This legislation imposed a statutory duty of collaboration on healthcare organisations, police forces, social services authorities and the relevant inspection and regulatory bodies. This enables information to be shared about potential controlled drug offences and potential or actual system failures.

Standard Operating Procedures (SOPs): Under the terms of the Health Act (2006) Standard Operating Procedures (SOPs) are required for any service that handles controlled drugs. SOPs describe in detail how controlled drugs are to be managed; this includes the clinical monitoring of patients prescribed controlled drugs.

4.1.1 **Key Policy Statement(s)**
The standard operating procedure is described in Appendix 1

Any new / reviewed BHSCT policies/ guidelines/ pathways which specifically relate to controlled drugs must refer to the standard operating procedure on the clinical monitoring of patients prescribed controlled drugs and indicate clinical monitoring requirements

4.2 Policy Principles

4.2.1 The Controlled Drugs (Supervision of Management and Use) Regulations 2009 and Amendments 2015 apply to all schedules to controlled drugs.

4.2.2 This policy applies to all schedules of controlled drugs – refer to BHSCT controlled drugs policy for further definition of controlled drug schedules.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This policy is relevant to registered trust staff with involvement in the clinical monitoring of patients prescribed controlled drugs defined as:

- Prescribing controlled drugs
- Administration of controlled drugs by BHSCT registered staff
- Pharmacist prescription monitoring and review of controlled drug prescriptions at ward level
- Pharmacist professional screen of controlled drug prescriptions at dispensary level
- Dispensing and issue of controlled drug prescriptions by pharmacy staff

The lead author should be notified if there are significant barriers to implementation of this policy.

5.2 Resources

The policy will be accessible via the intranet.
The policy will be disseminated through the relevant service groups.

5.3 Exceptions

This policy does not apply to residential care home staff, care staff in community facilities and domiciliary care staff involved in administering controlled drugs in patient's homes or community facilities.
The policy does not apply to the ordering and supply processes of controlled drugs via controlled drug requisition, supplementary orders, or ward top-up supply to in-patient areas.

6.0 MONITORING

All errors and near misses involving controlled drugs will be reported in line with local reporting procedures and will include notification to the Accountable Officer/designated Officer or other as nominated.

7.0 EVIDENCE BASE / REFERENCES

1. NICE Controlled drugs: safe use and management NG 46 2016
2. BHSCT Medicines Code 2011
3. BHSCT Community Medicines Code 2013
4. BHSCT Controlled Drugs Policy – Inpatient Areas 2013
5. BHSCT Controlled Drugs Procedures – Inpatient Areas 2013
6. BHSCT Dealing with Discrepancies or Concerns involving Controlled Drugs 2015
7. BHSCT Non-Medical Prescribing Policy 2013
8. BHSCT Northern Ireland Clinical Pharmacy Standards 2014
9. DOH The Health Act 2006

10. DHSSPSNI The Controlled Drugs (Supervision of Management and Use) Regulations (NI) 2009
11. DHSSPSNI The Controlled Drugs (Supervision of Management and Use) Regulations (NI) 2015
12. DHSSPSNI Safer Management of Controlled Drugs: A guide to Strengthened Governance Arrangements in Northern Ireland 2015 (V4)
13. DHSSPSNI Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Northern Ireland 2009
14. DHSSPSNI Safer Management of Controlled Drugs: A guide to good practice in Primary Care (Northern Ireland) 2013
15. DHSSPNI Safer Management of Controlled Drugs: A guide to good practice in Secondary Care (Northern Ireland) 2012
16. DHSSPSNI The Misuse of Drugs Regulations (Northern Ireland) 2002
17. NMC Standards for Medicines Management 2010

8.0 CONSULTATION PROCESS

Version 0.1 circulated to Pharmacy Executive team for comments.
Version 0.2 circulates to Drugs and Therapeutics Committee

9.0 APPENDICES / ATTACHMENTS

Appendix 1 – Standard Operating Procedure – Clinical Monitoring of patients prescribed controlled drugs
Appendix 2 – BHSCT polices and guidance referencing controlled drugs
Appendix 3 – HSCB Accountable Officer letter to Accountable Officers – March 2016

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. ☐

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

_____ Date: _____November 2016____
Author

_____ Date: _____November 2016_____
Director

Appendix 1: Standard operating procedure for clinical monitoring of patients who have prescribed controlled drugs

1.0 Prescribing Controlled Drugs

1.1 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) when making a decision to prescribe controlled drugs should consider the following

- The benefits of controlled drug treatment
- The effect of prescribing on other co-morbidities
- Potential drug interactions or contraindications
- The risks of prescribing, including dependency, overdose and diversion
- All prescribed and non-prescribed medicines the patient is taking (particularly any centrally acting agents) and whether the patient is opioid naive
- Consult evidence based sources e.g. relevant BHSCT policies, guidelines, care pathways, BNF (British National Formulary), NI Formulary for product selection and dosing information

1.2 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) must adhere to BHSCT controlled drug procedures CDSOP A4 and CDSOP A9 when prescribing for in-patients. When prescribing for patients in out of hours settings, community registered facilities and in patient's homes prescribers should refer to guidance in BHSCT community controlled drugs policy.

1.3 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) when prescribing controlled drugs should be aware of safety alerts pertaining to controlled drugs including:

- NPSA RRR011 reducing risk of overdose with midazolam injection in adults
- NPSA SPN012 Ensuring safer practice with high dose ampoules of diamorphine and morphine
- HSCB Medicines Safety advice letters: Transdermal Fentanyl patches, risks with buccal midazolam, prescribing and dispensing controlled drugs

1.4 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) when prescribing controlled drugs that are opioids should be aware of the NPSA RRR005 Reducing dosing errors with opioid medicines and should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medication prescribed for the patient
- 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)
- Check the usual starting dose, frequency of administration. Standard

dosing increments, symptoms of overdose and common side effects

1.5 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) should follow protocols in BHSCT policies which reference controlled drugs. See appendix 2 for current list of policies and guidance.

1.6 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) should:

- Document clearly the indication and regimen for the controlled drug on the patient's in-patient prescription and administration record or care record as appropriate, this includes any trust approved supplementary charts
- Assess and review the patient's current clinical needs and if appropriate adjust the dose of the controlled drug
- Discuss with the patient the arrangements for reviewing and monitoring treatment with controlled drugs
- Discuss the prescribing decision with other health professionals if further information is requested about the controlled drug prescription

1.7 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) when prescribing controlled drugs should review and document any monitoring requirements in relation to the prescription, e.g. frequency of patient observations including but not limited to:

- Pain scores
- Nausea scores
- Sedation scores
- Respiratory rate
- Oxygen saturation rate
- Blood pressure

1.8 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) when prescribing controlled drugs for in-patients that are to be administered by different routes must prescribe each drug as a separate prescription and clearly state when the drugs are to be given to avoid administration errors.

1.9 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) should document and provide information to the patient taking the controlled drug or the health professional/ carer administering the controlled drug. This should include:

- The reason for the prescription
- How long the patient is expected to be prescribed the drug
- How long the controlled drug will take to work
- If appropriate how to take sustained release and immediate release preparations of controlled drugs if they are prescribed together
- How it may affect the patient's ability to drive or operate machinery; it is important to highlight legislation on drugs and driving and direct

patients to read the “patient information leaflet” (PIL) for additional advice
- The controlled drug is to be used only by the patient it is prescribed for

1.10 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) when prescribing “when required” controlled drugs should:
- Document clear instructions on the inpatient prescription and administration record or patient notes
- Include dosage instructions on the prescription (with the maximum daily amount or frequency of doses)
- If prescribing at discharge or in an outpatient or out of hours setting ask about and take into account any existing supplies the person has of “when required” controlled drugs

1.11 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) should inform patients that they or their representative may need to show identification when they collect controlled drug prescriptions from pharmacy.

1.12 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) when reviewing or changing controlled drug prescriptions should follow BHSCT guidance and NI formulary guidance and take into account the:
- Appropriate route
- Dose (including when dose conversions or dose equivalence are needed)
- Formulation (including changes to formulations)

If guidance on prescribing is not followed the reasons should be documented in the patient’s clinical record.

1.13 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) should use the regional guidance on “Approximate equivalent doses of opioid analgesics for adults”, when prescribing, reviewing or changing opioid prescriptions to ensure that the total opioid load is considered.

1.14 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) when prescribing controlled drugs e.g. in out of hours settings should inform the patient’s GP of all prescribing decisions and record this information in the patient’s clinical record so that the GP has access to it.

1.15 BHSCT Prescribers (medical, dental, non-medical independent prescribers and non-medical supplementary prescribers) must report any adverse incident involving the prescribing of a controlled drug on the trust datix incident recording system.

2.0 Administration of controlled drugs by registered BHSCT staff

2.1 BHSCT registered staff administering controlled drugs to in-patients must follow BHSCT Controlled Drug procedures CDSOPA 8 and CDSOP A9.

2.2 BHSCT registered staff administering controlled drugs to patients in their own homes or registered facilities must follow procedures outlined in BHSCT Community Controlled Drugs policy.

2.3 BHSCT registered staff when administering controlled drugs should check with the prescriber if they have concerns about the controlled drug prescription including:

- if the prescribed dose is safe for the patients
- Whether other formulations have already been prescribed for the patient
- Whether the formulation is appropriate
- That any past doses prescribed have been taken

2.4 BHSCT registered staff when administering a controlled drug should be aware of the patient's written monitoring plan that specifies which physiological observations should be recorded and how often. *(See BHSCT policy for measuring and recording physiological observations SG 07/09.)*

2.5 BHSCT registered staff when administering a controlled drug that is an opioid should be aware of the NPSA RRR005 Reducing dosing errors with opioid medicines and should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medication prescribed for the patient
- 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)
- Check the usual starting dose, frequency of administration. Standard dosing increments, symptoms of overdose and common side effects

2.6 BHSCT registered staff when administering a controlled drug must follow the principles of administration of medicines in the BHSCT Medicine Codes (Acute and Community) and BHSCT controlled drug policies and procedures for in-patients and BHSCT community controlled drug policy.

2.8 BHSCT registered staff must provide advice to patients on how different formulations of controlled drugs are administered and check that the patient understands the advice.

2.9 BHSCT registered staff must ensure that the appropriate equipment is available so that the correct dose of controlled drug may be administered.

2.10 BHSCT registered staff must report any adverse incident involving the administration of a controlled drug on the trust datix incident recording system.

3.0 Clinical check of controlled drug in-patient kardexes and discharge prescriptions by clinical pharmacy staff

3.1 BHSCT clinical pharmacists must follow procedures outlined in the Northern Ireland Clinical Pharmacy standards in relation to monitoring and reviewing prescriptions for patients prescribed controlled drugs.

3.2 BHSCT clinical pharmacists must check with the prescriber if there any safety concerns with the controlled drug prescription, e.g. if the prescribed dose in safe for the patient.

3.3 BHSCT clinical pharmacists when reviewing prescriptions or in-patient kardexes for controlled drugs that are opioids should be aware of the NPSA RRR005 Reducing dosing errors with opioid medicines and should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medication prescribed for the patient
- 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)
- Check the usual starting dose, frequency of administration. Standard dosing increments, symptoms of overdose and common side effects

3.4 BHSCT clinical pharmacists should report any adverse incident involving the prescribing, administration or monitoring of a controlled drug on the trust datix incident recording system.

4.0 Supply of controlled drug prescriptions by pharmacy staff

4.1 BHSCT Pharmacists must follow the “Guideline on the completion of the professional screen of prescriptions within BHSCT dispensaries.”

4.2 BHSCT Pharmacy staff must follow departmental standard operating procedures on dispensing and checking controlled drugs prescriptions.

4.3 BHSCT pharmacy staff must check with the prescriber if there are any safety concerns with the controlled drug prescription, e.g. if the prescribed dose is safe for the patient.

Appendix 2: BHSCT polices and guidance referencing controlled drugs

1. Approximate equivalent doses of opioid analgesics for adults policy. February 2015 SG25/09
2. Epidural analgesia for adult patient's policy. August 2011 SG 19/08
3. Patient controlled analgesia and Nurse controlled analgesia in children (0-16 years) in RBHSC policy. February 2016 – SG19/16
4. Prescribing opioids in palliative care: BHSCT Supportive and Palliative care team. May 2015
5. Clinical guideline for the management and care of children (0-16 years) with epidural analgesia in the post-operative setting. December 2014 SG55/09
6. Epidural analgesia during labour – midwifery care of women policy. August 2010 SG200/10
7. Prescribing and supply information: Prescribing alfentanil in palliative care. December 2010
8. Prescribing and supply information: prescribing hydromorphone in palliative care. September 2013
9. Guidelines for the use of intranasal diamorphine in children for pain relief. March 2014
10. Sustained release morphine – first line choice of strong opioid in primary and secondary care in non-specialist settings. HSCB November 13
11. Management of patient controlled analgesia in adult patients. January 2010
12. Guidance on the administration of medications in peri-operative adult patients: elective surgery. October 2015 SG13/15
13. Remifentanil: administration of remifentanil patient controlled analgesia in labour ward. February 2011
14. Post-operative analgesia with intrathecal opioids for adult non-obstetric patients. April 2016 SG27/16
15. A guide for foundation year one doctors (2015-2016) V7

Appendix 3 – Correspondence from HSCB Accountable Officer

Health and Social Care Board

Directorate of Integrated Care
12-22 Linenhall Street
Belfast
BT2 8BS

Tel : 028 90553782
Fax : 028 90553622
Web Site:
www.hscboard.hscni.net

Sent by Email

To all Accountable Officers

18th March 2016

Dear Colleague

RE: Review of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 – scoping exercise to changes in AO responsibilities regarding clinical issues

Following the LIN meeting of 3rd March 2016, members endorsed the enclosed document which I developed to assist Accountable Officers with the changes in their responsibilities regarding the clinical monitoring of controlled drugs.

I had asked at the meeting that if anyone had any further comments to make that they should be submitted to me by 12th March. No additional comments were received.

Therefore, I would ask you to now to review this document and to implement it accordingly in relation to your respective organisation.

Yours sincerely

Joe Brogan
Assistant Director of Integrated Care
Head of Pharmacy and Medicines Management
Accountable Officer for Controlled Drugs, HSCB

cc. Responsible Bodies

Clinical Monitoring of Controlled Drugs

Background

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 require organisations to have in place adequate and up to date standard operating procedures covering:

- Who has access to the controlled drugs;
- Where the controlled drugs are stored;
- Security in relation to the storage and transportation of controlled drugs;
- Disposal and destruction of controlled drugs;
- Who is to be alerted if complications arise; and
- Record keeping, including:
  - Maintaining relevant controlled drugs registers and
  - Maintaining a record of Schedule 2 controlled drugs that have been returned by patients.

The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015[1] came into operation on 16 July 2015 and require procedures to now also include, best practice relating to:

- the prescribing, supply and administration of controlled drugs, and
- clinical monitoring of patients who have been prescribed controlled drugs.

This paper provides guidance to organisations regarding requirements for clinical monitoring of patients who have been prescribed controlled drugs.

Processes already in place to comply with the amended Regulations

Organisations across Northern Ireland have a range of procedures in place for managing controlled drugs which include aspects of clinical monitoring of patients prescribed controlled drugs. It is important that procedures are reviewed to incorporate the clinical monitoring requirements outlined below.

Clinical monitoring of patients who have been prescribed controlled drugs

The following points should be included within procedures for clinical monitoring of all patients prescribed controlled drugs:

- Who is responsible for carrying out the monitoring and within what timescales

- What should be monitored (and how). Examples of this include:

  - therapeutic benefit

  - dosage and compliance
  - effects of dose increases/medication changes
  - response in relation to treatment plan
  - adverse effects/toxicity
  - effect on driving/operating machinery
  - long term risks eg addiction
  - effects of other co-morbidities eg ckd
  - drug interactions/contraindications
  - continued appropriateness

- Action to be taken where necessary including where there are concerns

- Patient education including risks

- Clinical records of monitoring activity

- Reporting of adverse incidents for shared learning

A range of guidance documents is available to support the development of best practice clinical monitoring procedures. *See Appendix 1*.

Action

1. Review the guidance documents in Appendix 1 below as appropriate.

2. Develop your procedures for the clinical monitoring of all patients prescribed controlled drugs, ensuring that these procedures include the items above.

3. Keep these procedures under review, specifically with reference to changes to any of the guidance documents.

1. http://www.legislation.gov.uk/nisr/2015/278/contents/made

Appendix 1

The following guidance should be referred to where relevant in the development of best practice clinical monitoring procedures. (Note: this list is not exhaustive).

Regional Guidance

- Northern Ireland Guidelines on Converting Opioid Analgesics for adult use
- Reducing dosage errors with opioid medicines - incomplete cross tolerance - letter to GPs
- Guidance for the Management of Symptoms in Adults in the Last Days of Life (Regional Palliative Medicines Group)
- GAIN: General Palliative Care Guidelines for the Management of Pain at the End of Life in Adult Patients
- Primary and Secondary Care Opioid Substitute Treatment Guidelines
- Morphine first line strong opioid
- Opioids in Chronic Pain

HSCB Guidance

- Medication Review Guidance for Primary Care Prescribers
- Medicines Safety Advice Letters: Transdermal Fentanyl Patches, Risks with Buccal Midazolam, Prescribing and Dispensing Controlled Drugs
  http://www.medicinesgovernance.hscni.net/primary-care/medicines-safety-advice-letters/

National Patient Safety Agency (NPSA) Guidance

- NPSA RRR: Reducing risk of overdose with Midazolam
- NPSA RRR: Reducing dosing errors with opioid medicines
- NPSA Safer Practice Notice: High strength Morphine and Diamorphine

Other

- British National Formulary
- Product Summary of Product Characteristics
- National Early Warning Scores https://www.rcplondon.ac.uk/projects/outputs/national-early-warning-score-news
- British Pain Society Guidance https://www.britishpainsociety.org/british-pain-society-publications/professional-publications/
  The British Pain Society aims to produce up-to-date guidance, supported by available evidence, on clinical and other pain matters, for patients and healthcare professionals.
- The Pain Toolkit http://www.paintoolkit.org/

It is expected that the following will be updated in due course with guidance in relation to clinical monitoring of CDs:

- HSCB Guidance for Developing CD Procedures for Primary Care Prescribers

- DHSSPS Guidance for the Safe Management and Use of Controlled Drugs in Primary Care
- DHSSPS Guidance for the Safe Management and Use of Controlled Drugs in Secondary Care

Belfast Health and Social Care Trust
caring supporting improving together

Reference No: SG 01/11

Title:	Controlled Drugs Policy – Inpatient Areas			
Author(s)	Aideen O'Kane, Lead Pharmacist, Controlled Drugs Julia Tolan, Deputy Head of Pharmacy, Pharmacy Services Manager			
Ownership:	Caroline Leonard, Director, Surgery and Specialist Services			
Approval by:	Drugs and Therapeutics Committee Standards and Guidelines Committee Policy Committee Executive Team Meeting		**Approval date:**	01/12/2017 24/01/2018 01/02/2018 16/03/2018
Operational Date:	February 2017		**Next Review:**	February 2022
Version No.	V3.0	**Supercedes**	V2-June 2013 -2016	
Key words:	Controlled drug, CD, accountable officer			
Links to other policies	BHSCT Controlled Drug Procedures Dealing with discrepancies or concerns involving controlled drugs (2015) BHSCT Medicines Code (2011) BHSCT Non-Medical prescribing Policy (2013) BHSCT Clinical monitoring of patients prescribed controlled drugs (2016) BHSCT Management of patients admitted to hospital who are on oral substitution therapy (Methadone, Subutex or Suboxone) (2017)			

Date	Version	Author	Comments
24/12/2012	1.1	J Tolan A O'Kane	Review and update of version 1.0
08/02/2013	1.2	J Tolan	Updated with comments from E McCusker, A O'Kane, S McNeill
14/02/2013	1.3	J Tolan	Appendices updated by A O'Kane
20/03/2013	1.4	J Tolan	CDSOPA appendix g reviewed and updated by A O'Kane following feedback from CD workshop
21/03/2013	1.5	J Tolan	Separate Policy from Standard Operating Procedures (SOPs) Amendments following policy review by Pharmacy and nursing workshop
28/03/2013	1.6	J Tolan	Inclusion of ADNs in roles/ responsibilities
12/04/2013	1.7	J Tolan	Amendment to cannabis (Sativex™) to part 1 of Schedule 4 but retained as BHSCT category A. Inclusion of the associated legislation in the list of references (updated in both Policy and

			Procedures).
23/04/2013	1.8	J Tolan	Procedures document: Correction to stated review dates of SOPs, relocation of midazolam advice on Pg 50 to Pg 47
23/06/2013	1.9	J Tolan	Updates with comments from Dr Robinson and J Flannagan at S&G
01/12/2015	1.10	A O'Kane	Updated to include 2 appendices
25/04/2016	2.1	A O'Kane	Policy review
17/10/2015	2.2	A O'Kane	Comments E McCusker
25/10/2016	2.3	A O'Kane	Update appendix 3 following comments from NIAS
22/12/2016	2.4	A O'Kane	Comments received from E McCusker and Drugs and Therapeutics Committee
04/07/2017	2.5	A O'Kane	Amendment to 3.1.5 and 13.4

Contents

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care. However, as a result of the actions of Harold Shipman, and the recommendations arising from the Shipman Inquiry, significant changes have been made in both governance and legislation surrounding the use and management of controlled drugs.

Controlled drugs (CDs) are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm.

The Misuse of Drugs Regulations 2001 define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities and lay down the conditions under which these activities may be carried out. Further information is provided in section 4.0.

The Health Act 2006 provided for regulations to be made relating to the strengthened governance and monitoring arrangements for CDs. The Health Act 2006 is primary legislation and applies to the whole of the UK. The Regulations developed under the Health Act may differ to some extent in the different administrations. The Northern Ireland legislation, The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation on 1st October 2009. These regulations were updated on 16th July 2015 and included the requirement for additional standard operating procedures relating to the use of controlled drugs.

The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2012 provide that Nurse and 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 is not permitted, except for the purpose of treating organic disease or injury.) Refer to the BHSCT non-medical prescribing policy for further information.

All healthcare organisations are accountable, through the Accountable Officer, for ensuring the safe management of CDs. **The Accountable Officer (AO) for controlled drugs for the BHSCT is the Head of**

1.2 Purpose

The purpose of this policy is to ensure the safe and effective use and management of controlled drugs in hospital in-patient sites within BHSCT and should be read in conjunction with:

BHSCT Controlled Drug Procedures	
BHSCT Dealing with discrepancies or concerns involving controlled drugs (2015)	SG 18/11
BHSCT Medicines Code and Policy	SG 09/11
BHSCT Non-Medical Prescribing Policy	SG 14/13
BHSCT Community controlled drugs policy	SG 23/15
BHSCT Clinical monitoring of patients prescribed controlled drugs	SG 64/16

This policy is for all staff working within BHSCT and aims, through the associated Controlled Drug Procedures document, to provide clear instructions for storing, supplying, transporting, prescribing, administering, recording, monitoring and disposing safely of controlled drugs in accordance with legislation, professional standards and best practice standards including:

- Misuse of Drugs Act 1971
- Misuse of Drugs Regulations (NI) 2002 and associated amendments
- The Controlled Drugs (Supervision of Management and Use) Regulations (NI) 2009 and associated amendments
- Safer Management of Controlled Drugs, A guide to Good Practice in Secondary Care (Northern Ireland) updated August 2012
- NMC Standards Medicines Management, August 2008 updated 2010

1.3 Objectives

To ensure:

1.3.1 Controlled drugs are used and managed safely and securely whilst ensuring patients have timely access to the medicines prescribed for them.

1.3.2 All staff involved in the use and management of controlled drugs are aware of their roles and responsibilities in relation to medicines management.

2.0 SCOPE OF THE POLICY

2.1 This policy applies to all BHSCT staff including medical, dental, nursing and midwifery staff, operating department practitioners, allied health professionals, non-medical prescribers (who prescribe controlled drugs) and pharmacy staff, involved in the use and/or management of controlled drugs. The policy applies to Independent Sector staff working within BHSCT in-patient facilities and to all staff contracted by the BHSCT who may be involved in the transport of controlled drugs or those trained and authorised to witness destruction of pharmacy stock.

2.2 The policy is primarily intended for BHSCT hospital in-patient facilities and hospital day case units.

2.3 The policy is not intended specifically to address clinical trials involving controlled drugs however the principles may be adopted in addition to legislation governing clinical trials.

3.0 ROLES/RESPONSIBILITIES

3.1 Chief Executive Officer

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

3.2 The Accountable Officer – Controlled Drugs

The BHSCT Accountable Officer (AO) for controlled drugs is the Head of Pharmacy and Medicines Management. The AO is responsible for all aspects of the safe and secure management of CDs in the BHSCT and is accountable to the Chief Executive in this regard. This includes:

- Ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigation of concerns and incidents related to controlled drugs and reports to BHSCT Medicines Optimisation Committee in this regard
- To ensure that members of staff who are involved in prescribing, supplying, administering, clinically monitoring or disposing of controlled drugs receive appropriate training to enable them to carry out their duties
- Attendance at the Northern Ireland Local Intelligence Network (LIN) and to submit quarterly occurrence reports identify concerns and incidents relating to controlled drug management in BHSCT and annual declaration and self-assessment

3.3 All Staff

All staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in this policy, and the associated controlled drug procedures and standard operating procedures (SOPs) and the BHSCT policy for dealing with discrepancies or concerns involving controlled drugs (SG18/11).

3.4 Nursing and midwifery staff

3.4.1 All nursing and midwifery staff

- Adherence to BHSCT policy for management of controlled drugs and the standard operating procedures (SOPs) contained within the BHSCT controlled drugs procedures document
- Adherence to professional standards as outlined in NMC Standards for Medicines Management

3.4.2 The registered nurse or midwife, **on duty and in charge**, is responsible:

- For the controlled drug key which should be held on their person
- For keeping the Controlled Drug Record Book (CDRB) up to date, accurate, in good order and compliant with the Trust controlled drug SOPs
- For ensuring the stock balance of all controlled drugs entered in the CDRB, are checked and reconciled in accordance with the relevant Trust controlled drug SOPs
- For ensuring that all records of patients own controlled drugs and discharge prescriptions containing controlled drugs are entered in the CD POD register and that stock balances are checked and reconciled in accordance with relevant trust controlled drug SOPs

3.4.3 The ward sister/charge nurse, as well as team leads and nurse or midwife in charge of a ward or department is responsible for:

- **The safe and appropriate management of controlled drugs in that area**
- Ensuring that staff comply with the Trust systems and that procedures are in place for the management of controlled drugs within their area of responsibility
- Ensuring stock levels of controlled drug preparations held in wards, departments and facilities match what is routinely used in that clinical area
- Ensuring that a robust audit trail exists for patients own CDs brought into hospital on admission or supplied at discharge
- Ensuring compliance with pharmacy quarterly CD check and where actions are identified, ensure implementation
- Ensuring that their staff, especially new employees, locum staff and agency staff, have access to and adhere to this policy and associated procedures
- The completion of quarterly observational audits of practice

3.4.4 The Ward Sister/Charge Nurse (theatre, day procedure units and recovery areas) in charge of a department, where operating department practitioners are working, are responsible for and:

- Must ensure that any ODPs working within their theatre or recovery

area are registered with the Health and Care Professions Council (HCPC)

- Must ensure that ODPs have access to and adhere to the BHSCT controlled drugs policy and associated procedures
- Must ensure that ODPs have access to and adhere to the BHSCT (Acute) Medicines Code policy
- Should complete quarterly observational audits of controlled drug practice as outlined in the BHSCT CD policy, this should include both registered nurses/midwifes and ODPs

3.4.5 Associate Directors of Nursing (ADNs)
Support Co-Directors in monitoring and ensuring compliance at quarterly CD checks.

3.5 Operating Department Practitioners

3.5.1 All Operating Department Practitioner (ODPs) staff:

- Must be registered with the HCPC
- Must adhere to HCPC Standards of Proficiency for Operating Department Practitioners

3.5.2 The registered Operating Department Practitioner on duty may be assigned responsibility for **the safe and appropriate management of controlled drugs in that area including:**

- The controlled drug key, which should be held on their person
- Keeping the Controlled Drug Record Book (CDRB) up to date, accurate, in good order and compliant with the trust controlled drug standard operating procedures (SOPs)
- Ordering controlled drugs on trust approved controlled drug stationery
  Ensuring the stock balance of all controlled drugs entered in the CDRB are checked and reconciled each time a controlled drug is required and at each change of shift in accordance with trust controlled drug procedures
- Ensuring stock levels of controlled drug preparations held in wards, and theatres match what is routinely used in that clinical area

3.6 Prescriber (medical, dental and non-medical prescribers)
Responsibilities of Trust prescribers (medical, dental and non-medical prescribers) are:

- Adherence to the BHSCT policy for management of controlled drugs and the associated controlled drug procedures
- Compliance with controlled drug prescription writing requirements as described in the British National Formulary and BHSCT controlled drug SOPs
- To avoid creating dependence by introducing drugs to patients without sufficient reason and to avoid being used as an unwitting source of supply for addicts
- Medical staff, including FY1s, are only permitted to prescribe

medicines, including CDs, as part of their required duties in their post and should not prescribe for private patients or their own use

- Non-medical independent prescribers - to prescribe within their competence, administer, or direct anyone to administer a limited range of controlled drugs solely for specified medical conditions (see latest edition of the British National Formulary). See also BHSCT non-medical prescribing policy
- Supplementary prescribers – to act under and in accordance with the terms of an agreed individual clinical management plan (CMP). To prescribe and administer and/or supply or direct any person to administer any controlled drug provided that the controlled drug is included in the CMP
- To prescribe in accordance with NI Formulary

3.7 Pharmacy Staff

- The Head of Pharmacy and Medicines Management through the Pharmacy Services Managers and the Pharmacy Procurement and Production lead is responsible for the safe and appropriate management of controlled drugs in BHSCT pharmacy sites
- Pharmacy department Standard Operating Procedures are developed and maintained and cover each of the aspects of the safe management of controlled drugs including ordering, receipt, safe custody, record-keeping, auditing, issuing of stock, dispensing prescriptions, transporting of supplies, and destruction of unwanted drugs. Pharmacy SOPs should be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived. SOPs should be approved by the AO or by the person to whom he has delegated this task
- All relevant pharmacy staff must be trained in the pharmacy department SOPs and must adhere to the SOPs
- Pharmacy stocks of controlled drugs must be checked and reconciled each month by a competent person and recorded indelibly in the Pharmacy CD register(s)
- Quarterly controlled drug checks at ward levels are a mandatory requirement and must be completed by the designated member of pharmacy staff within each 3 monthly reporting period

3.8 Controlled drug messengers (e.g. nursing auxiliaries, ward housekeepers, student nurses or student midwives, porters or drivers or taxi drivers)

The person who conveys the controlled drug acts as a messenger, that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container.

Responsibilities of the CD messenger include:

- Ensure the destination known, be aware of safe storage and security, the importance of handing over the intact and sealed container to an authorised person and obtaining a signature for delivery
- Must have a valid ID badge (e.g. BHSCT photographic ID, valid

university ID, taxi photographic ID)
- Ensure whereby an attempt to make a delivery is unsuccessful, the intact container is returned to the collection point and that a signature is obtained to verify return of delivery

3.9 Independent Sector (IS) activity on trust premises

An Independent Sector (IS) company is responsible for ensuring that IS staff are familiar with key BHSCT medicines management policies, e.g. Medicines Code, Controlled Drugs policy and Controlled Drugs Procedures. IS staff must operate in accordance with the BHSCT Medicines Code, BHSCT Controlled Drugs policy and other policies relevant to the areas of practice. IS registered nursing staff must comply with NMC Medicines management guidelines.

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 controlled drug stock check must be completed in the theatre/ward area before commencing activity and when the activity is completed.

IS prescribers must prescribe in accordance with the NI Formulary

3.10 Designated Governance Leads

Designated governance leads trained and authorised by DHSSPSNI are responsible for witnessing the destruction of pharmacy-held stock of obsolete, expired or unwanted Schedule 2 controlled drugs and associated record keeping in accordance with pharmacy SOPs.

3.11 Co-Directors

Co-Directors are responsible for ensuring compliance with quarterly CD checks and that any actions / recommendations from quarterly CD checks are completed within 4 weeks of completion of the check.

4.0 KEY POLICY PRINCIPLES

4.1 Definitions

Controlled Drugs: Controlled drugs are “dangerous or otherwise harmful drugs” as controlled by the Misuse of Drugs Act 1971. The Misuse of Drugs Regulations 2001 define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities and lay down the conditions under which these activities may be carried out. Controlled drugs are divided into five schedules each specifying the minimum requirements governing such activities as import, export, production, supply, possession, prescribing, storage and record keeping which apply to them. Table 1 provides examples of controlled drug by schedule.

Table 1: Examples of Controlled drugs by Schedule

Schedule	Description of Schedule as per Misuse of Drugs Regulations 2002 (NI) and associated amendments
1	Drugs such as cannabis and lysergide. Possession and supply are prohibited except in accordance with Home Office authority.
2	Drugs such as diamorphine, morphine, remifentanil, pethidine, **Ketamine**, secobarbital, glutethimide, amfetamine, and cocaine. Schedule 2 CDs are subject to the full controlled drug requirements relating to prescriptions, safe custody (except for secobarbital); the need to keep registers, etc. (unless exempted in Schedule 5).
3	Includes the barbiturates (except secobarbital), buprenorphine, diethylpropion, mazindol, **midazolam**, pentazocine, phentermine, temazepam and **tramadol.** They are subject to the special prescription requirements but not to the safe custody requirements (except for buprenorphine, diethylpropion, and temazepam) nor to the need to keep registers (although there are requirements for the retention of invoices for 2 years).
4	Includes in Part I benzodiazepines (except temazepam and midazolam, which are in Schedule 3) and zolpidem, zopiclone and zaleplon, which are subject to minimal control. Part II includes androgenic and anabolic steroids, clenbuterol, chorionic gonadotrophin (HCG), non-human chorionic gonadotrophin, somatotropin, somatrem, and somatropin. CD prescription requirements do not apply and Schedule 4 CDs are not subject to safe custody requirements.
5	Includes those preparations which, because of their strength, are exempt from virtually all controlled drug requirements other than retention of invoices for two years e.g. co-codamol 8/500

A summary of the BHSCT categorisation of controlled drugs and their management and examples of Controlled Drugs held in stock in BHSCT hospital sites are included in Appendix 1 & 2.

Controlled Drug Standard Operating Procedures (SOPs) are contained within BHSCT Controlled Drug Procedures Document.

The BHSCT management of controlled drugs in relation to prescribing, storage and record keeping may exceed the Misuse of Drugs Regulations or non-CDs may be managed in the same way as CDs. This is to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

4.2 Key Policy Statement(s)

4.2.1 All controlled drugs in BHSCT must be used/managed in accordance with this policy, the Trust controlled drug procedures and the BHSCT Medicines Code whilst ensuring patients have timely access to the medicines prescribed for them.

4.2.2 BHSCT categorises controlled drugs, including high risk medicines, into three categories with guidance on handling, storage, administration and returns procedures provided for each category.

4.2.3 The prescribing, ordering and usage patterns for controlled drugs will be monitored in accordance with the Health Act 2006 and under the Controlled Drugs (Supervision of Management and Use) Regulations 2009.

4.2.4 Standard Operating Procedures (SOPs) cover the management of the BHSCT categories of controlled drugs within hospital in-patient facilities and ensure compliance with the current legal requirements for controlled drugs and best practice guidance for high risk medicines. Any local deviations from the SOPs must be documented and approved by a Pharmacy Services Manager.

4.2.5 Each ward or department which may use or store controlled drugs must have a printed and signed copy of each SOP available on the ward.

4.2.6 BHSCT management of controlled drugs in relation to prescribing, storage and record keeping may exceed the Misuse of Drugs Regulations. This is to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

4.2.7 Certain high risk medicines are ordered, stored or recorded as controlled drugs to ensure a higher level of governance and risk management.

4.2.8 Healthcare professionals authorised to prescribe, administer or manage controlled drugs must do so in accordance with professional standards of practice, relevant legislation, this controlled drugs policy and associated Standard Operating Procedures.

4.2.9 All medicines including controlled drugs available in BHSCT are for use only for patients within BHSCT.

Healthcare professionals are not permitted to use stocks of medicines on wards, departments or facilities for their personal use.

4.2.10 **Independent Sector** staff must operate in accordance with the BHSCT Medicines Code, BHSCT Controlled drugs policy and other policies relevant to the areas of practice. Independent Sector registered nursing staff must comply with NMC Medicines management guidelines.

4.2.11 A clear audit trail exists for the movement and use of all CDs. At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties.

4.2.12 Controlled drugs (ALL BHSCT CD categories) **MUST NOT** be supplied

from one ward/dept. to another ward/dept. A controlled drug may be transferred only (when attached to a patient) when a patient receiving a controlled drug by means of a syringe, infusion, epidural or transdermal patch is transferred to another ward/dept. Patients own controlled drugs (admission or discharge supplies) may be transferred with a patient to another ward/dept.

4.2.13 BHSCT Medicine prescription and in-patient administration records must comply with regulation 15 of Misuse of Drugs Regulations if controlled drugs are administered from supplies prescribed and dispensed for individual patients (rather than from items ordered as ward stock).

4.2.14 Controlled drugs **MUST NOT** be administered following only a verbal order even if in the presence of a doctor.

4.2.15 Processes are in place to protect the security of the stock of controlled drugs held in the ward or department and to ensure that stocks of CDs correspond with the details shown in the controlled drug record book.

4.2.16 There should be a separate CDRB for each CD cabinet where the CD cabinets are in separate ward/dept. or separate rooms within a ward/dept.

4.2.17 Wards or departments with automated controlled drugs cabinets must adhere to the principles of this policy as well as pharmacy approved standard operating procedures for the use of the automated controlled drugs cabinet.

4.2.18 Access to controlled drugs is restricted to appropriate, designated and legally authorised personnel.

4.2.19 Parents or carers of in-patients must not be involved in the administration of controlled drugs at ward level.

4.2.20 The use of controlled drugs is audited and action taken as necessary.

4.2.21 BHSCT controlled drug discharge prescriptions not issued directly to patients and which are collected by patient representatives or others at ward/ department level may be subject to an identification check of the person collecting discharge prescription. The request for identification and verification of relationship of person collecting controlled drug prescription will be recorded in the CD POD register. A signature of receipt of the controlled drug prescription may also be requested.

4.2.22 BHSCT controlled drug discharge prescriptions not issued directly to patients but instead delivered to the patient's residence by a trust driver or taxi driver will be subject to the provision of photographic ID by the driver. A record of the taxi licence will be recorded in the CD POD register. The driver must be informed to return the prescription to the ward in the event of delivery failure.

4.3 Policy Principles

4.3.1 BHSCT categorises controlled drugs into three categories with guidance in handling, storage, returns procedures etc. provided for each category. Refer to Appendix 1 and 2.

4.3.2 Standard Operating Procedures cover the management of controlled drugs in each category and are contained within the BHSCT Controlled Drug Procedures document. SOPs:

4.3.2.1 CD Standard Operating Procedure A (CDSOPA): Management of schedule 2 and certain schedule 3 and 5 Controlled Drugs and controlled high risk Medicines

4.3.2.2 CD Standard Operating Procedure B (CDSOPB): Management of Schedule 3 CDs (excluding Temazepam, diethylpropion, buprenorphine and Flunitrazepam)

4.3.2.3 CD Standard Operating Procedure C (CDSOPC): Management of Schedule 4 and 5 CDs excluding those specified within CDSOPA

4.3.3 The Standard Operating Procedures cover, either in detail or summary format, the following activities:

- Storage of Controlled Drugs
- Key holding and access to CDs
- CD Stationery
- Prescribing of Controlled Drugs
- Ordering CDs for ward/dept. stock
- Collection / transportation and receipt of ward stock CDs onto a ward or department
- CD Record Keeping
- Administration of CDs (except in theatres[1])
- Prescribing, administration, destruction and record keeping of Controlled Drugs in theatres and recovery
- Destruction of Controlled Drugs on wards/departments including theatre areas
- Returns
- Patient's own controlled drugs
- Management of Sativex™ in BSHCT
- Transfer of CDs with a patient
- Discrepancies with stock balance
- Ward/Department CD stock checks
- Three monthly (quarterly) CD checks by pharmacy staff

[1] *Including areas where anaesthesia involving the administration of controlled drugs is practiced*

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This policy is relevant to:
Prescribers (Medical, dental and non-medical prescribers)
Nursing and midwifery staff
Operating Department Practitioners
Pharmacy Staff
CD Messengers (nursing auxiliaries, student nurses or student midwives, porters or drivers)
Designated directorate Governance Leads with responsibility for destruction of controlled drugs

The Lead author should be notified if there are significant barriers to implementation of this policy.

5.2 Resources

Implementation will include a series of training events and local workshops led by the Lead Pharmacist for Controlled Drugs.

5.3 Exceptions

Refer to section 2.0.

6.0 MONITORING

Quarterly audits on adherence to the Controlled Drug Policy and procedures therein are undertaken in all locations where controlled drugs are stored and used. Audit results are collated and disseminated by Co-Directors requiring completion of audit findings / recommendations within 4 weeks of the audit.

Key performance Indicator: Each ward / department must maintain full compliance with the CD Policy and procedures therein as measured at quarterly CD audits.

The prescribing, ordering and usage patterns for controlled drugs will be monitored in accordance with the Health Act 2006 and under the Controlled Drugs (Supervision of Management and Use) Regulations 2009.

7.0 EVIDENCE BASE / REFERENCES

- Medicines Act 1968
- Misuse of Drugs Act 1971
- Misuse of Drugs (Safe Custody) Regulations 1973
- Misuse of Drugs Regulations 2001 (MDR) and Misuse of Drugs Regulations Northern Ireland (NI) 2002
- The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009
- The Misuse of Drugs (Amendment) Regulations (Northern Ireland)

2012
- Misuse of Drugs Amendment Regulations (Northern Ireland) 2013
- DOH Prescription Only Medicines (Human Use) Order 1997
- DOH Health Act 2006
- NMC Standards for Medicines Management August 2008
- DHSSPSNI Safer Management of Controlled Drugs. A guide to good practice in secondary care (Northern Ireland), August 2009 updated August 2012
- DHSSPSNI Controls Assurance Medicines Management Framework (2008)

8.0 CONSULTATION PROCESS

Review by:
Head of Pharmacy and Medicines Management, Deputy Heads of Pharmacy and Medicines Management
Drugs and Therapeutics Committee

9.0 APPENDICES / ATTACHMENTS

Appendix 1: BHSCT Categorises of controlled drugs including high risk medicines.

Appendix 2: Examples of controlled drugs in stock in BHSCT and controlled high risk medicines by schedule and BHSCT category.

Appendix 3: Issue of BHSCT discharge Schedule 2 (Category A) controlled drug prescriptions at ward/ department level – responsibilities of BHSCT staff

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:

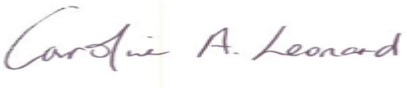
Major impact ☐

Minor impact ☐

No impact. X

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

_____ **Date: __February 2017_____**
Author



_____ **Date: _____**
Director

Appendix 1: BHSCT categories of controlled drugs including controlled high risk medicines

BHSCT CD category	CD category A CDSOPA – refer to BHSCT CD Procedures	CD category B CDSOPB – refer to BHSCT CD Procedures	CD category C CDSOPA – refer to BHSCT CD Procedures
Schedule	ALL Schedule 2 CDs Specific Schedule 1, 3, 4.1 and 5 CDs Certain controlled high risk medicines	Schedule 3 CDs (except Temazepam, diethylpropion and buprenorphine. Flunitrazepam)	Schedule 4 and 5 CDs excluding those specified within CDSOPA
Drugs by schedule	**Schedule 2**: morphine, oxycodone, pethidine, diamorphine, nabilone, methylphenindate, methadone, fentanyl, alfentanil, hydromorphone, remifentanil, **ketamine** **Schedule 3**: temazepam, flunitrazepam, buprenorphine, diethylpropion **Schedule 4**: Sativex* **Schedule 5**: Morphine sulphate liquid 10mg/5ml **Controlled High Risk medicines;** 1. Strong Potassium Chloride 15% injection 2. Addiphos injection (30mmol potassium / 20ml) 3. Potassium Dihydrogen Phosphate (1mmol potassium, 1mmol Phosphate)	**Schedule 3**: Includes the barbiturates (amylobarbitone, phenobarbital), mazindol, **midazolam**, pentazocine, phentermine, **tramadol**	**Schedule 4 (part 1):** Examples include diazepam, oxazepam, lorazepam, chlordiazepoxide, flurazepam, nitrazepam, zolpidem, zopiclone, zaleplon **Schedule 4 (part 2):** androgenic and anabolic steroids **Schedule 5**: co-codamol 8/500, co-codamol 30/500, codeine phosphate tabs, dihydrocodeine tablets
Requisition Book	**CD order/returns book**	**Schedule 3 (Category B) Order/Returns book**	Pharmacy requisition book (investigate requisitions if on top-up)
Permitted on top-up?	No	No	Yes
Prescription writing requirements	Yes	Yes	No
Validity of prescription	28 days (6 months for controlled high risk medicines)	28 days	28 days (6 months for schedule 5 CDs)
Ward storage/Safe Custody including PODs and returns	**CD cabinet** (excludes Sativex® and Epidolex®)	Ward medicines cupboard/cabinet	Ward medicines cupboard/cabinet
Ward register	Yes	No	No
Pharmacy storage	Schedule 2 & specified high risk medicines: CD room Sativex: **Separate** lockable fridge Sch 3 & 5: CD room / robot	CD room / robot	Robot
Pharmacy register	Yes(except Temazepam, Flunitrazepam, buprenorphine, diethylpropion, specified high risk medicines)	No	No
Retention of invoices for 2 years	Yes	Yes	Yes
Permitted in Emergency cupboard	No	No	No
Returns	Must be returned by pharmacist / nurse or midwife in charge directly to pharmacy using Procedure in **CDSOP A11**	Must be returned by pharmacist / nurse or midwife in charge directly to pharmacy using Procedure in **CDSOP B**	Return unused stock to pharmacy when no longer required **See CDSOP C**

Appendix 2: Examples of controlled drugs in stock in BHSCT and controlled high risk medicines by Schedule & BHSCT Category

Schedule 1	Schedule 2	Schedule 3	Schedule 4 (part 1)	Schedule 4 (part 11)	Schedule 5	High Risk Medicines*
Cocaine	Alfentanil	Amylobarbitone	Alprazolam	Chorionic gonadotrophin (HCG)	Codeine[2]	Addiphos™ inj
	Codeine inj[1]	Butobarbital (butobarbitone)	Chlordiazepoxide	Danazol	Codeine linctus	Potassium Chloride 15% inj
	Dexamfetamine	Buprenorphine	Clobazam	Nandrolone	Dihydrocodeine[2]	Potassium Dihydrogen Phosphate (1mmol k 1mmol PO4) inj
	Dextromoramide	Flunitrazepam	Clonazepam	Oxandrolone	Pholcodine[2]	
	Diamorphine	Mazindol	Diazepam	Oxymetholone	Morphine Sulphate 10mg/5ml oral solution Oramorph™	
	Dihydrocodeine [illegible][1]	Midazolam	Flurazepam	Testosterone		
	Dihydromorphine	Pentazocine	Loprazolam	Somatropin		
	Fentanyl	Phenobarbital	Lorazepam	Stanozolol		
	Hydromorphine	**Tramadol**	Lormetazepam	DHEA (dehydroepiandrosteron)		
	Ketamine	Temazepam	Nitrazepam			
	Morphine		Oxazepam		BHSCT – CD Category A	
	Methadone		Zopiclone		BHSCT – CD Category B	
	Methylphenidate		Zaleplon		BHSCT – CD Category C	
	Nabilone		Zolpidem			
	Oxycodone					
	Papaveretum[3]					
	Pethidine					
	Pholcodine[1]					
	Remifentanil					
	Secobarbital [illegible]					

Notes

1. Falls within paragraph 6 of Part 1 of Schedule 2 MDA 1971 if in a preparation designed for administration by injection
2. Falls within Schedule 5 if in a preparation either alone or with one or more of the drugs referring to this note not being a preparation designed for administration by injection, when compounded with one or more active or inert ingredients and containing a total of not more than 100mg of the substances (calculated as base) per dosage unit or with a total of not more than 2.5% (calculated as base) in undivided preparations.
3. Falls within Schedule 2 but Schedule 5: (a) if in any preparation from which the opium cannot be readily recovered in amounts which constitute a risk to health and with maximum strength 0.2%, (b) if in a powder containing opium 10%, 10% ipecacuanha root and 80% of another powdered ingredient (not a controlled drug),(c) if for non-parenteral use in unit preparations diluted to at least one part million (6x) in response to a specific request or (d) if for non-parenteral use in unit preparations diluted to at least one part in a million (6c)

* Non-CDs - denotes high risk drugs which are legal category POM but are managed as controlled drugs as per BHSCT policy

Appendix 3

Issue of BHSCT Discharge Schedule 2 (Category A) controlled drug prescriptions at ward/ department level – responsibilities of BHSCT staff

	Identification check **by BHSCT staff** for category A (Schedule 2) discharge prescriptions	Category A (Schedule 2) discharge prescription check **by BHSCT Staff**	CD POD CDRB **check by BHSCT staff**	Delivery Confirmation
In-patient	Confirm patients full name, DOB, and address (check arm bands if still present)	Verify: Label information Quantity on prescription & quantity recorded in POD register	2 registered nurses complete CD POD register Patient signs CD POD register if feasible	n/a
Out-patient	Confirm patients full name, DOB, and address *Check patient identification*	Verify Label information Quantity on prescription & quantity recorded in POD register	2 registered nurses complete CD POD register Patient signs CD POD register if feasible	n/a
Family member/carer/ representative	Confirm patients full name, and address Check identification of person collecting –	Verify Label information Quantity on prescription & quantity recorded in POD register	2 registered nurses complete CD POD register Family member/patient's representative signs CD POD register if feasible	n/a
Trust/ non trust HCP (collecting on patient's behalf)	Confirm patients full name, and address Check identification of person collecting – must have valid ID badge Should be in trust uniform	Verify Label information Quantity on prescription & quantity recorded in POD register	2 registered nurses complete CD POD register HCP signs POD register	Must inform ward of delivery failure and return prescription to ward
NIAS	Confirm patients full name, and address	Verify Label information Quantity on prescription & quantity recorded in POD register	2 registered nurses complete CD POD register RN should record name of staff member and station in POD register	Not required
Other, e.g. transport, courier, taxi	Check identification of person collecting– must have valid ID badge Verify delivery address –full post code is stated	Verify Label information Quantity on prescription & quantity recorded in POD register	2 registered nurses complete CD POD register Record taxi registration number/ licence number Record role e.g. taxi driver, trust transport	Must inform ward of delivery failure and return prescription to ward

Valid forms of identification include:

- Proof of professional membership for a healthcare professional
- Driving licence (both parts)
- Any official photo ID
- Cheque guarantee, debit or credit card
- Birth/marriage certificate
- Cheque book
- Utility bills (2 different ones – mobile phone bill not acceptable)
- Pension/benefit book
- Recent bank statement (within last 6 months)
- Bank/building society book
- Store charge card (not loyalty card)
- National savings book
- Household bills including Northern Ireland rates bills

List obtained from Safer Management of Controlled Drugs in Primary Care 2013

Belfast Health and Social Care Trust
caring supporting improving together

Controlled Drug Procedures (In-Patient Areas)

October 2016 V2

(Supersedes V1 Feb 2013 – April 2016)

Associated policy: Controlled Drugs Policy – Inpatient areas (Reference No. SG 01/11)

Introduction

Belfast HSC Trust Standard Operating Procedures (SOPs) cover the management of controlled drugs within hospital in-patient facilities and ensure compliance with the current legal requirements for controlled drugs and best practice guidance for high risk medicines. Any local deviations from the SOPs must be documented and approved by a Pharmacy Services Manager.

The Standard Operating Procedures contained within this document should be read in conjunction with;

1. BHSCT Controlled Drug Policy (inpatient areas) (SG 01/11 October 2016)
2. BHSCT Dealing with discrepancies or concerns involving controlled drugs policy (March 2015)
3. BHSCT Clinical monitoring of patients prescribed controlled drugs policy (August 2016)
4. Management of patients admitted to hospital who are on oral substitution therapy (Methadone, Subutex or Suboxone) (2017)

BHSCT Controlled Drug Categories

BHSCT categorises controlled drugs into three categories with guidance in handling, storage, returns procedures etc. provided for each category. Table 1 summarises the three categories and Table 2 provides examples of controlled drugs held in stock in BHSCT by category. Standard Operating Procedures (SOPs) describe the management of each CD category.

BHSCT Controlled Drug Standard Operating Procedures

SOP page borders are colour coded to aid identification of the correct SOP

Table 1: BHSCT categories of controlled drugs including controlled high risk medicines

BHSCT CD category	CD category A CDSOPA – refer to BHSCT CD Procedures	CD category B CDSOPB – refer to BHSCT CD Procedures	CD category C CDSOPA – refer to BHSCT CD Procedures
Schedule	ALL Schedule 2 CDs Specific Schedule 1, 3, 4.1 and 5 CDs Certain controlled high risk medicines	Schedule 3 CDs (except Temazepam, diethylpropion and buprenorphine. Flunitrazepam)	Schedule 4 and 5 CDs excluding those specified within CDSOPA
Drugs by schedule	**Schedule 2**: morphine, oxycodone, pethidine, diamorphine, nabilone, methylphenindate, methadone, fentanyl, alfentanil, hydromorphone, remifentanil, **ketamine** **Schedule 3**: temazepam, flunitrazepam, buprenorphine, diethylpropion **Schedule 4**: Sativex* **Schedule 5**: Morphine sulphate liquid 10mg/5ml **Controlled High Risk medicines;** 4. Strong Potassium Chloride 15% injection 5. Addiphos injection (30mmol potassium / 20ml) 6. Potassium Dihydrogen Phosphate (1mmol potassium, 1mmol Phosphate)	**Schedule 3**: Includes the barbiturates (amylobarbitone, phenobarbital), mazindol, **midazolam**, pentazocine, phentermine, **tramadol**	**Schedule 4 (part 1):** Examples include diazepam, oxazepam, lorazepam, chlordiazepoxide, flurazepam, nitrazepam, zolpidem, zopiclone, zaleplon **Schedule 4 (part 2):** androgenic and anabolic steroids **Schedule 5**: co-codamol 8/500, co-codamol 30/500, codeine phosphate tabs, dihydrocodeine tablets
Requisition Book	**CD order/returns book**	**Schedule 3 (Category B) Order/Returns book**	Pharmacy requisition book (investigate requisitions if on top-up)
Permitted on top-up?	No	No	Yes
Prescription writing requirements	Yes	Yes	No
Validity of prescription	28 days (6 months for controlled high risk medicines)	28 days	28 days (6 months for schedule 5 CDs)
Ward storage/Safe Custody including PODs and returns	**CD cabinet** (excludes Sativex® and Epidolex®)	Ward medicines cupboard/cabinet	Ward medicines cupboard/cabinet
Ward register	Yes	No	No
Pharmacy storage	Schedule 2 & specified high risk medicines: CD room Sativex: **Separate** lockable fridge Sch 3 & 5: CD room / robot	CD room / robot	Robot
Pharmacy register	Yes (except Temazepam, Flunitrazepam, buprenorphine, diethylpropion, specified high risk medicines)	No	No
Retention of invoices for 2 years	Yes	Yes	Yes
Permitted in Emergency cupboard	No	No	No
Returns	Must be returned by pharmacist / nurse or midwife in charge directly to pharmacy using Procedure in **CDSOP A11**	Must be returned by pharmacist / nurse or midwife in charge directly to pharmacy using Procedure in **CDSOP B**	Return unused stock to pharmacy when no longer required **CDSOP C**

Table 2: Examples of controlled drugs in stock in BHSCT and controlled high risk medicines, by Schedule and by BHSCT category

Schedule 1	Schedule 2	Schedule 3	Schedule 4 (part 1)	Schedule 4 (part 11)	Schedule 5	High Risk Medicines *
Cocaine	Alfentanil	Amylobarbitone	Cannabis (Sativex)	Chorionic gonadotrophin (HCG)	Codeine[2]	Addiphos™ inj
	Codeine inj[1]	Butobarbital (butobarbitone)	Alprazolam	Danazol	Codeine linctus	Potassium Chloride 15% inj
	Dexamfetamine	Buprenorphine	Chlordiazepoxide	Nandrolone	Dihydrocodeine[2]	Potassium Dihydrogen Phosphate (1mmol potassium, 1mmol Phosphate) inj
	Dextromoramide	Flunitrazepam	Clobazam	Oxandrolone	Pholcodine[2]	
	Diamorphine	Mazindol	Clonazepam	Oxymetholone	Morphine Sulphate 10mg/5ml oral solution Oramorph™	
	Dihydrocodeine inj[1]	Midazolam	Diazepam	Testosterone		
	Dihydromorphine	Pentazocine	Loprazolam	Somatropin		
	Fentanyl	Phenobarbital (Phenobarbitone)	Lorazepam	Stanozolol		
	Hydromorphone	Tramadol	Lormetazepam	DHEA (dehydroepiandrosteron)		
	Ketamine	Temazepam	Nitrazepam		BHSCT – CD category A	
	Morphine		Oxazepam		BHSCT – CD category B	
	Methadone		Zopiclone			
	Methylphenidate		Zolpidem		BHSCT – CD category C	
	Nabilone					
	Oxycodone					
	Papaveretum[3]					
	Pethidine					
	Pholcodine[1]					
	Remifentanil					
	Secobarbital (quinalbarbitone)					

Notes

1. Falls within paragraph 6 of Part 1 of Schedule 2 MDA 1971 if in a preparation designed for administration by injection
2. Falls within Schedule 5 if in a preparation either alone or with one or more of the drugs referring to this note not being a preparation designed for administration by injection, when compounded with one or more active or inert ingredients and containing a total of not more than 100mg of the substances (calculated as base) per dosage unit or with a total of not more than 2.5% (calculated as bas) in undivided preparations.
3. Falls within Schedule 2 but Schedule 5: (a) if in any preparation from which the opium cannot be readily recovered in amounts which constitute a risk to health and with maximum strength 0.2%, (b) if in a powder containing opium 10%, 10% ipecacuanha root and 80% of another powdered ingredient (not a controlled drug),(c) if for non-parenteral use in unit preparations diluted to at least one part million (6x) in response to a specific request or (d) if for non-parenteral use in unit preparations diluted to at least one part in a million million (6c)

* Non-CDs - denotes high risk drugs which are legal category POM but are managed as controlled drugs as per BHSCT policy

Standard Operating Procedure - CDSOPA

SOP reference:	**CDSOPA**		
Title:	Standard Operating Procedure (SOP) for the management of BHSCT category A controlled drugs		
Ownership:	BHSCT Pharmacy and sister/charge nurse, team leader or nurse or midwife in charge	**Status:**	Current
Publication Date:	October 2016	**Next Review:**	October2019
Ward:		**Site:**	
Local approval by:	**Sister/charge nurse, team leader or nurse or midwife in charge:**	Date:	
	Pharmacist responsible for quarterly CD checks:	Date:	

Objective

To ensure that the management of BHSCT category A controlled drugs (CDs) across BHSCT is carried out to agreed standards and meets the requirements of Controlled Drug Legislation.

Scope

Standard Operating Procedures (SOPs) are required for every activity relating to every stage of the CDs journey from ordering, transport, receipt, safe storage, supply, administration, destruction to guidance for dealing with an incident. This SOP – CDSOPA will encompass all these elements in turn.

From July 2015 there has been the additional requirement to have a standard operating procedure for the clinical monitoring of patients prescribed controlled drugs, this is subject to a separate policy and procedure.

In BHSCT the management of category A controlled drugs may exceed the Misuse of Drugs Regulations or Medicines Act to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

Table 1 (page 2) summarises the ordering, storage and record keeping requirements of category A CDs and Table 2 (Page 3) provides examples of category A CDs which are in stock in BHSCT.

Responsibility

The sister/charge nurse, team leader, or nurse or midwife in charge, of a ward/dept. is responsible for the safe and appropriate management of CDs in that area. The sister/charge nurse, team leader or nurse or midwife or operating department practitioner (ODP) in charge in charge of a ward/dept. operating theatre or theatre suite is responsible for ensuring that staff comply with the Trust systems and that procedures are in place for the management of CDs within their area of

responsibility. Any local deviations from CDSOPA must be documented and approved by a Pharmacy Services Manager.

The sister/charge nurse, team leader or nurse or midwife or ODP in charge of a ward/dept. must ensure that all relevant staff are appropriately trained in CDSOPA. All staff have a responsibility to notify the sister/charge nurse, team leader or nurse or midwife or ODP in charge of a ward/dept. of any variations or inability to follow the CDSOPA which must be discussed with pharmacy in order to resolve the issues.

All staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in CDSOPA and the BHSCT policy for dealing with discrepancies or concerns involving controlled drugs.

CDSOPA should be used in conjunction with the guidance in the BHSCT Medicines Code 2016.

CDSOPA should be approved on each ward/dept. by the sister/charge nurse, team lead or nurse or midwife or ODP in charge and the pharmacist responsible for controlled drug checks. It should be used locally for induction training and as a source of information for any queries relating to CDs.

Document control

The sister/charge nurse, as well as team lead and nurse or midwife or ODP in charge of a ward/dept. is responsible for ensuring all relevant staff are notified of any changes to the CDSOPA and for removing the superseded SOP from the clinical area.

CDSOPA will be reviewed every 3 years but in the event of any incident or near miss of a serious nature it will be reviewed immediately.

Procedures

The following procedures are detailed within CDSOPA:

[1] *Including areas where anaesthesia involving the administration of controlled drugs is practiced*

CDSOPA (1)	Storage of category A Controlled Drugs

1.0 Storage of category A CDs

1.1 General

1.1.1 Category A CDs must be stored separately from all other drugs in a cabinet identified solely for this purpose which must be kept locked when not in use. Controlled drugs must be locked away when not in use. No other medicines or items should be stored in the CD cabinet except in accordance with this Controlled Drug Policy.

1.1.2 A CD stock check must be carried out following any breach in security involving the storage of controlled drugs. A datix incident report must also be completed.

1.1.3 Standards of Controlled drug cabinets and locks

1.1.3.1 Ward CD cabinets should conform to the British Standard reference BS2881:1989 ("specification for cabinets for the storage of medicines in healthcare premises" ISBN 058017216 3) or be otherwise approved by the pharmacy department.

1.1.3.2 The cabinet must provide in its construction a level of security at least comparable to that laid down for CD cabinets in the Misuse of Drugs (Safe Custody) Regulations 1973.

1.1.3.3 The lock must not be common to any other lock in the hospital.

1.2 Storage of controlled drugs when ward/dept. is closed (overnight /weekends)

1.2.1 A ward or department may be closed at night or weekends and therefore unmanned for periods of time. A risk assessment should determine if the CDs should remain on the ward or department or whether they should be returned to pharmacy. The risk assessment must be documented on the BHSCT general risk assessment form and approved by a Pharmacy Services Manager. The risk assessment should include the length of time the ward/dept. is unmanned, the location of the ward/dept. to manned areas, the barriers to entry to the ward/dept., the presence of an intruder alarm and the range and quantity of CDs in storage.

1.2.2 In general, wards or departments should return CDs to pharmacy in a locked or tamper evident container if the area is closed for greater than 48 hours. Where tamper evident seals are used the seal must be checked

and confirmed as intact at receipt by pharmacy and the transfer of responsibility documented.

1.3 Storage of Patients own controlled drugs on admission

1.3.1 Patients' own CDs should not be stored on the ward but should be sent home with the patient's representative (family member or carer) as soon as possible after admission. The patient's representative should be given advice regarding the necessity for safe storage of the medicines and that other people must not use them**.**

1.3.2 If the CDs cannot be sent home immediately, they must be;

1.3.2.1 Counted and recorded in the CD POD register. See CDSOP 7 and CDSOP 16 for further details of daily stock checks and record keeping.

1.3.2.2 Placed in a bag/ envelope and clearly marked with the patient identifier. A sealable plastic tamper evident bag may be used; the serial number must be recorded in the CD POD register.

1.3.2.3 Placed in the CD cabinet and kept separate from ward CD stock.

1.3.3 The ward CD POD register must be completed by two registered nurses or a registered nurse and an ODP or pharmacist when the CDs are subsequently returned to the patient or patient's representative or returned to pharmacy for destruction.

1.4 Storage of CD discharge medication, out-patient prescriptions and temporary leave prescriptions (weekend or pass medication)

1.4.1 When CD discharge medicines, out-patient prescriptions and temporary leave prescriptions (weekend or pass medication) are sent to the ward/dept. the medicines must be:

- recorded in the CD POD register regardless of the time of supply to the patient/patient representative
- stored in the CD cabinet if not for immediate supply to the patient / patient representative. These medicines should be segregated from the ward CD stock and be clearly marked and should remain in a sealed bag

1.4.2 The record of the supply of controlled drugs to a patient or their representative (including courier), or transfer with a patient to another ward or return to pharmacy must be documented in the CD POD register.
If the patient and their medication are being transferred by Ambulance transport, the name of the ambulance personnel and station base may be recorded in the CD POD register. It is not necessary to request ambulance

personnel to complete the CD POD register. See appendix 3 Controlled Drugs Policy for details.

1.4.3 If the medication is no longer needed then the medication should be returned to pharmacy as soon as possible following the returns procedure. (see section CDSOP 11).

1.5 Storage of epidural infusions containing controlled drugs

1.5.1 Epidural infusions should be stored in separate cabinets or refrigerators from those holding intravenous and other types of infusions in accordance with recommendation from NPSA alert 'Safer practice with epidural injections and infusions'.

1.6 Storage requirements for preparations with multiple strengths

1.6.1 Wards/departments should not routinely hold diamorphine or morphine ampoules of 30mg or more or Oxycodone ampoules of 50mg unless it is has been agreed as a stock item by ward sister and pharmacist or has been supplied for patient whose dose justifies supply.

1.6.2 If high strength ampoules are kept they should be physically separated from other medicines within the CD cabinet.

1.6.3 High strength ampoules no longer required should be returned to pharmacy as soon as possible.

1.7 Automated controlled drug cabinets

1.7.1 Wards and departments which have automated controlled drug cabinets – should refer to local approved standard operating procedures.

CDSOPA (2)	Key holding and access to category A CDs

2.0 Key-holding and access to category A CDs

2.1 The key of the CD cabinet must be carried on the person of the registered nurse or midwife or operating department practitioner (ODP) on duty and in charge in the ward/dept. and, at shift change, must be handed over personally to the registered nurse/midwife or ODP responsible for taking over custody of the cabinet.

2.2 Key-holding may be delegated to another suitably trained registered nurse or midwife or operating department practitioner but the legal responsibility rests with the registered nurse or midwife or ODP on duty and in charge.

2.3 Whilst the task of key holding can be delegated to another authorised nurse or midwife, the responsibility cannot.

2.4 The CD key should be returned to the registered nurse or midwife or ODP on duty and in charge immediately after use by another nurse or midwife or operating department practitioner.

2.5 The CD key **must not** be handed to medical staff or to other unauthorised staff.

2.6 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of pharmacy staff.

2.7 The registered nurse or midwife or ODP on duty and in charge is responsible for the CD key and should know its whereabouts at all times.

2.8 The key of the CD cabinet must be held separately from other medicine cabinet keys i.e. separate key ring so that medicine cabinet keys may be given to an authorised member of staff but with CD key retained by nurse or midwife or OPD in charge.

2.9 The sister/charge nurse, team leader or nurse or midwife or ODP in charge of a ward/dept. is responsible for ensuring the CD key is secure when the ward/ dept. is closed. Local arrangements must be documented in a key management SOP.

2.10 If the key of the CD cabinet cannot be found urgent efforts should be made to retrieve the key as quickly as possible e.g. by contacting staff who have just gone off duty. If the search is not successful, then pharmacy must be informed immediately. It may be possible to arrange to get a spare key to ensure that patient care is not impeded. However, if the loss of the key

remains unexplained, estate services must be informed within two hours to get the lock changed. The registered nurse/midwife or registered ODP in charge must complete a Datix incident form. The Pharmacy Services Manager must be informed who, depending on the circumstances, may decide to contact security and/or the police. The Accountable Officer and the Head of the Medicines Regulatory Group should be made aware of the situation.

2.11 The storage and management of spare CD keys is the responsibility of the ward/department sister/charge nurse, as well as team lead and nurse or midwife or ODP in charge. Spare CD keys will usually be in a central location for a site and accessible by a senior nurse/midwife for the site. Issue of spare CD keys should be documented. If a spare key is accessed and used for interim access to a CD cabinet, it must be replaced as soon as possible after the CD keys are found. Local arrangements for access to spare CD keys must be documented in a key management SOP.

2.12 A CD stock check must be carried out following any breach in the security of the key. This must be completed as soon as access to the cabinet contents is obtained.

CDSOPA (3)	CD Stationery

3.0 CD Stationery

3.1 CD Stationery – general

3.1.1 Only approved CD stationery should be in use.

3.1.2 Approved CD stationery is available from the pharmacy department.

3.1.3 All stationery used to order, return or record CDs must be stored securely in a locked cabinet or drawer and access to them should be restricted to guard against unauthorised use. It is not acceptable for CD stationery to be stored within a room accessible by a keypad.

3.1.4 All CD stationery must be ordered using a controlled drug order/returns book. A new CD order/returns book should be ordered on the last page of the current book.

3.1.5 Completed and/or closed CD stationery must be retained in secure storage as follows:

Stationery	Retention period	Responsibility for Retention
CD order / returns book	2 years from date of last entry	**Ward**
Schedule 3/ category B controlled drugs order/returns book	2 years from date of last entry (See also CDSOP B ordering of schedule 3/ Category B controlled drugs).	**Ward**
CDRB including Theatre CDRB	11 years from last entry https://www.health-ni.gov.uk/topics/good-management-good-records Check the online disposal schedule for revisions	**Ward** -Sister/Charge Nurse, Midwife, or ODP in charge
CD POD register	7 years from date of last entry https://www.health-ni.gov.uk/topics/good-management-good-records Check the online disposal schedule for revisions	**Ward** -Sister/Charge Nurse, Midwife, or ODP in charge

3.2 Controlled drug order/returns book

3.2.1 A controlled drug order/returns book must be used for ordering stock of a category A controlled drug from pharmacy. (See also CDSOP B ordering of schedule 3/ Category B controlled drugs).

3.2.3 Each ward/dept./theatre should have only one Category A / (Schedule 2) CD order/returns book on the ward/dept. and in use at any one time.

3.2 Controlled Drug Record Book (CDRB)

3.2.4 The BHSCT CDRB bound book with sequentially numbered pages **must** be used.

3.2.5 There should be a separate CDRB for each ward / department / theatre. More than one CDRB may be in use e.g. for different formulations of CDs in a ward/dept./theatre if there is a large range of CDs in stock.

3.2.6 There should be a separate CDRB for each CD cabinet where the CD cabinet(s) are in separate ward/dept. or separate rooms within a ward/dept.

3.3 Controlled Drug Patients Own Drug (POD) register

3.3.4 The CD POD register is used to record ALL patients own controlled drugs received / supplied / returned / transferred.

3.3.5 Each ward/dept. should have only one CD POD register in use at any one time.

3.5 Controlled Drug Record Book – Theatres, Recovery and Critical Care

3.5.1 BHSCT theatres, recovery and critical care areas may use a specific CDRB bound book for the purposes of maintaining more detailed records of issue, administration and disposal of controlled drugs. See CDSOP A9 for further information.

CDSOPA (4)	Prescribing of Controlled Drugs

4.0 Prescribing of Controlled Drugs

4.01 Prescribers must comply with the relevant legislation when prescribing controlled drugs. In addition, prescribers must adhere to the BHSCT Medicines Code and the British National Formulary (BNF) under 'General Information and Prescription writing'.

4.02 Controlled drugs must not be prescribed for personal use, friends or family members.

4.03 Medical staff including FY1s are only permitted to prescribe medicines, including CDs, as part of their required duties in their post and should not prescribe for private patients.

4.1 Prescribing for inpatients

4.1.1 For hospital inpatients directions for administration of controlled drugs from ward/dept. stocks must be written on the inpatient Medicine Prescription and Administration record or the anaesthetic chart kardex.

4.1.2 Prescriptions for BHSCT category A CDs for administration by subcutaneous syringe pump must be prescribed on the 'Prescription and administration record of medicines via subcutaneous syringe pump' chart and reference must be made on the main inpatient Medicine Prescription and Administration record. Doses of opioids must be stated **in both words and figures** when prescribing opioids on the 'Prescription and administration record of medicines via subcutaneous syringe pump' chart.

4.1.3 The written requirements for controlled drugs on these charts are the same as for other medicines as described in the BHSCT Medicines Code and include:

- Start date
- Drug name, form and strength (where appropriate) – (see BHSCT policy on generic prescribing for list of preparations which must be prescribed by brand)
- Route of administration, and where appropriate, the site of application
- Dose
- Time of administration or frequency (if prescribed "When required" e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum daily dose)
- Include a finish date where appropriate
- Signature of prescriber

4.1.4 On the rare occasion that controlled drugs are administered from supplies prescribed and dispensed for individual patients (rather than from items ordered as ward stock), then in addition to the requirements as stated in the BHSCT Medicines Code, and in order to comply with the Misuse of Drugs Regulations (Regulation 15), the total quantities of the controlled drugs prescribed for the individual patients must be present in both words and figures on the prescription.

4.2 Prescribing for discharge patients and outpatients

4.2.1 A 7-day supply of controlled drugs should be prescribed at discharge. Patients being discharged to Intermediate Care facilities may receive a 28- day supply of controlled drugs.

4.2.2 Controlled drugs dispensed on a discharge prescription MUST NOT be administered to an in-patient e.g. if the discharge is delayed.

4.2.3 All BHSCT category A CDs prescribed for patients on discharge, temporary leave or for out-patients must be prescribed using the BHSCT Discharge Prescription for Controlled Drugs and must also be referenced on the main discharge prescription form.

4.2.4 Belfast Trust Discharge Prescriptions for Controlled Drugs must conform to all requirements of the Misuse of Drugs Regulations for a controlled drug prescription.

4.2.5 An exemplar example of a completed Belfast Trust Prescription for Controlled Drugs is attached in CDSOPA Appendix a (Page 51.)

4.2.6 Incorrectly written CD prescriptions will not be dispensed and will be returned to the prescriber for amendment, which may result in a delay in the patient receiving their discharge medication.

4.2.7 It is a criminal offence for a pharmacist to dispense a CD against a prescription that does not meet the criteria below.

4.2.8 A prescription for a BHSCT Category A CDs and high risk medicines MUST contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated:

- The patient's full name and address. **The use of pre-printed adhesive addressogram labels on prescriptions is not permitted**
- The patient's age and health and care number
- The name and pharmaceutical form of the drug. The form must be stated irrespective of whether it is implicit in the proprietary name (e.g. MST Continus) or of whether only one form is available

- The strength of the preparation, where appropriate. Check the available strengths of the preparation as two strengths may be required to obtain the prescribed dose. If this is the case use words and figures for the total quantity required for each strength
- The dose to be taken. The instruction 'One as directed' constitutes a dose but 'as directed' does not
- Either the total quantity (in both words and figures) of the preparation for the total number of days (usually 7) or the number (in both words and figures) of dosage units, as appropriate, to be supplied. In exceptional circumstances where more than 7 days' supply is required, the prescribing doctor must contact the pharmacy to discuss
- All controlled drug prescriptions MUST be dated and are only valid for 28 days from the date on the prescription
- The prescriber must sign the prescription, in his own handwriting, and print their name (include bleep number if applicable)
- If the prescriber is a non-medical prescriber –they must indicate this on the prescription

4.2.9 Discharge prescriptions for BHSCT patients in intermediate care beds may receive 28 day supply of controlled drugs.

4.3 Prescribing of opioids - Reducing dosing errors with opioids

4.3.1 When opioid medicines are prescribed, in anything other than acute emergencies, the doctor, dentist or non-medical prescriber, should:

- 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
- 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)
- ensure familiarity with the following characteristics of the medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects

4.4 Management of patients receiving Opioid Substitution Therapy

4.4.1 Please refer to the BHSCT policy Management of patients admitted to hospital who are on oral substitution therapy (Methadone, Subutex or Suboxone) (2017).

4.5 Clinical monitoring of controlled drugs

4.5.1 The Controlled Drugs (Supervision of Management and Use) (Amendment)

Regulations (Northern Ireland) 2015 came into operation on 16th July 2015 and require controlled drug procedures to include best practice relating to clinical monitoring of patients prescribed controlled drugs.

4.5.2 See BHSCT policy, Clinical Monitoring of Controlled Drugs (2016).

CDSOPA (5)	Ordering CDs for ward/dept. stock

5.0 Ordering CDs for ward/dept. stock

5.1 Ward stock holding

5.1.1 Each ward must hold a stock list (with minimum stock level of 4 days' supply) which reflects current use of CDs in the ward or department.

5.1.2 Only CDs listed on the stock list should be routinely requisitioned.

5.1.3 Ward stock levels of stock items should be checked at designated times each week, and a CD order prepared to ensure adequate stock of CDs are available for patient care.

5.1.4 The ward stock list and stock levels should be regularly reviewed (at least annually) and the stock levels agreed between the sister/charge nurse, as well as team lead and nurse or midwife or ODP in charge of a ward/dept., operating theatre or theatre suite and the pharmacist responsible for monitoring the ward CDs.

5.1.5 A proforma for recording the ward stock list and minimum stock levels is provided in CDSOPA appendix b (Page 52).

5.2 Responsibility for ordering CDs

5.2.1 The sister/charge nurse, as well as team lead and nurse or midwife or ODP in charge of a ward, department, operating theatre or theatre suite is responsible for the ordering of CDs for use in that area.

5.2.2 The sister/charge nurse, as well as team lead and nurse or midwife or ODP in charge can delegate the task of preparing an order to another, such as a registered nurse or midwife or ODP. However, legal responsibility remains with the registered nurse or midwife or ODP on duty and in charge.

5.2.3 The sister/charge nurse, team leader or nurse or midwife or ODP in charge of a ward/dept. must retain a record of staff authorised by them to order CDs from pharmacy (CDSOPA Appendix c Authorised Signatory List (Page 53). The list should be regularly updated and should include a sample signature. A copy of the record of authorised signatories will be kept in pharmacy for validation and updated at each quarterly CD check.
Bank and agency staff should not be authorised to order controlled drugs.

5.3 Procedure for ordering CDs

5.3.1 Orders for CDs are made by writing a requisition(s) in the ward CD order/returns book ensuring each copy (original and 2 duplicates) of the requisition is completed.

5.3.2 The requisition(s) must be signed by an authorised signatory.

5.3.3 One CD is ordered per requisition.

5.3.4 See CDSOPA Appendix d (Page 54) for an exemplar example of a completed CD order / returns book.

5.3.5 The CD order/returns book should be sent to pharmacy by ward messenger. The CD order / returns book **must not** be sent to pharmacy via pneumatic tube.

5.3.6 Requisitions must include:

- the date of ordering
- the name of the hospital and the ward/theatre or clinical area
- the drug name
- the drug form (i.e. capsules, injection etc.)
- the drug strength
- ampoule size (if more than one available)
- total quantity required
- name of patient (if appropriate) e.g. an unlicensed CD
- name in block capitals and signature of the member of staff placing the order

5.3.7 In pharmacy: When the CD(s) has been supplied the requisition must be signed and dated by pharmacy staff to show that it has been complied with. The original copy of the requisition must be retained at the dispensary at which the drug was supplied.

5.4 Arrangements for CDs required outside pharmacy opening hours

5.4.1 Exchange or supply of CDs between wards is illegal and is strictly forbidden (Misuse of Drugs Act (NI) Regulations 1986-89, Misuse of Drugs Act 1971).

5.4.2 If a CD is required outside pharmacy opening hours, the registered nurse or midwife or ODP on duty and in charge should contact the on-call pharmacist through the hospital switchboard.

CDSOPA (6)	Collection / transportation and receipt of ward stock CDs onto a ward or department

6.0 Collection / transportation and receipt of ward stock CDs onto a ward or department

6.0.1 At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties.

6.1 Transportation of ward stock CDs

6.1.1 CDs will be transferred to the ward/department in a secure, locked or sealed, tamper-evident container, usually an envopak sealed with a tamper-evident seal, by a member of ward/dept. staff, pharmacy porter, hospital porter, hospital driver or contracted taxi driver who must be wearing a valid photographic identification badge.

6.1.2 The ward/dept. staff, porter or driver will sign for the CDs before leaving the pharmacy department.

6.2 Procedure for collection / delivery of ward stock CDs from a pharmacy department

6.2.1 If a registered nurse or midwife or ODP or ward messenger **collects** the order from the pharmacy, they will be required to sign the CD requisition(s). It is good practice that the person who collects the CDs should not be the person who ordered the CDs. Staff will be asked to confirm their identity and produce a valid photographic identity badge.

6.2.2 When CDs are **delivered** to a ward/dept. the nurse or midwife or ODP at ward/dept. level who accepts the sealed bag must sign the relevant duplicate CD requisition in the CD order/returns book or in a separate book/delivery log kept for this purpose. CDs must never be left unattended and must be locked in the CD cabinet.

6.2.3 As soon as possible after **delivery/collection** the registered nurse or midwife or ODP should check the CDs against the original requisition to ensure that the correct drug and quantity have been supplied.

6.2.4 All tamper-evident seals should be left intact; however, pack seals should be checked to ensure they are intact.

6.2.5 If the CDs are correct then the duplicate requisition in the CD order/returns book should be countersigned in the received by section and returned to pharmacy as follows:

- Supplying pharmacy on site: The duplicate requisition must be returned to the pharmacy department before the end of the working day. The duplicate requisition may be returned via pneumatic tube

- Supplying pharmacy not on site i.e. supply is made by BHSCT extended hours' service or by BHSCT on-call pharmacist: The duplicate requisition must be returned to the supplying pharmacy on the next working day. The duplicate requisition may be returned via pneumatic tube, if applicable

6.2.6 If there are any discrepancies between the CDs and the original requisition the registered nurse or midwife or ODP performing the check should contact the supplying pharmacy immediately.

6.2.7 Check the index of the CDRB to ascertain the appropriate page for the recording of the CDs.

6.2.8 The receipt of CDs should be recorded on the appropriate page in the CDRB by a registered nurse or midwife or ODP and be witnessed by another registered nurse, midwife or ODP. Refer to section 7.2 (page 22).

CDSOPA (7)	CD Record Keeping

7.0 Record keeping

7.0.1 A clear audit trail must exist for the movement and use of all CDs. At each point where a controlled drug moves from the authorised possession of one person to another or when a controlled drug is administered or destroyed, the transfer/administration/destruction must be recorded by means of the signatures of both parties on approved CD stationery.

7.1 Controlled Drug order / returns book

7.1.1 Refer to section 3.2 and section 5.3

7.2 Controlled Drug Record Book (CDRB)

7.2.1 See SOP Appendix e (Page 55) for an exemplar example of a completed CDRB.

7.2.1 Each ward or department that holds stocks of category A CDs must keep a record of the CDs received and administered in the CDRB.

7.2.2 Completion of CDRB (see Table 3). The CDRB entries are as specified in CD legislation and MUST therefore be completed. Failure to complete CDRB entries is therefore unlawful.

7.2.3 It is the responsibility of the registered nurse or midwife or ODP who supplies a CD to a doctor, for administration, or who administers a CD to ensure that all sections of the CDRB are completed appropriately.

7.3 Records of controlled drugs received

7.3.1 A record must be kept of all category A controlled drugs that are received or administered.

7.3.2 For controlled drugs received the following details should be recorded on the appropriate page in the CDRB:

- Date on which controlled drug was received
- Name of pharmacy making supply and the serial number of the requisition
- Quantity received
- Form (name, formulation and strength in which received)
- Name and signature of registered nurse/midwife/ODP making entry
- Name and signature of witness
- Balance in stock

- Confirmation of stock balance which should be signed and dated

7.4 Correction of mistakes

7.4.1 If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible.

7.4.2 Tippex or labels must not be used to delete or amend the entries.

7.4.3 A brief explanation of the error must be written on the next line of the register with the balance confirmed. This entry must be signed and dated by the person making the entry and witnessed preferably by a second registered nurse or midwife or ODP. If a second registered nurse or midwife is not available, then the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist or ODP).

7.5 Transfer of balance to a new page

7.5.1 On reaching the end of a page in the CDRB, the balance must be transferred to a new page.

7.5.2 The balance must be written in the top line of the new page and this page number must be added to the bottom of the finished page (i.e. complete the 'balance transferred to page' section).

7.5.3 The balance being transferred must be written on the first line of the new page in the allocated space stating clearly which page the balance was transferred from.

7.5.4 Balance transfers should be signed by a witness who can be a registered nurse or midwife or ODP or a pharmacist (if available on the ward).

7.5.5 The CDRB index page must be updated.

7.6 Transfer to a new CDRB

7.6.1 Transfer to a new CDRB must be carried out by an appropriately trained pharmacist or pharmacy technician.

7.6.2 A ward or department must estimate when a new CDRB will be required and contact pharmacy, providing at least one week's notice, to arrange a suitable time to transfer to a new CDRB.

7.6.3 The balances must be transferred to the new book and each entry for current stock balances must be signed and dated by a pharmacist, or appropriately trained pharmacy technician, and witnessed by a registered

nurse or midwife or ODP.

7.6.4 In the appropriate section of the CDRB the pharmacist will enter the date and write 'Opening balance checked and verified by' and the stock in the 'Stock balance' column on the first line of the page. The pharmacist and nurse or midwife or ODP will sign and print name in appropriate columns.

7.6.5 An entry should be made in the old CDRB that stock has been transferred to a new CDRB.

7.6.6 The pharmacist should write the 'quantity' of drug transferred and the statement 'Transferred to new register' e.g. '24 tablets transferred to new register'.

7.6.7 The pharmacist should sign and print name together with the date of transfer.

7.7 Controlled Drug Patients Own Drug (POD) Register

7.7.1 The movement of controlled drugs within a clinical setting must be recorded in the CD POD register i.e. ALL patients own controlled drugs received / supplied / returned / transferred e.g.

- Patient admitted to hospital with CDs and reissue of patients own CDs at discharge
- Patients discharged on newly prescribed controlled drugs, temporary leave medications (weekend or pass medication)
- CD PODs which are transferred with a patient as they are moved between clinical areas
- CD PODs which are returned to pharmacy for disposal
- Out-patient prescriptions

7.7.2 Administration of controlled drugs must not be recorded in the CD POD register.

7.7.3 ALL appropriate sections of the CD POD register must be completed to provide an audit trail for the management of CD PODs including discharge prescriptions, out-patient prescription and temporary leave (weekend and pass medication). Entries must be made at the time of the transaction.

7.7.4 Entries must be made in chronological order, be in ink or otherwise indelible.

7.7.5 If a mistake is made it must be bracketed in such a way that the original entry is still clearly legible. It must be signed, dated and witnessed by a second registered nurse or midwife or ODP or other registered healthcare professional. An explanation must be made if necessary by a marginal note

or footnote.

7.7.6 The patient's own controlled drug **must** be checked on each check of ward stock of controlled drugs. See section 15.0 (Page 46).

7.7.7 A separate line should be used for each controlled drug being handled.

7.7.8 Refer to Appendix f (Page 56) for exemplar example of completed CD POD register.

7.8 CDRB – theatres, recovery and critical care

7.8.1 The theatre and critical care controlled drug record book permits the recording of more detailed records of controlled drugs issued, administered and destroyed.

7.9 Record Keeping in theatre and critical care CDRB

7.9.1 Receipts of controlled drugs are recorded as per 7.3.2

7.9.2 Supply of a controlled drug to anaesthetist; the following details should be recorded

1. Date
2. Name of patient
3. Quantity issued and time
4. Sign and print name of responsible person (nurse/ODP/anaesthetist) as applicable
5. Sign and print name of witness
6. Update running balance
7. Verify and sign that stock balance is correct

7.9.3 Administration of a controlled drug

1. Record total quantity of drug administered
2. Sign and print name of responsible person
3. Sign and print name of witness (if in recovery, critical care)

7.9.4 Disposal of a controlled drug

1. Record quantity disposed
2. Record time
3. Sign and print name of responsible person
4. Sign and print name of witness

If an amount of controlled drug is not destroyed in the theatre area but is transferred with a patient as part of ongoing patient care to a different location an entry should be made in the "D destroyed" section stating X (units) transferred to < clinical area description>.

Table 3: Completion of CDRB – see also exemplar completed example (Appendix e)

Section of CDRB	**Requirement**
Front cover	
Date record book opened	Complete using indelible ink Record book to be archived until (11 years from last entry) https://www.health-ni.gov.uk/articles/records-disposal-schedules
Date record book closed	
Index page	
Generic name	The index at the front of the CDRB should accurately reflect the current pages in use for all CDs that have been ordered by the ward/dept.
Brand name (if applicable)	
Strength / concentration	
Form	
Page numbers	
For injections: ampoule/vial size	
Pages 1-100 - Title	
Generic name	The title entries should be made in capital letters.
Brand name	
Strength	
Form	
Ampoule/vial size (if applicable)	
Pages 1-100 – Amount(s) obtained from pharmacy – **legislative requirements**	
Date received	Entries must be made in chronological order, in ink or be otherwise indelible. For each drug a running total of the stock should be maintained. **The running total is recorded in units of the CD e.g. number of tablets. It is not recorded as the number of boxes in stock.** Each time a CD is received into stock, the stock balance of an individual preparation MUST be recorded. Once the stock balance has been updated, the nurse or midwife or ODP should check that the balance tallies with the quantity that is physically present in the CD cabinet. The entry should be signed and dated in the 'stock balance confirmed as correct' column by the nurse/midwife/ODP.
Amount received	
Name of Pharmacy & Serial No. of Requisition	
Name and **signatures** of persons • Taking receipt of CD • witnessing receipt of CD	
Stock balance	
Confirmation stock balance correct (Signature and date)	
Pages 1-100 – Amount(s) removed from CD cupboard - **legislative requirements**	
Date given	'Date given' and 'time given, of when dose administered or refused in the case of a CD prepared for a patient. **Times should be recorded using 24-hour clock notation when administering controlled drugs.**
Time given (24hr clock)	
Patients Name and Unit number	i.e. health and care number
Amount given	An oral syringe must always be used to accurately

	measure volumes of oral liquids / suspensions. CD liquids issued as ward stock must have a bung insitu.
Amount wasted	In the event **of a patient not** requiring a full dose or refusing medication it should be disposed of appropriately by a registered nurse, midwife, ODP or doctor in the presence of a witness and the volume/dose wasted recorded in the 'Amount wasted' column of the CDRB with the signatures of the registered nurse, midwife, ODP or doctor and witness involved. Controlled drugs must be denatured prior to disposal. (see table 5 page 40 for further details)
Name and **signatures** of persons • Administering CD • witnessing **ACTUAL** administration of CD	All entries must be signed by two registrants. See also section 8.0.9 Refer to table 4 (page 29) for the designation of staff who may administer/destroy or witness the administration/destruction of controlled drugs. **Both the name and signature MUST be recorded.** Exceptionally, the second signature can be by another practitioner (e.g. doctor or pharmacist) provided they have witnessed the administration of the drug.
Stock balance	For each drug a running total of the stock should be maintained. **The running total is recorded in units of the CD e.g. number of tablets. It is not recorded as the number of boxes in stock.** **The balance of a liquid CD must be confirmed to be correct on completion of a bottle**
Confirmation stock balance correct (Signature and date)	Once the stock balance has been updated, the nurse or midwife or ODP should check that the balance tallies with the quantity that is physically present in the CD cabinet. The entry should be signed and dated in the 'stock balance confirmed as correct' column by the nurse/midwife/ODP.

CDSOPA (8)	Administration of CDs (except in theatres[1])

8.0 Administration of CDs (except in theatres[1] – see section 9.0 for administration of CDs in theatre areas)

8.0.1 Registered nurses and midwives must follow the Nursing and Midwifery Council standards and guidance (http://www.nmc-uk.org) and the BHSCT Medicines Code in relation to the administration of medicines.

8.0.2 Registered operating department practitioners must follow the Health and Care Professions Council standards and guidance (http://www.hcpc-uk.org) and the BHSCT Medicines Code in relation to the administration of medicines.

8.0.3 The BHSCT management of controlled drugs in relation to prescribing, storage, administration and record keeping may exceed the Misuse of Drugs Regulations or non-CDs may be managed in the same way as CDs. This is to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

8.0.4 Controlled drugs MUST not be administered on the basis of only a verbal order even if the verbal order is given in the presence of a doctor.

8.0.5 Self administration by patients for category A CDs is not permitted.

8.0.6 Administration of controlled drugs by the patient's carer is not permitted.

8.0.7 Pharmacy must be contacted immediately if, on opening the box, ampoules are found to be broken or any other discrepancy occurs.

8.0.8 **Two practitioners**, authorised to administer/witness administration of CDs, must be involved in the administration of CDs. The practitioner who witnesses the administration cannot be the same person(s) that administered the drug.

8.0.9 Liquid medicines must be endorsed with the date of opening and discarded after 1 month or as directed by the manufacturer.

8.0.10 Both practitioners **must be present during the whole administration procedure** and both MUST witness:

- The preparation of the CD to be administered.
- The CD being administered to the patient.

[1] Including areas where anaesthesia involving the administration of controlled drugs is practiced

- The destruction of any surplus drug (e.g. part of an ampoule or infusion not required)

8.0.11 Table 4 (Page 29) summarises the designation of staff who may administer/destroy or witness the administration/destruction of controlled drugs.

8.0.12 Where wards/departments do not have a system of second checking the administration of a controlled drug e.g. only one registrant on duty, the sister/charge nurse, team leader or nurse or midwife in charge of a ward/dept. should undertake a risk assessment with their professional line manager and Pharmacy Services Manager to determine whether the introduction of second checking as an additional risk reduction measure is necessary. A ward/department/facility/site may consider the use of an unregistered healthcare worker to provide a second check within the risk assessment. A written record of this risk assessment should be made and forwarded to the Pharmacy Services Manager.

Table 4: Designation of staff who may administer/destroy or witness the administration/destruction of controlled drugs

Activity	Administration / destruction by;	Witnessed by;
Administration of a CD & destruction of unused portion	Registered nurse or midwife or ODP	• Registered nurse or midwife • Registered ODP • Doctor including FY1 doctor • Student nurse or student midwife AND supervising registered nurse or midwife • Pharmacist (exceptionally)
	Doctor including FY1 doctor	• Registered nurse or midwife • Registered ODP • Pharmacist (exceptionally)
	Student nurse or student midwife AND supervising registered nurse or midwife	• Registered nurse or midwife • Registered ODP • Doctor including FY1 doctor • Pharmacist (exceptionally)

8.1 Process for administration of CDs

8.1.1 Chart 1 (Page 32) provides a flowchart for the administration of controlled drugs. (Adapted from Portsmouth Controlled Drug Policy). Reference NPSA/2008/RRR05.

8.2 Record of administration in the CDRB

8.2.1 It is the responsibility of the registered nurse or midwife or ODP who supplies a CD to a doctor, for administration, or who administers a CD to ensure that all sections of the CDRB are completed appropriately.

8.1.2 See section 7.2 (Page 22) for details of records to be made in the CDRB.

8.1.3 A student nurse or student midwife may destroy or witness the destruction of a controlled drug under supervision by a registered nurse or midwife in the presence of a second registered nurse or midwife or ODP. Individual doses of controlled drugs which have been prepared but not administered should be destroyed by following the above procedure and the reason documented in the CDRB.

8.3 Midwives Exemptions

8.3.1 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.

8.3.2 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

8.3.3 Midwives will record the administration of a BHSCT category A CD in the once only section of the Medicines prescription and Administration Record (Kardex). The administration record must be endorsed 'midwife's exemption'.

8.3.4 For further information click on the link below;
http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/Midwives/index.htm

8.4 Administration of opioids - Reducing dosing errors with opioids

8.4.1 When opioid medicines are administered, in anything other than acute emergencies, the doctor, nurse or midwife, should, in conjunction with the witness:

- Check the previous dose administered in comparison with the dose to be administered and 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)

- ensure familiarity with the following characteristics of the medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects

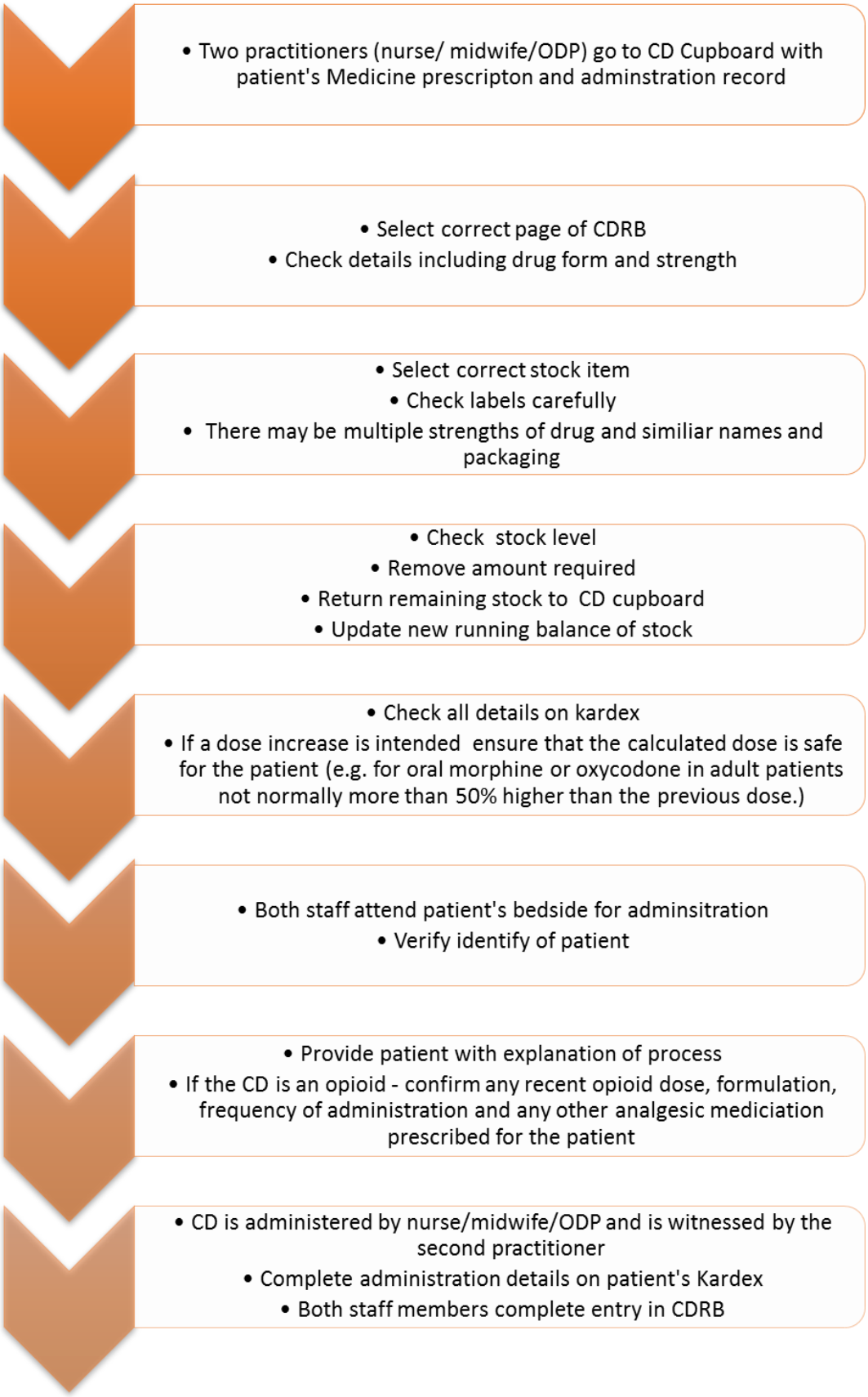
8.5 Clinical monitoring of controlled drugs

8.5.1 The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015 came into operation on 16th July 2015 and require controlled drug procedures to include best practice relating to clinical monitoring of patients prescribed controlled drugs.

8.5.2 Staff administering controlled drugs to patients should refer to the standard operating procedure for clinical monitoring of patients prescribed controlled drugs.

8.5.3 See BHSCT policy, Clinical monitoring of patients prescribed controlled drugs policy (2016).

Chart 1: Flowchart for the administration of CDs



CDSOPA (9)	Prescribing, administration, destruction and record keeping of Controlled Drugs in theatres and recovery

9.0 Prescribing, administration, destruction and record keeping of CDs in theatres and recovery

9.0.1 Registered nurses and midwives must follow Nursing and Midwifery Council standards and guidance (http://www.nmc-uk.org) and the BHSCT Medicines Code in relation to the administration of medicines.

9.0.2 Registered operating department practitioners must follow the Health and Care Professions Council standards and guidance (http://www.hcpc-uk.org) and the BHSCT Medicines Code in relation to the administration of medicines.

9.0.3 The BHSCT management of controlled drugs in relation to prescribing, storage, administration and record keeping may exceed the Misuse of Drugs Regulations or non-CDs may be managed in the same way as CDs. This is to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

9.0.4 The sister/charge nurse, team leader or nurse or midwife or ODP in charge of an operating theatre or theatre suite is responsible for ensuring that staff comply with the Trust systems and that procedures are in place for the management of CDs within their area of responsibility.

9.0.5 The requirements for storage and access, record keeping and prescribing of controlled drugs, described previously, and in the BHSCT Medicines Code apply equally to theatres.

9.0.6 Controlled drugs MUST not be administered on the basis of only a verbal order even if the verbal order is given in the presence of a doctor.

9.1 General principles for the supply, administration and destruction of CDs in theatres

9.1.1 There should be a separate CD record book (CDRB) for each theatre.

9.1.2 Theatre and recovery and critical care areas should use a CDRB which permits more detailed records of controlled drugs issues, administrations and disposal.

9.1.3 Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.

9.1.4 The supply of a CD to an anaesthetist must be witnessed by a registered nurse or midwife or ODP. This must be recorded in the CDRB.

9.1.5 The anaesthetist is responsible for the safe and appropriate preparation and administration of a CD to the patient, in the presence of, but not necessarily witnessed by, a registered nurse/midwife/ODP.

9.1.6 The destruction of any surplus drug (e.g. part of an ampoule or infusion not required) must be safely disposed of and witnessed by a registered nurse/midwife, before the anaesthetist leaves the theatre with the patient. The anaesthetist and registered nurse/midwife/ODP must record the destruction of the controlled drug in the CDRB (see 'record keeping' below).

9.2 Anaesthetic chart / anaesthetic chart kardex

9.2.1 The anaesthetic chart is used to record the prescribing and administration of any drugs, including controlled drugs, intra-operatively and immediately post-operatively.

9.2.2 The anaesthetic chart is also referred to as the anaesthetic chart kardex. The anaesthetic chart kardex is used in conjunction with the main Medicine Prescription and Administration Chart (main kardex) when the patient is in theatre or recovery ward.

9.3 Record keeping

9.3.1 Intra-operative documentation and handover

9.3.2 Controlled drugs prescribed and administered during surgery including epidural / IV PCA infusions must be recorded on the intra-operative section of the anaesthetic chart kardex.

A record of administration should be made on the appropriate chart immediately after administration by the practitioner who administered in the controlled drug. This should include:

- Identity of the person
- The dose administered
- Time of administration

9.3.3 Times must be recorded using the 24-hour clock annotation when prescribing / administering controlled drugs.

9.3.4 A list of names and signatures of anaesthetic staff should be retained by theatre sister and reviewed every 6 months for changes and additions.

9.3.4 The witnessed supply of controlled drugs and witnessed destruction of waste must be recorded in the controlled drug record book (CDRB). Refer also to section 9.6.

9.3.5 Anaesthetists are responsible for any CD supplied to them and registered nurses or midwives or ODPs must not dispose of any syringes or infusions labelled as containing CDs at the end of a list. This is the anaesthetist's responsibility. A registered nurse or midwife or ODP must witness the destruction and both must record the witnessed destruction in the CDRB

9.4 General principles for managing epidural/IV PCA infusions commenced in theatre

9.4.1 The checking and connection of an epidural/IV PCA infusion into an epidural/IV PCA pump by a registered nurse/midwife or ODP in recovery ward must be witnessed by another registered nurse/midwife or ODP following written prescription by an anaesthetist.

9.4.2 Both will record the preparation of the CD in the recovery CDRB.

9.4.3 One of these nurses or midwives or ODP is responsible for transferring the epidural/IV PCA infusion into theatre, to check the labelled contents of the pre filled bag and the programme settings on the pump for epidural infusion with the prescribing anaesthetist in the presence of the theatre nurse/midwife.

9.4.4 The responsibility for the controlled drug transfers from the recovery nurse/midwife or ODP (discharging ward/dept.) to the theatre nurse/midwife/ODP (receiving ward/dept.).

9.4.5 A record of the transfer from one area to another must be recorded on the epidural observations chart by both the recovery and theatre nurse/midwife/ ODP.

9.4.6 The anaesthetist must connect the epidural infusion to the patient's epidural catheter in the presence of, but not necessarily witnessed by, a registered nurse or midwife or ODP in theatre.

9.4.7 Additional information may be found in the relevant trust policies on epidural analgesia and patient controlled analgesia.

9.4.1.1 Immediate post-operative documentation and handover (recovery ward)

9.4.1.2 The anaesthetist and anaesthetic nurse provide a handover to the recovery nurse/midwife which includes the medications, including controlled

drugs, administered intra-operatively and confirmation of pump settings if an epidural / IV PCA pump is present.

9.4.1.3 When a patient is transferred from theatre to recovery, with an epidural or IV PCA infusion containing a controlled drug, the responsibility for the controlled drug transfers from the theatre nurse or midwife (discharging ward/dept.) to the recovery nurse or midwife (receiving ward/dept.).

9.4.1.4 A record of the transfer from one area to another must be recorded on the epidural / IV PCA observations chart by both the recovery and theatre nurse/midwife.

9.4.1.5 The following details must be recorded on the Epidural / IV PCA Observations Chart: date, time, the remaining volume of the controlled drug, signature and ward/dept. name of discharging nurse/midwife and signature and ward/dept. name of receiving nurse/midwife.

9.4.1.6 Medications, including controlled drugs, required during the immediate post-operative period, usually recovery ward, should be prescribed on the section of the anaesthetic chart kardex entitled 'Postoperative instructions'.

9.4.1.7 The witnessed administration of controlled drugs in recovery and witnessed destruction of waste must be recorded in the controlled drug record book See theatre register example.

9.4.1.8 All medications, including injections or infusions of controlled drugs for postoperative administration after the patient leaves recovery ward must be prescribed in the patient's main Medicine Prescription and Administration Chart (main kardex).

9.4.2 Patient transfer to ward

9.4.2.1 The recovery nurse/midwife/ ODP must provide a verbal handover to the ward nurse or midwife. The handover must include:

- a review of medicines prescribed and administered during surgery
- a review of medicines prescribed and administered immediately post-operatively (recovery)
- a review of any additions / amendments made to the medications prescribed on the main Medicine Prescription and Administration Chart (main kardex)

9.4.2.2 When a patient is transferred from recovery to ward, with an epidural or PCA infusion containing a controlled drug, the responsibility for the controlled drug transfers from the nurse/midwife/ODP in the discharging ward/dept. to a registered nurse/midwife from the receiving ward/dept.

9.4.2.3 A record of the transfer from one area to another must be recorded on the epidural/ IV PCA observations chart by both the recovery and ward nurse/midwife/ODP.

9.4.2.4 The following details must be recorded on the Epidural/IV PCA Observations Chart: date, time, the remaining volume of the controlled drug, signature and ward/dept. name of discharging nurse/midwife/ODP and signature and ward/dept. name of receiving nurse/midwife.

9.4.2.5 Medications, including controlled drugs, required on return of the patient to the ward are prescribed by the anaesthetist on the main Medicine Prescription and Administration Chart (main kardex).

9.5 Controlled drugs prescribed as Patient Controlled Analgesia (PCA) or for epidural administration

9.5.1 All controlled drug infusion bags for PCA and epidural analgesia must be prescribed on the patient's Medicine Prescription and Administration Chart (main kardex) in the section headed 'Regular Injectable'.

9.5.2 The minimum prescription details required is shown in the following examples:

For IV PCA	MORPHINE SULPHATE 250 mg in 250 ml sodium chloride 0.9% Start date: (e.g.) 27.07.10 Signature of prescribing doctor or independent nurse prescriber Signature for administration (connection to the patient and infusion initiated)
For epidural analgesia	Concentration of LEVOBUPIVACAINE 1 mg/ml Concentration of FENTANYL 2 micrograms/ ml Volume in bag in 250 ml sodium chloride 0.9% Start date: (e.g.) 27.07.10 Signature of prescribing doctor or independent nurse prescriber..... Signature for administration (connection to the patient and infusion initiated)

9.5.3 In addition to prescribing an epidural or IV PCA on the main Medicine prescription and Administration chart the above information is also recorded as follows:

- The prescription and programme is recorded on the Epidural or PCA Observations Chart
- The prescription and administration is recorded on the intra-operative section of the anaesthetic chart kardex by the anaesthetist
- The prescription is recorded on the post-operative section of the anaesthetic chart Kardex

9.6 Record in the Theatre CDRB

9.6.1 It is the responsibility of the registered nurse or midwife or ODP who supplies a CD to an anaesthetist, for administration, to ensure that all sections of the CDRB are completed appropriately.

9.6.2 The following details should be recorded in the CDRB:

- **Supply**
- Date and time of supply of a CD supplied. Times should be recorded using 24-hour clock notation
- Patient's name and health and care number
- Amount supplied
- Name, formulation and strength – should already be recorded on top of page
- Name and signature of supplying nurse/midwife/ODP and anaesthetist
- **Balance of stock.** Once the stock balance has been updated, the nurse or midwife or ODP should check that the balance tallies with the quantity that is physically present in the CD cabinet. The entry should be signed and dated in the 'stock balance confirmed as correct' column by the nurse/midwife/ODP
- **Administration**
- **Disposal**
- An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed
- In the event **of a patient not** requiring a full dose i.e. wastage of CD it should be disposed of appropriately by the anaesthetist and witnessed by a registered nurse/midwife/ODP. The anaesthetist must record the amount wasted: both the anaesthetist and witness must fully complete the entry in CDRB.

9.6.3 Incremental dosing/ morphine/ fentanyl recovery protocols
Individual doses of a medicine such as that referred to as, "recovery protocols" of morphine sulphate injection that are prepared but the full dose is not administered immediately should document each part dose administered with eth date time and signature of person administering and signature of witness on the appropriate prescription or anaesthetic chart. The entry in the CDRB should reflect the total amount of drug administered and document details of disposal if applicable.

9.6.4 Pharmacy must be contacted immediately if, on opening the box, ampoules are found to be broken or any other discrepancy occurs.

CDSOPA (10)	Destruction of Controlled Drugs on wards/departments including theatre areas

10.0 Destruction of Controlled Drugs on wards/departments

10.1 General

10.1.1 Only small amounts of CDs should be destroyed on wards and departments – for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or the dose is drawn up but not used.

10.1.2 Destruction should be by a registered nurse, midwife, ODP, doctor on the ward or department and witnessed by a second competent professional such as a registered nurse, midwife, ODP, doctor or pharmacist.

10.1.3 Individual doses of controlled drugs which have been prepared but not administered should be destroyed by following the procedure in section 10.2.1 and the reason documented in the CDRB.

10.1.4 All destruction must be documented in the CDRB. Both persons complete the CDRB stating the amount destroyed and the date of the destruction and sign and print names.

10.1.5 Any expired stock must not be disposed of at ward level. Follow the returns procedure detailed in section 11.0 (Page 41). Expired stock must continue to be counted in twice daily CD checks until returned to pharmacy.

10.1.6 Quarantine and contact pharmacy if any controlled drugs are suspected as being tampered with or substandard. Do not destroy at ward level.

10.1.7 Anaesthetists are responsible for any CD supplied to them and registered nurses and midwives or ODPs must not dispose of any syringes or infusions labelled as containing CDs at the end of a list. This is the anaesthetist's responsibility. A registered nurse or midwife or ODP must witness the destruction and both must record the witnessed destruction in the CDRB.

10.1.8 The witnessed destruction of a partially used epidural infusion or IV PCA infusion must be documented on the Epidural or IV PCA Observations Chart.

10.2 Method of Disposal

10.2.1 Follow the guidance in table 5 overleaf.

Table 5 – Method of disposal of various formulations of CDs

Formulation	Method of disposal
Oral drugs dispensed for a patient who has refused administration	Place in a burn bin (designated for pharmaceutical waste), into the bottom of which has been placed liquid soap. Record on the medicine kardex and CDRB that the patient has refused the drug. *Record destruction in CDRB – section 7.2 page 22*
Opened or partly used ampoules or broken ampoules	Empty contents into a sharps bin, which contains some absorbent material (e.g. paper towel) and liquid soap. Place empty ampoules also into the Sharps bin. The sharps bin must be labelled 'mixed pharmaceutical waste and sharps – for incineration' *Record destruction in CDRB – section 7.2 page 22*
Discontinued or partly used patient controlled analgesia (PCA), epidural preparations and solutions administered via a syringe pump	Empty into a burn bin (designated for pharmaceutical waste), into the bottom of which some absorbent material (paper towel) and liquid soap has been placed. Two members of staff must record the volume wasted, print name and sign on the Epidural / IV PCA Observations Chart or syringe pump prescription chart. *Record destruction in CDRB – section 7.2 page 22*
Used or partly used CD transdermal patches (e.g. Durogesic, Transtec, and Butrans)	Fold patch firmly in two and place in the Burn Bin (designated for pharmaceutical waste). *Record destruction in CDRB – section 7.2 page 22*
Sprays	Empty spray containers should be confirmed to be empty (refer to Summary of Product Characteristics) before disposal in a pharmaceutical burn bin. *Record destruction in CDRB – section 7.2 page 22* Partially used sprays must not be disposed of at ward level and must be returned to pharmacy.

CDSOPA (11)	Returns

11.0 Returns

11.1 Returns – general

11.1.1 Unused CD stock, CD stock no longer required, CDs that are time-expired or otherwise unfit for use and patients' own CDs (see section 12) should be returned to pharmacy. Returns will only be processed during normal pharmacy opening hours on Monday to Friday and preferably before 10am.

11.1.2 CD returns should be processed regularly and should not be permitted to accumulate until quarterly CD checks.

11.2.3 CDs that are not ward stock items or which are restricted e.g. Midazolam 10mg/2ml or high strength morphine or diamorphine (30mg or greater) MUST be returned as soon as possible when no longer required.

11.2 Returns procedure

11.2.1 The ward/ dept. should contact pharmacy or the designated pharmacist to arrange for CDs to be returned. The pharmacist will call with the ward at the agreed date/time.

11.2.2 The ward sister or midwife in charge will complete the details of CDs to be returned in the CD order/returns book (**one page per item**). Include:

- Date, name, strength, formulation and quantity
- Complete "reason for return" section. Include the patients name and hospital number / health & care number on the requisition if returning patients own CDs
- Sign and print name by nurse/midwife and pharmacist
- Circle 'return' on the requisition

11.2.3 **If return is ward stock** - Make an entry in CDRB, include date, CD order/returns requisition number, reason for return, sign and print names of /midwife and pharmacist. Update the stock balance column in the CDRB. Sign and date CDRB to confirm balance is correct.

11.2.4 **If return is Patients own CD** – make an entry in the CD POD register, on corresponding line to entry record date, time, quantity (returned) sign and print name of pharmacist and nurse/midwife. Complete the 'Additional comments / transfer' column by recording 'CD PODS returned to pharmacy'.

11.2.5 Items should then be placed in the CD envopak.

11.2.6 The nurse or midwife on duty and in charge will phone pharmacy, before the pharmacist leaves the ward, informing pharmacy staff that the pharmacist is returning CDs. The following details are recorded; name of ward/dept., pharmacist name and the number of items being returned.

11.2.7 The pharmacist remains on the ward and listens whilst the nurse or midwife on duty and in charge makes the call to pharmacy.

11.2.8 The pharmacist will retain the first copy of the requisition and bring to pharmacy together with the drugs to be returned.

11.2.9 A ward may wish to return CDs directly to pharmacy either by the nurse/midwife on duty and in charge or via transport e.g. Muckamore, Knockbracken, Beechcroft. The ward must complete the details of the CDs to be returned to pharmacy in the CD order/returns book including the drug name, strength, formulation and quantity to be returned. In addition, the requisition must be endorsed '**controlled drugs to be returned to pharmacy'**. The ward should contact pharmacy to advise that the CDs are to be returned to pharmacy by the nurse/midwife on duty and in charge. The CD order/returns book and the CDRB must be sealed in the CD envopak along with the CD items being returned and given directly to transport driver. Or the nurse/midwife on duty and in charge must bring the CD order/returns book, the CDRB or CD POD register and the drugs for return to pharmacy at the agreed time. All documentation of the return, as described above, must be completed.

CDSOPA (12)	Patients' own Controlled Drugs

12.0 Patients' own Controlled Drugs (CDs)

12.1 Patients own CDs should not be used for inpatient use and must never be used to treat other patients.

12.2 Patients own CDs should not routinely be stored in the clinical area and should be returned home with the patient's representative (family member or carer) as soon as possible after admission, if considered appropriate.

12.3 The patient's representative should be given advice regarding the necessity for safe storage of the medicines and that other people must not use them**.**

12.4 If the CDs cannot be sent home immediately, they **must** be recorded in the Controlled Drug Patients Own Drug (POD) Register. See section 7.7 (Page 24).

12.5 **CD PODS recorded in the CD POD register must be counted and verified as correct as part of the twice daily CD handover checks.**

12.6 There should be a record made in the CD POD register at each stock check to confirm that a check of the CD cabinet for CD PODs and CD Discharge prescriptions which may have been received since the previous check.

12.7 There should be a review of the CD POD register at each stock check to ensure that all entries have been updated i.e. all CD discharge prescriptions and CD PODs that have been issued to patients have been completed.

12.8 The CDs should be placed in a re-sealable bag or envelope and clearly marked with a patient identifier if available a tamper evident bag may be used; the serial number must be recorded in the CD POD register.

12.9 The bag / envelope must be placed in the CD cabinet and kept separate from ward stock.

12.10 The CD POD register must be completed if the CDs are subsequently returned to the patient or patient's representative.

12.11 If the CDs have been discontinued, and if the patient or the patient's representative agrees, the CDs should be returned to the pharmacy for safe destruction – following the procedure described in section 11.0 (Page 41).

CDSOPA (13)	Management of Sativex® in BHSCT

13.0 Management of Sativex® in BHSCT

13.1 Sativex® is a MHRA licensed preparation of botanical extract of cannabis and is regulated as schedule 4.1 controlled drug, however there is a record keeping requirement pertaining to issues and returns.

13.2 Sativex® will be managed as a schedule 2/ BHSCT category A controlled drug in relation to:

- Prescribing for patients – prescriptions must be written on BHSCT Controlled Drug prescription form
- Returns – must be managed using the schedule 2 order/returns book

13.3 Safe custody requirements do not apply to Sativex®- it must be stored in a locked fridge (or in a locked medicine cupboard once the spray has been opened and in use).

13.4 Administration of Sativex® must be recorded on the in-patient prescription and administration record.

13.5 Patients who bring their own supply of Sativex® into hospital will be permitted to use Sativex® during their in-patient stay if it is deemed appropriate to do so. All administrations of Sativex® must be recorded on the in-patient prescription and administration record.

13.6 Returns of Sativex® must be completed using the schedule 2/ BHSCT category A controlled drug book.

CDSOPA (14)	Transfer of CDs with a patient

14.0 Transfer of CDs with a patient

14.1 The circumstances are limited where a CD will move with a patient. This is due to the restriction in the Misuse of Drugs Regulations 2002 which prevents CDs being supplied from ward to ward.

14.2 Patient controlled analgesia (IV PCA), epidural or administration via syringe pump or by transdermal patch are examples of occasions when a CD may need to move with the patient only when attached to the patient.

14.3 All information relating to the transfer of PCA, epidural or syringe pump (including signatures of those involved in the transfer) should be in line with transferring responsibility of a CD. The date and time (using 24-hour clock) of transfer, should be recorded on the PCA/epidural monitoring chart or syringe pump prescription chart.

14.4 Patients own controlled drugs in storage on a ward/dept. may be transferred with a patient when the patient is transferring to a new ward/dept. The patient's own CDs must be signed out of the transferring ward's CD POD register and entered into the CD POD register of the receiving ward. This transfer of CDs must be verbally communicated between nursing staff from transferring to receiving ward.

CDSOPA (15)	Discrepancies with stock balance

15.0 Discrepancies with stock balance

15.1 Refer also to BHSCT policy 'Dealing with discrepancies or concerns involving Controlled Drugs'

15.2 If there is a discrepancy in the stock balance of BHSCT category A CDs this must be reported, investigated and resolved promptly. It is important to remember that a discrepancy may indicate diversion.

15.3 In the first instance check that:

- All CDs administered have been entered into the CDRB correctly
- Arithmetic is correct, to ensure that balances have been calculated correctly
- All requisitions received have been entered into the correct page of the CDRB
- Items have not been accidentally put into the wrong place in the cabinet

15.4 If the error or omission is traced then the registered nurse/midwife should make an entry in the CDRB, clearly stating the reason and the correct balance. This should be witnessed by a second registered health professional, both of whom must sign the CDRB.

15.5 Any volume discrepancies with oral liquid formulations of +/- 10% of expected volume must be recorded on Trust IR1 form.

15.6 **If the discrepancy is not resolved by the above measures the nurse or Midwife on duty and in Charge and a designated / senior pharmacist must be informed without delay and an incident form completed. The nurse or midwife lead for the clinical area must also be informed.**

15.7 **The Pharmacy Services Manager will decide on the action required and will inform the police if appropriate.**

Refer also to:

BHSCT policy 'Dealing with discrepancies or concerns regarding controlled drugs'

Link: http://intranet.belfasttrust.local/policies/Documents/Controlled Drugs- **dealing** with discrepancies or concerns.pdf

CDSOPA (16)	Ward / Department CD stock checks

16.0 Ward / Department CD stock checks

16.1 The stock balance of ALL CDs recorded in the CDRB and CD POD register **must** be checked at each change of shift with the minimum of a TWICE DAILY check. This applies to all wards and day units.

16.2 The CD check must be carried out by two registered nurses or midwives one of whom will be the nurse/midwife on duty and in charge or a nurse/midwife delegated by the nurse or midwife on duty and in charge.

16.3 If the check occurs at the change of shift the two members of staff carrying out the check should be composed of one from the day staff and one from the night staff.

16.4 Where the CD stock check is undertaken at shift change this represents the transfer of responsibility for controlled drugs. The controlled drug keys must also be formally transferred to the registered nurse or midwife, on duty, and in charge.

16.5 The CD check must involve checking the exact quantity of each CD recorded in the CDRB and CD POD register against the quantity in cabinet. **Always check from register to cabinet. Not the reverse.**

16.6 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**.

16.7 Packs with the tamper proof seal still intact should not be opened but counted as containing the amount specified on the box label. The check should confirm that the tamper evident seal is intact.

16.8 The CD checks must be recorded on the section provided at the back of the CDRB or CD POD register.

16.9 Appropriate action must be taken to report and resolve any discrepancies. It is not sufficient to only record discrepancies in the CDRB / CD POD register and not take the necessary action.

16.10 Staff signatures **must not** be recorded in advance of the CD check i.e. staff undertaking a CD check in the morning MUST NOT pre-sign the evening CD check in anticipation of undertaking the evening CD check.

16.11 The sister/charge nurse, team leader or nurse or midwife in charge of a ward/dept. should carry out a quarterly observational audit of practice and

record this using the proforma in SOP Appendix g. A copy of the audit should be forwarded to pharmacy.

CDSOPA (17)	Three monthly (quarterly) CD checks by pharmacy staff

17.0 Three monthly (quarterly) CD checks by pharmacy staff

17.1 A pharmacist will arrange a suitable time with the sister/charge nurse, team leader or nurse or midwife or ODP in charge of the ward/dept. for the 3 monthly check to be carried out. Alternatively, three monthly CD checks may be carried out as unannounced checks with the registered nurse or midwife or ODP on duty and in charge. Quarterly controlled drugs checks are mandatory.

17.2 The three monthly CD check documentation is provided in SOP Appendix h (page 45). Each standard will be checked in turn in the presence of the nurse or midwife or ODP on duty and in charge. Any variations from the standard are recorded on the quarterly CD check form.

17.3 The pharmacist will perform a physical check of the CDs and check the stock balance in the CDRB in the presence of the nurse or midwife or ODP on duty and in Charge.

17.4 The actual volume of CD liquids must be measured and recorded. Note that liquid medicines must be endorsed with the date of opening and discarded after 1 month or as directed by the manufacturer.

17.5 The pharmacist and registered nurse or midwife or ODP must record the CD check in the CDRB confirming the stock balance to be correct. See exemplar example in appendix e (Page 43).

17.6 The check includes a review of entries and returns in both the CDRB and CD POD Register and a review of the twice daily CD handover check documentation. The check also includes a spot check of authorised signatory list.

17.7 A review of CDRB entries is undertaken for unexplained exceptional usage or peculiar patterns of usage of CDs.

17.8 Any deviations from the trust policy will be recorded and the ward/dept. Sister / Nurse or Midwife in Charge will agree a date for remedial action to be completed usually within 4 weeks.

17.9 A copy of the CD check form is provided to the registered nurse or midwife or ODP undertaking the check and must be provided to the sister/charge nurse, team leader or nurse or midwife or ODP in charge of a ward/dept. Quarterly CD check forms are subsequently emailed to Co-Directors and copied to the appropriate Associate Director of Nursing and service manager

17.10 It may be necessary to complete checks more frequently than at 3 monthly intervals.

17.11 A pharmacist designated to complete quarterly CD checks for a ward / dept. must complete a final or handover check before handing over this responsibility to another pharmacist.

17.12 A CD check must be competed at the closure of a ward/dept.

17.13 CD check documentation must be retained for 5 years.

CDSOPA Appendix a: BHSCT Discharge Prescription for Controlled Drugs

Belfast Health and Social Care Trust
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Prescription for Controlled Drugs

CDA 49301

This prescription must be completed in ink and must be signed by the prescriber with their usual signature.

Patient's Name: JOSEPH BLOGGS
Hospital Number: 102030
Patient's Home Address: (IN FULL) 1 PAIN STREET BELFAST
H & C Number: 12345789
Post Code: BT99 XYZ
Patient's D.O.B: 10/09/52
Hospital: MATER
Ward/Dept: A

Please supply:

Presentation			Prescription				Pharmacy Use Only
Medicine Brand Name	Form	Strength	Dose	Frequency	Route	Quantity	
MST CONTINUS	TAB	10MG	10MG	BD	PO	Words FOURTEEN Figures 14	
						Words ... Figures ...	
						Words ... Figures ...	
						Words ... Figures ...	
						Words ... Figures ...	

Cross out any unused lines. If a dose is prescribed which can only be met by two different strengths then the total quantity (words and figures) of each strength must be specified.

Signature of Prescriber: A Doctor
Date: 2/2/16
(Prescription valid for 28 days from this date)
Prescriber Name: (PRINT) A DOCTOR
Bleep No: # 123

Notes

1. DISCHARGE PRESCRIPTION / PASS / WEEKEND LEAVE PRESCRIPTION

- It is normal practice to supply a maximum of 7 days of prescribed controlled drugs for DISCHARGE prescriptions.
- Send the prescription to Pharmacy as early as possible in advance of discharge / leave.
- Ensure that the controlled drug(s) ordered on this prescription are also referenced on the main discharge prescription form.

2. OUTPATIENT

- Except during titrations or dose adjustments prescriptions for outpatients should be prescribed in multiples of one original pack but with exact quantities specified as above.

LPC 05/11/015

CDSOPA Appendix b: **Controlled Drug Ward/Dept. Stock List**

Ward Stock items should only be removed from stock after consultation between the sister/charge nurse, team leader or nurse or midwife in charge and the assigned pharmacist.

Ward / Department:	

Stock agreed by: (Signature & printed name of the sister/charge nurse, team leader or nurse or midwife in charge):	**Stock agreed by:** (Signature & printed name of Pharmacist):	**Date of CD stock review:**

Quantity of 'active' Controlled Drug Record Books on ward/dept.:	

Ward stock Items – Original Packs only

Controlled Drug (include approved name, form and strength)	**Minimum Stock level (4 days usage)**	**Maximum Stock Level (for guidance only)**

SOP Appendix c: Controlled Drug Signature Registered Nurses / Midwives /ODPs

The ward/dept. Sister / Nurse or Midwife in Charge must approve staff who are authorised to order controlled drugs. The sheet will be subject to regular update.

Ward/Dept.:	Sister/charge nurse, team leader or nurse or midwife or ODP in charge:

Date added	Forename (BLOCK CAPITALS)	Surname (BLOCK CAPITALS)	Staff Number	Signature	Grade	Authorised by* (Signature)	Date removed
In exceptional circumstances Ward Sister/ Charge Nurse may authorise the addition of BHSCT Bank staff to authorised signatory list							

* sister/charge nurse, team leader or nurse or midwife in charge

CDSOPA Appendix d: exemplar completed CD order/returns requisition

Belfast HSC Trust Controlled Drug **Order / Returns** Requisition No: BTCD 32051

Site: MATER | Ward/Dept: A | Order / Return (Circle as required)

One Controlled Drug item per requisition

Please supply the following: Medicine name	Form	Strength	Quantity ordered	Quantity supplied (Pharmacy Use Only)
OxyNORM	CAPs	5MG	56	

Additional Information (*e.g. Patient details if applicable, Reason for return of Controlled drug*)

Authorised Signatory *(Registered Nurse / Midwife in Charge)*

Signature: Anurse
Print Name: A NURSE
Registration/staff No: 12345
Date: 1/2/13

Collected by / Returned to pharmacy by *(Circle as appropriate)*

Signature:
Print Name:
Role/Grade:
Date of collection:

Received and checked by: ward / pharmacy *(Circle as appropriate)*

Signature: Print name: Date:

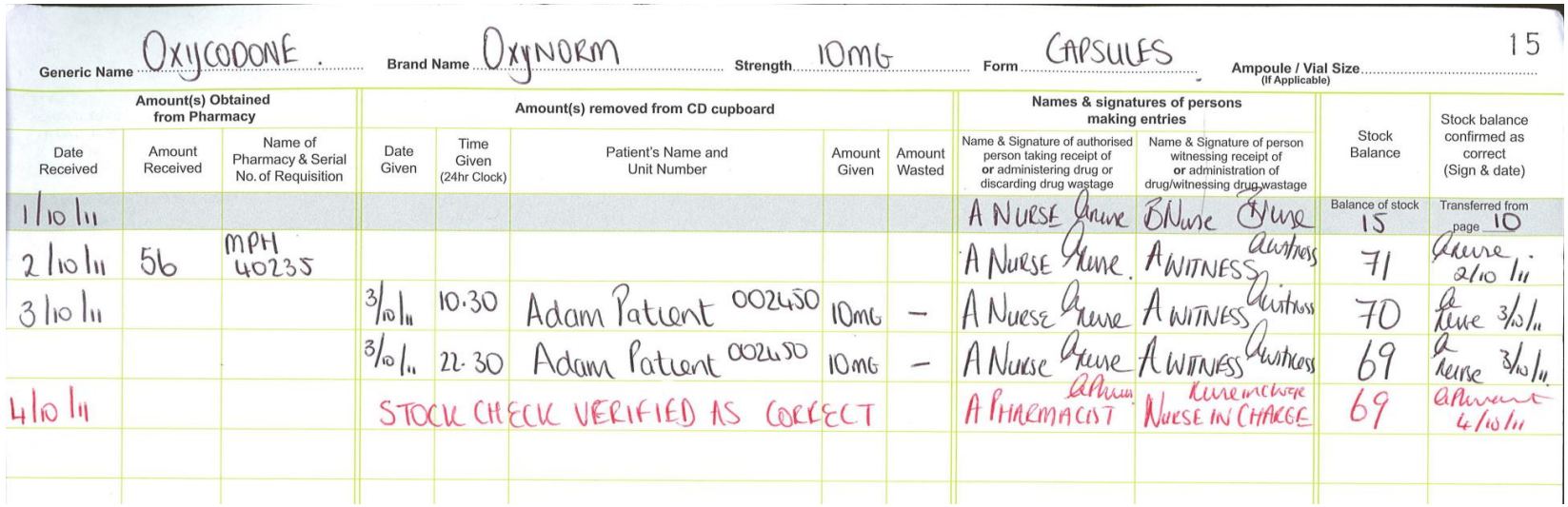
For Pharmacy Use Only

Signature of Dispenser: Date Dispensed:
Name of Dispenser:
Signature of Checker: Date Checked:
Name of Checker:
Signature of Supplier: Date of Supply:
Name of Supplier:

Identification requested	Yes	No
If 'no' above why? (e.g. Known)		
Identification provided	Yes	No

Entered into Pharmacy CD Register by: (Signature and printed name)

CDSOPA Appendix e: exemplar example of completed Ward CDRB



Generic Name: OXYCODONE. Brand Name: OXYNORM. Strength: 10MG. Form: CAPSULES. Ampoule / Vial Size (If Applicable): 15

Amount(s) Obtained from Pharmacy			Amount(s) removed from CD cupboard					Names & signatures of persons making entries		Stock Balance	Stock balance confirmed as correct (Sign & date)
Date Received	Amount Received	Name of Pharmacy & Serial No. of Requisition	Date Given	Time Given (24hr Clock)	Patient's Name and Unit Number	Amount Given	Amount Wasted	Name & Signature of authorised person taking receipt of or administering drug or discarding drug wastage	Name & Signature of person witnessing receipt of or administration of drug/witnessing drug wastage		
1/10/11								A NURSE Anurse	B Nurse Bnurse	Balance of stock 15	Transferred from page 10
2/10/11	56	MPH 40235						A NURSE Anurse.	A WITNESS Awitness	71	Anurse 2/10/11
3/10/11			3/10/11	10.30	Adam Patient 002450	10MG	–	A Nurse Anurse	A WITNESS Awitness	70	Anurse 3/10/11
			3/10/11	22.30	Adam Patient 002450	10MG	–	A Nurse Anurse	A WITNESS Awitness	69	Anurse 3/10/11
4/10/11			STOCK CHECK VERIFIED AS CORRECT					A PHARMACIST APharm	Nurse in charge NURSE IN CHARGE	69	APharm 4/10/11

CDSOPA Appendix f: exemplar example of completed CD POD register

CD POD Register: Receipt of CD

Received on Ward

(Record of Patient's own controlled drugs on admission or record of receipt of Discharge script on ward)

9

Date received	Time (24hr)	Patient's Name	Hosp. No.	Prescription number (for discharge scripts)	Drug Name	Strength	Form	Quantity Received	Signature 1 of authorised person taking receipt of drug (sign and print)	Signature 2 of authorised person taking receipt of drug (sign and print)
22/12/12	19.30	JOHN MILLAR	MPH06347	/	OXYCONTIN	10MG	TAB	10	AOkane ADkane	DRdun DRdun
24/12/12	15.00	JAMES JOSEPH	MPH95-12	10240	OXYNORM	20MG	CAP	14	DRdun DRdun	ADun ADun
26/12/12	15.00	JAMES JOSEPH	MPH95-12	10240	OXYCONTIN	10MG	TAB	14	DRdun DRdun	ADun ADun.

Return of CD

Supply / Return to patient / patients representative / pharmacy

(Record of movement of Patient's own controlled drugs from the ward)

10

Date of supply at discharge/transfer	Time (24hr)	Quantity supplied	Signature 1 of authorised person returning (sign and print)	Signature 2 of authorised person returning (sign and print)	Patient/Representative (sign and print)	Relationship of Representative	Additional Comments/Transfer info
27/12/12	10.00	10	ADun ADun	ADun ADun	Jack Mullan	patient	

CD SOP A appendix g: Completed example of BHSCT Theatre and Critical Care CDRB

3

Generic Name	Brand Name	Strength	Form	Ampoule/Vial Size (if applicable)
MORPHINE SULPHATE		10MG/1ML	INJECTION	1ML

Received from Pharmacy			Name and Signatures for Receipts AND Records of Issues								Stock balance	Stock balance confirmed as correct
Date received	Amount received	Name of Pharmacy & Serial No. of Requisition	Date	Time	Patient's Name and NHS Number	Amount S = Supplied A = Administered D = Disposed (state if transferred)	Responsible Person Print Name	Responsible Person Signature	Witness Print Name	Witness Signature	Stock Balance	Signature Date
							Balance transferred from page number.....					
10/11/16	10	RVH 4567			NHS No.	S	A NURSE	Anurse	B NURSE	Bnurse	10	Anurse 10/11/16
						A						
			10/11/16	10.00	JOE BLOGGS NHS No. RVH99-1234	S 10MG	ANAESTHETIST	Danaes.	C NURSE	Cnurse.	9	Cnurse 10/11/16
						A 7.5MG.	D ANAESTHETIST	Danaes.				
						D 2.5MG.	D ANAESTHETIST	Danaes.	D NURSE	Dnurse.		
						S						
						A						
					NHS No.	D						

CDSOPA Appendix h: Controlled Drug Quarterly Check Audit

Date		Time taken	A CD audit will be completed for each ward / department every three months by a pharmacist. A copy of the completed audit will be given to the Ward Sister/ Charge Nurse, Pharmacy Services Manager and the appropriate Co-director. **All remedial actions must be completed within 4 weeks**
Ward/Dept.			
Audit completed by	Sign	Print	
Role			
Witnessed by	Sign	Print	
Role			

Policy Ref	Audit Standard	Y/ N	Problem Identified (inc page numbers and dates) & action(s) required
1.1.1	No unauthorised items stored in CD cabinet		
1.1.3. &3.1	Regulation CD cabinet in use, all CDs and CD stationery stored securely		
2.0	Keys are held by the appropriate person and are separate from main drug keys		
5.2.3	Authorised signatories list is up-to-date (Copy to pharmacy)		
7.0	Running balance maintained, signed and dated		
7.0	Receipts are recorded correctly, name of supplying pharmacy stated		
8.0	All administration / destruction details recorded accurately (including signature and printed name)		
12.5	Patients' Own CDs & discharge CD scripts are documented correctly in CD POD register		
15.1	Twice daily stock checks occur, are signed by two registered nurses; recorded in register		
16.3	Quantity in stock tallies with balance in CDRB & CD POD register		
16.5	A record of stock check has been made in CDRB		
16.7	No unexplained exceptional usage or peculiar patterns of usage of CDs		
16.0	A bung is present in CD liquids dispensed by BHSCT pharmacy departments for ward stock		

Spot checks:

Date of issue	Requisition No.	Item	Quantity issued	CDRB correct	Authorised signatory

Date of return	Requisition No.	Item	Quantity returned	CDRB correct	Pharmacy log completed

Ward / Dept. compliant with BHSCT CD Procedures	Yes	No
IR 1 form completed if required	Yes	No
	IR1#	
Copy to Ward Sister/ Charge Nurse (Insert Name)		
Pharmacy Services Manager (Sign & Date)		

CDSOPA appendix i: Observational audit of administration CD practice

Ward:

Observed by:

Observation of Practice	Observed		Comments
	Yes	No	
Check all details on kardex If a dose increase is intended, it is not normally more than 50% of previous dose. If CD is an opioid, check previous administration and any other prescribed analgesics.			
Obtain controlled drug key from nurse in charge			
Two practitioners go to CD Cupboard with patient's Kardex			
Select correct page of CDRB			
Select correct stock item NB: there may be multiple strengths and similar names and packaging			
Remove amount required, update and sign the new running balance of stock			
Both staff attend patient's bedside for administration			
Verify identify of patient			
Provide patient with explanation of process			
CD is administered and second practitioner witnesses administration			
Both members of staff complete entry and sign CDRB			
Return controlled drug key to nurse in charge			

Feedback:

CDSOPA appendix j: Observational audit of CD handover checks

Ward:

Observed by:

Observation of Practice	Observed		Comments
	Yes	No	
The Controlled Drug handover check must be carried out by two registered nurses/ ODPS one of whom will be the nurse/midwife/ODP in charge (or delegated by nurse/midwife in charge)			
If CD check occurs at the end of shift it will be completed by nurse/ODP in charge from the outgoing check and the nurse/ODP in charge from the incoming shift			
Always check from CD Register Book (CDRB) to cabinet. **Not the reverse**			
Select correct page of CDRB to verify exact quantity recorded in the CDRB and CD POD register against the quantity in the CD cupboard NB: there may be multiple strengths and similar names and packaging			
Stock balances of liquids may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle			
Packs with the tamper proof seal still intact should not be opened but counted as containing the amount specified on the box label. The check should confirm the tamper evident seal is intact			
Record date, time of check, and signatures and designation of both staff members in the stock check section of CDRB and/or CD POD register			
Staff signatures must not be recorded in advance of the CD check i.e. staff undertaking a CD check in the morning MUST NOT pre-sign the evening CD check in anticipation of undertaking the evening CD check			
Check what action would be taken if there was a discrepancy. (knowledge of “Dealing with discrepancies or concerns involving controlled drugs” policy)			

Feedback:

Appendix 4: Standard Operating Procedure - CDSOPB

SOP reference:	**CDSOPB**		
Title:	Standard Operating Procedure (SOP) for the management of BHSCT category B (Schedule 3) controlled drugs		
Ownership:	BHSCT Pharmacy and relevant ward sister/charge nurse, team leader or nurse or midwife in charge	**Status:**	Current
Publication Date:	October 2016	**Next Review:**	October 2019
Ward:		**Site:**	
Local approval by:	**Ward/Dept. sister/charge nurse, team leader or nurse or midwife or ODP in charge:**	Date:	
	Pharmacist responsible for quarterly CD checks:	Date:	

Objective

To ensure that the management of BHSCT category B (Schedule 3) controlled drugs (CDs) across BHSCT is carried out to agreed standards and meets the requirements of Controlled Drug Legislation.

Scope

Standard Operating Procedures (SOPs) are required for every activity relating to every stage of the CDs journey from ordering, transport, receipt, safe storage, supply, administration, destruction to guidance for dealing with an incident. This SOP – CDSOPB will encompass all these elements in turn.

In BHSCT the management of category B controlled drugs may exceed the Misuse of Drugs Regulations or Medicines Act to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

Table 1 (page 2) summarises the ordering, storage and record keeping requirements of category B CDs and Table 2 (Page 3) provides examples of category B CDs which are in stock in BHSCT.

Responsibility

The sister/charge nurse, team leader or nurse or midwife or ODP in charge is responsible for the safe and appropriate management of CDs in that area. The ward/department Sister / Nurse or Midwife or ODP in Charge of a ward, department, operating theatre or theatre suite is responsible for ensuring the staff comply with the Trust systems and that procedures are in place for the management of CDs within

their area of responsibility. Any local deviations from CDSOPB must be documented and approved by a Pharmacy Services Manager.

The sister/charge nurse, team leader or nurse or midwife or ODP in charge must ensure that all relevant staff are appropriately trained in CDSOPB. All staff have a responsibility to notify the sister/charge nurse, team leader or nurse or midwife or ODP in charge of any variations or inability to follow the CDSOPA which must be discussed with pharmacy in order to resolve the issues.

All staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in CDSOPB and the BHSCT policy for dealing with discrepancies or concerns involving controlled drugs

CDSOPB should be used in conjunction with the guidance in the BHSCT Medicines Code.

CDSOPB should be approved on each ward / dept. by the sister / charge nurse, team lead and nurse or midwife or ODP in charge and the pharmacist responsible for controlled drug checks. It should be used locally for induction training and as a source of information for any queries relating to CDs.

Document control
The sister/charge nurse, team leader or nurse or midwife or ODP in charge is responsible for ensuring all relevant staff are notified of any changes to the CDSOPB and for removing the superseded SOP from the clinical area.

CDSOPB will be reviewed every 3 years but in the event of any incident or near miss of a serious nature it will be reviewed immediately.

Procedures
Table 6 (Page 48) details the procedures applicable to BHSCT category B controlled drugs.

Midazolam
Midazolam 10mg/2ml is restricted issue in accordance with the recommendations from the NPSA Rapid Response Report, Reducing risk of overdose with midazolam injection in adults (NPSA/2008/RRR011). Midazolam 10mg/2ml must be ordered on a named patient basis by wards not authorised to hold as a stock item.
Flumazenil must be available on a ward / dept. where midazolam is in stock, prescribed or in use.

Table 6: Management of BHSCT category B controlled drugs

BHSCT CD category (SOP ref CD SOP B)	CD category B (CDSOPB)
Schedule	Schedule 3 CDs (except temazepam, diethylpropion, buprenorphine, flunitrazepam)
Drugs by schedule (Refer to Table 2 (Page 3) for examples of CDs held in stock in BHSCT - Dec12)	**Schedule 3**: Includes the barbiturates (amylobarbitone, butobarbitone, phenobarbital), mazindol, meprobamate, **Midazolam**, pentazocine, phentermine, **Tramadol**
Storage – including patients own drugs (PODs) and returns	Ward medicines cupboard or medicines trolley or Patient's bedside medicines storage locker.
Key holding and access to category B CDs	Sister/charge nurse, team leader or nurse or midwife or ODP in charge is responsible for medicine cupboard keys which should be separate from CD keys. Medicines keys MUST NOT be handed to staff unauthorised to access medicine cupboards including medical staff.
CD Stationery	Requisitions for Category B (Schedule 3) controlled drugs must be written in the Category B/Schedule 3 Order returns book (Blue book). The Category B/Schedule 3 CD order/returns book must be stored securely in a locked drawer or in medicines cupboard.
Prescribing of Controlled Drugs	**Prescription writing requirements apply** **Follow guidance in CDSOPA (4)** **Discharge, out-patient and temporary leave (weekend and pass) prescriptions must be written on the BHSCT Discharge Prescription for Controlled Drugs.**
Ordering CDs for ward/dept. stock	BHSCT Category B/Schedule 3 CD order/returns book must be used for ordering category B controlled drugs. Follow the guidance in CDSOPA (5). **Midazolam 10mg/2ml injection must be ordered on a named patient basis by wards not authorised to hold as a stock item.**
Collection / transportation and receipt of ward stock CDs onto a ward or department	Follow the guidance in CDSOPA(6).
CD Record Keeping	Category B controlled drugs **are not** recorded in the controlled drug record book (CDRB).
Administration of CDs (except in theatres[1])	The administration of category B controlled drugs should follow the guidance in BHSCT Medicines Code.
Prescribing, administration, destruction and record keeping of Controlled Drugs in theatres and recovery	CDSOPA(9) applies however category B CDs do not require record keeping in the CDRB.
Destruction of Controlled Drugs on wards/departments	Follow guidance in CDSOPA (10) however record keeping in the CDRB is **not required.** Only small amounts of CDs should be destroyed at ward level, e.g. the surplus when a dose is smaller than the total

[1] Including areas where anaesthesia involving the administration of controlled drugs is practiced

	quantity in a vial. All controlled drugs must be denatured before disposal see guidance in table 5.
Destruction of Controlled Drugs in theatre areas	Follow guidance in CDSOPA (10) however record keeping in the CDRB is **not required.** Only small amounts of CDs should be destroyed at ward level, e.g. the surplus when a dose is smaller than the total quantity in a vial. All controlled drugs must be denatured before disposal see guidance in table 5.
Returns	**Must be returned by pharmacist / nurse or midwife in charge directly to pharmacy using** BHSCT Category B/Schedule 3 CD order/returns book. One item per page is completed with the relevant information**,** for guidance see procedure in CDSOPA (11) **Record keeping in CDRB or CD POD register not required.**
Patients own Controlled drugs	Follow guidance in CDSOPA (12) however record keeping in CD POD register is **not required.**
Transfer of CDs with a patient	Patients own controlled drugs in storage on a ward / dept. may be transferred with a patient when the patient is transferring to another ward/dept.
Transfer of ward stock CDs	Transfer of ward stock controlled drugs is strictly prohibited.
Discrepancies with stock balance	Category B CDs are not recorded in the CDRB however if any concerns or discrepancies arise refer to BHSCT policy for dealing with discrepancies or concerns involving controlled drugs.
Ward / Department CD stock checks	Not applicable
Three monthly (quarterly) CD checks by pharmacy staff	Not applicable
Pharmacy storage	CD room / robot
Pharmacy CD register	No
Retention of invoices for 2 years	Yes
Permitted in Emergency cupboard	No

Appendix 5: Standard Operating Procedure - CDSOPC

SOP reference:	**CDSOPC**		
Title:	Standard Operating Procedure (SOP) for the management of BHSCT **category C (Schedule 4 and 5)** controlled drugs		
Ownership:	BHSCT Pharmacy and relevant ward sister/charge nurse, team leader or nurse or midwife in charge	**Status:**	Current
Publication Date:	October 2016	**Next Review:**	October 2019
Ward:		**Site:**	
Local approval by:	**Ward/Dept. sister/charge nurse, team leader or nurse or midwife or ODP in charge:**	Date:	
	Pharmacist responsible for quarterly CD checks:	Date:	

Objective

To ensure that the management of BHSCT category C controlled drugs (CDs) across BHSCT is carried out to agreed standards and meets the requirements of Controlled Drug Legislation.

Scope

Standard Operating Procedures (SOPs) are required for every activity relating to every stage of the CDs journey from ordering, transport, receipt, safe storage, supply, administration, destruction to guidance for dealing with an incident. This SOP – CDSOPC will encompass all these elements in turn.

In BHSCT the management of category C controlled drugs may exceed the Misuse of Drugs Regulations or Medicines Act to ensure a higher level of governance and to achieve clear and consistent procedures across the Trust.

Table 1 (page 2) summarises the ordering, storage and record keeping requirements of category C CDs and Table 2 (Page 3) provides examples of category C CDs which are in stock in BHSCT.

Responsibility

The sister/charge nurse, team leader or nurse or midwife or ODP in charge is responsible for the safe and appropriate management of CDs in that area. The ward/department Sister / Nurse or Midwife or ODP in Charge of a ward, department, operating theatre or theatre suite is responsible for ensuring the staff comply with the Trust systems and that procedures are in place for the management of CDs within their area of responsibility. Any local deviations from CDSOPC must be documented and approved by a Pharmacy Services Manager

The sister/charge nurse, team leader or nurse or midwife or ODP in charge must ensure that all relevant staff are appropriately trained in CDSOPC. All staff have a responsibility to notify the sister/charge nurse, team leader or nurse or midwife or

ODP in charge of any variations or inability to follow the CDSOPA which must be discussed with pharmacy in order to resolve the issues.

All staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in CDSOPC and the BHSCT policy for dealing with discrepancies or concerns involving controlled drugs

CDSOPC should be used in conjunction with the guidance in the BHSCT Medicines Code.

CDSOPC should be approved on each ward / dept. by the sister / charge nurse, team lead and nurse or midwife or ODP in charge and the pharmacist responsible for controlled drug checks. It should be used locally for induction training and as a source of information for any queries relating to CDs.

Document control

The sister/charge nurse, team leader or nurse or midwife or ODP in charge is responsible for ensuring all relevant staff are notified of any changes to the CDSOPC and for removing the superseded SOP from the clinical area.

CDSOPC will be reviewed every 3 years but in the event of any incident or near miss of a serious nature it will be reviewed immediately.

Procedures

Table 7 details the procedures applicable to BHSCT category C controlled drugs.

Table 7: Management of BHSCT category C controlled drugs

BHSCT CD category (SOP ref CD SOP C)	CD category C (CDSOPC)
Schedule	Controlled Drugs Schedule 4 & 5 (excluding controlled drugs managed as BHSCT Category A & B)
Drugs by schedule (Refer to Table 2 (Page 3) for examples of CDs held in stock in BHSCT)	**Schedule 4 (part 1):** Examples include diazepam, oxazepam, lorazepam, chlordiazepoxide, flurazepam, nitrazepam, zolpidem, zopiclone, zaleplon **Schedule 4 (part 2):** androgenic and anabolic steroids **Schedule 5**: co-codamol 8/500, co-codamol 30/500, codeine phosphate tabs, dihydrocodeine tabs
Storage – including patients own drugs (PODs) and returns	Ward medicines cupboard or medicines trolley or Patient's bedside medicines storage locker.
Key holding and access to category C (Schedule 4 and 5) CDs	Sister/charge nurse, team leader or nurse or midwife or ODP in charge is responsible for medicine cupboard keys which should be separate from CD keys. Medicines keys MUST NOT be handed to staff unauthorised to access medicine cupboards including medical staff.
CD Stationery	Not applicable
Prescribing of Controlled Drugs	Prescription writing requirements **do not** apply. Follow guidance in the BHSCT Medicines Code.
Ordering CDs for ward/dept. stock	Category C controlled drugs should be on ward top-up if in routine use. Medications on top-up should not be routinely ordered on requisition. Usage trends will be monitored by pharmacy top-up staff. Category C medicines on top-up will be subject to a yearly review. BHSCT pharmacy requisition book must be used for ordering category C controlled drugs. Pharmacy will monitor requisitions for category C CDs. Follow guidance in the BHSCT Medicines Code section 5.5.
Collection / transportation and receipt of ward stock CDs onto a ward or department	Follow the guidance in the BHSCT Medicines Code section 8.2.
CD Record Keeping	Category C controlled drugs **are not** recorded in the controlled drug record book (CDRB).
Administration of CDs (except in theatres[1])	The administration of category C controlled drugs should follow the guidance in BHSCT Medicines Code – section 4.
Prescribing, administration, destruction and record keeping of Controlled Drugs in theatres and recovery	CDSOPA(9) applies however category C CDs do not require record keeping in the CDRB.
Destruction of Controlled Drugs	Follow guidance in CDSOPA(10) however record

[1] Including areas where anaesthesia involving the administration of controlled drugs is practiced

inwards/departments	keeping in the CDRB is **not required.**
Destruction of Controlled Drugs in theatre areas	Follow guidance in CDSOPA (10) however record keeping in the CDRB is **not required.**
Returns	Unused stock **must** be returned to pharmacy when no longer required. Follow the guidance in the BHSCT Medicines Code section 5.15.
Patients own Controlled drugs	Follow guidance in CDSOPA (12) however record keeping in CD POD register is **not required.**
Transfer of CDs with a patient	Patients own controlled drugs in storage on a ward / dept. may be transferred with a patient when the patient is transferring to another ward/dept.
Transfer of ward stock CDs	Transfer of ward stock controlled drugs is strictly prohibited.
Discrepancies with stock balance	Category C CDs are not recorded in the CDRB however if any concerns or discrepancies arise refer to BHSCT policy for dealing with discrepancies or concerns involving controlled drugs.
Ward / Department CD stock checks	Not applicable
Three monthly (quarterly) CD checks by pharmacy staff	Not applicable
Pharmacy storage	Pharmacy / pharmacy robot
Pharmacy CD register	No
Retention of invoices for 2 years	Yes
Permitted in Emergency cupboard	No

Belfast Health and Social Care Trust
caring supporting improving together

Reference No: SG 18/11

Title:	**Dealing with Discrepancies or Concerns involving Controlled Drugs**		
Author(s)	Eimear McCusker, Accountable Officer, Head of Pharmacy and Medicines Management [redacted] Aideen O'Kane, Lead Pharmacist Controlled Drugs [redacted]		
Ownership:	Caroline Leonard, Director Surgery and Specialist Services		
Approval by:	Drugs and Therapeutics Committee Standards and Guidelines Committee Trust Policy Committee Executive Team Meeting	**Approval date:**	03/04/2019 20/06/2019 01/08/2019 07/08/2019
Operational Date:	August 2019	**Next Review:**	August 2024
Version No.	3	**Supercedes**	V2 – October 2015 – October 2018
Key words:	Controlled Drugs, CD, discrepancies, concerns, accountable officer, incident, fraud		
Links to other policies	BHSCT Controlled Drug Policy Inpatient Areas 2017 http://intranet.belfasttrust.local/policies/Documents/Controlled Drugs Policy – Inpatient Areas.pdf BHSCT Community Controlled Drugs policy 2015 http://intranet.belfasttrust.local/policies/Documents/Community Controlled Drugs Policy.pdf		

Date	Version	Author	Comments
28/01/2011	0.1	E McCusker	Initial Draft
16/02/2011	0.2	S O'Donnell	Updated comments
16/03/2011	0.3	P King	Updated comments
27/04/2011	1.0	A Carrington	Final comments
17/06/2015	1.1	A O'Kane	Update of policy
22/01/2019	2.1	A O'Kane	Update of policy
11/03/2019	3	A O'Kane	Inclusion of 4.2.6

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

Controlled drugs are subject to special legislative controls because there is potential for them to be abused or diverted causing possible harm. The Health Act (2006) introduced regulations to strengthen governance and monitoring arrangements for controlled drugs. The principles of The Health Act were further defined in Northern Ireland by, The Controlled Drugs (Supervision of Management and Use) Regulations 2009.

All healthcare organisations or designated bodies are accountable through the Accountable Officer for ensuring the safe management of controlled drugs. Designated bodies include Health and Social Care Trusts, Northern Ireland Ambulance Service Trust, Health and Social Care Board, Independent Hospitals.

The Accountable Officer is responsible for all aspects of the safe and secure management of controlled drugs in their organisation. This includes ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigation of concerns and incidents relating to controlled drugs.

The Accountable Officer within BSHCT is the Head of Pharmacy and Medicines Management.

Accountable Officers must establish, operate and review appropriate arrangements for the management and use of controlled drugs within their Designated Body or ensure that the Designated Body does so. They must also ensure that any person or body acting on behalf of, or providing services under arrangements made with their Designated body, established, operated and reviews appropriates arrangements for the management and use of controlled drugs.

The Accountable Officer must establish and operate appropriate arrangements for:

- assessing concerns expressed about incidents that involved or may have involved the improper management or use of controlled drugs
- investigating such concerns

The Accountable officer has a statutory duty to share information giving rise to concerns about the management or use of controlled drugs by any “relevant person” As part of the arrangements for ensuring the sharing of information regarding the management and use of controlled drugs, Accountable Officers participate in a single network, covering Northern Ireland known as the Local Intelligence Network (LIN).

Membership of LIN is described in Regulation 18 of The Controlled Drugs (Supervision of Management and Use) Regulations (2009). LIN facilitates the timely and appropriate sharing of information and enables agencies that have a concern about the activities of any staff or organisation to liaise at an early

stage with other local agencies who may be affected or who have complimentary information.

Accountable Offices must provide the Chair of LIN with a quarterly occurrence report. The report may contain the following information:

- details of any concerns regarding the management or use of controlled drugs
- confirmation that there are no concerns to report regarding management or use of controlled drugs

1.2 Purpose

The purpose of this policy to define the process and procedures for dealing with discrepancies or concerns involving the management of controlled drugs within BHSCT. This policy outlines the governance arrangements for the management and use of controlled drugs within BSHCT.

This policy should be read in conjunction with:

BHSCT Controlled Drug Policy – In-patient areas	SG 01/11
BSHCT Controlled Drug Procedures – In-patient areas	SG 01/11
BHSCT Community Controlled Drugs Policy	SG 23/15
BHSCT Medicines Code	SG 09/11
BHSCT Community Medicines Code	SG 06/13

1.3 Objectives

To ensure;

- Appropriate arrangements are in place for managing concerns about incidents involving improper management or use of controlled drugs
- Appropriate action is taken to protect patients and/or the public in cases where concerns appear to be well-founded
- Arrangements are in place for sharing of appropriate information with other responsible bodies via the Local intelligence Network
- Staff are aware of their responsibilities in the reporting of discrepancies or concerns involving controlled drugs

2.0 SCOPE OF THE POLICY

The Dealing with discrepancies or concerns involving controlled drugs policy applies to;

2.1 All trust employed staff who provide BHSCT services within all settings incorporating controlled drug management, .e.g. in-patient, community, care home, intermediate care and domiciliary care settings, and custody suites.

2.2 Services, which may be provided to BHSCT facilities, or non-BHSCT facilities, which are regulated by the Regulations and Quality Improvement Authority (RQIA), including Independent Sector or in the patient's home.

2.3 The Dealing with discrepancies or concerns involving controlled drugs policy covers all schedules of controlled drugs.

3.0 ROLES/RESPONSIBILITIES

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

3.2 Accountable Officer
Accountable Officer responsibilities are defined in Regulations 8-18 of The Controlled Drugs (Supervision of Management and Use) Regulations 2009.

BHSCT Accountable Officer is The Head of Pharmacy and Medicines Management

3.3 Designated officers are the Deputy Heads of Pharmacy;

- Professional Manager Pharmacy Services Acute and Regional
- Professional Manager Pharmacy Services Specialist and Community Services
- Professional Manager Pharmacy Services Procurement and Production

3.4 All staff
All staff are accountable for properly discharging their duties and responsibilities in relation to controlled drugs as detailed in this policy. It is the responsibility of all staff to report any concerns about incidents involving improper management or use of controlled drugs to BHSCT Accountable Officer and any specific concerns relating to staff must also be reported either to the line manager or in line with BHSCT Whistle blowing Policy (TP022/08)

4.0 KEY POLICY PRINCIPLES

4.1 Definitions

Controlled Drugs: Controlled Drugs are "dangerous or otherwise harmful drugs" which are subject to strict legal controls to prevent them being misused; being obtained illegally; or causing harm. The Misuse of Drugs

Regulations includes five schedules that classifies all medicines and the associated legal controls.

Local Intelligence Network (LIN): A Local Intelligence Network (LIN) for Northern Ireland was established as per the legislative requirements of the Controlled Drugs (Supervision of management and Use) Regulations (Northern Ireland) 2009. This legislation imposed a statutory duty of collaboration on healthcare organisations, police forces, social services authorities and the relevant inspection and regulatory bodies. This enables information to be shared about potential controlled drug offences and potential or actual system failures.

4.2 Key Policy Statement(s)

4.2.1 The Controlled Drugs (Supervision of Management and Use) Regulations 2009 applies to all schedules of controlled drugs.

4.2.2 This policy applies to all schedules of controlled drugs – Refer to BHSCT Controlled Drugs Policy for further definition of controlled drug schedules.

4.2.3 Concerns involving improper management or use of controlled drugs must be reported in line with this policy, this includes and is not limited to the procurement, ordering, prescribing, admistering, supply of controlled drugs.

4.2.4 Healthcare professionals **are not permitted to** use stocks of medicines (including controlled drugs) on wards, departments or facilities for their personal use.

4.2.5 BHSCT has a statutory duty of collaboration to share information about potential controlled drug offences and potential or actual system failures.

4.2.6 BHSCT will cooperate fully with Police Service of Northern Ireland in sharing information about potential or actual controlled drug offences.

4.2.7 The Accountable Officer must provide the Chair of LIN with a quarterly occurrence report for the trust detailing concerns.

4.2.8 Healthcare managers must also comply with BHSCT Fraud Policy.

4.3 Policy Principles

4.3.1 Incidents relating to discrepancies

This refers to situations where the quantity of the controlled drug in stock (on a ward or in pharmacy) is different to the level recorded in the controlled drug register or, in the case of pharmacy, also different to that recorded on the JAC computerised stock system.

It is important to be aware that a discrepancy can indicate misuse. All suspected controlled drug discrepancies must be

investigated.

4.3.2 Any unresolved discrepancies during and outside working hours must be reported

4.3.3 Discrepancies Outside Working Hours

An unresolved discrepancy must be reported to the Head of Pharmacy or a Deputy Head of Pharmacy within one working day. All controlled drug related incidents and near misses must be reported in line with the Trust Adverse Incident Reporting and management policy

4.3.3 Other incidents (not relating to discrepancies)

All controlled drug related incidents and near misses must be reported in line with the Trust Adverse Incident Reporting and management policy.

When the Trust Adverse Incident Reporting and management policy is followed, the Accountable Officer for controlled drugs (Head of Pharmacy and Medicines Management) is made aware of all red and orange incidents involving controlled drugs.

4.3.4 Refer to appendix 2 (CD Accountable Officer process for dealing with suspected or confirmed unlawful activity) for details of the subsequent process which the Accountable Officer for controlled drugs will follow in the event of being notified of any issues relating to suspected or confirmed unlawful activity.

4.3.5 Raising and dealing with concerns relating to controlled drugs
Concerns may occur which do not involve specific incidents or near misses but include healthcare matters, such as suspected mistreatment of patients and / or issues relating to the quality of care given, concerns about professional / clinical practice and concerns relating to the competence of staff.

Concerns regarding increased or abnormal usage of controlled drugs may also be identified following a review of usage of drugs liable to misuse within that area.

Any concerns must be reported to the Trust Accountable Officer for controlled drugs and any specific concerns relating to staff must also be reported either to the line manager or in line with the Trust Whistle blowing Policy. Refer to appendix 2 (CD Accountable Officer Process for Dealing with Suspected or Confirmed Unlawful Activity) for guidance.

4.3.5 Individuals nominated by the Designated Officer or Accountable Officer for controlled drugs and a professional Lead for the area will undertake incident reviews. Depending on the nature of the incident / near miss, it may be necessary to include a member of the police force. The Accountable Officer/Designated Officer for controlled drugs should contact the Police in order to determine if this is necessary and for advice regarding the preservation of evidence collected during an investigation which may be required at a later stage for proceedings

instituted by police.

4.3.6 The incident review panel is responsible for investigating the incident and recommending actions. In order to ensure that there is clear separation between the investigation and decision making process, the Accountable Officer for controlled drugs will not be part of the incident review panel but will review the report and suggested actions as a result of the panel review and make the final decision regarding the outcome of the review. Findings and any final action taken, as decided by the Accountable Officer for controlled drugs, will be clearly documented as part of the formal incident review paperwork. The Accountable Officer for controlled drugs must inform the Local Intelligence Network (LIN) of all incident reviews so that trends may be monitored.

4.3.7 Following the implementation of actions from an incident review, the Accountable Officer / Designated Officer for controlled drugs may choose to conduct informal / formal inspections. If this is the case, they must clearly document the findings from the inspection.

4.3.8 In line with The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, there is a statutory duty of collaboration on healthcare organisations, police forces, social services authorities and the relevant inspection and regulatory bodies. This is to enable information to be shared about potential controlled drug offences and potential or actual systems failures. The Accountable Officer for controlled drugs will ensure all information is shared, as required.
A combined Local Intelligence Network (LIN) for Northern Ireland has been established.

4.3.9 Cases considered by the Accountable Officer should be recorded with a clear account of the findings and actions taken. This includes the outcome of any proceedings by the police, civil courts, regulatory body, and disciplinary proceedings as appropriate.

4.3.10 The Accountable Officer will follow the processes outlined in BHSCT Policy Northern Ireland Controlled Drugs Local Intelligence Network (LIN): Guidance for Disclosing Identifying Details of Relevant Persons; completing the necessary risk assessments on disclosure of names to the Controlled Drugs Local Intelligence Network.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This policy is relevant to all trust employed staff that provide services within in-patient and community settings and facilities

- Prescribers (medical, dental and non-medical prescribers)
- Nursing and Midwifery staff

- Pharmacy staff
- Other healthcare staff
- Nursing and residential care home staff
- Domiciliary care staff
- Designated governance leads

The lead author should be notified if there are significant barriers to implementation of this policy.

5.2 Resources

Regulation 7 of The Controlled Drugs (Supervision of Management and Use) Regulations 2009 requires a designated body to provide its Accountable Officer with funds and other resources necessary to enable them to carry out their responsibilities as Accountable Officer.

The Dealing with discrepancies or concerns involving controlled drugs policy will be disseminated through the relevant service groups.

Awareness of the policy will be raised at the Update of Administration of Medicines and Nurse Induction programs.

The policy will be accessible via the intranet.

5.3 Exceptions

Applicable to all BHSCT staff and non-BHSCT staff contracted to provide services for BSHCT involving controlled drugs.

6.0 MONITORING

All errors and near misses involving controlled drugs will be reported in line with local reporting procedures and will include notification to Accountable Officer/Designated Officer or other as nominated

7.0 EVIDENCE BASE / REFERENCES

1. BHSCT Medicines Code 2011
2. BHSCT Community Medicines Code 2013
3. BHSCT Controlled Drugs Policy – Inpatient Areas 2017
4. BHSCT Community Controlled Drugs policy 2015
5. BHSCT Non-Medical Prescribing Policy 2013
6. BHSCT Clinical Monitoring of patients prescribed controlled drugs 2016
7. BHSCT Policy Northern Ireland Controlled Drugs Local Intelligence Network (LIN): Guidance for Disclosing Identifying Details of Relevant Persons
8. DHSSPSNI Safer Management of Controlled Drugs: A guide to good practice in Secondary Care (Northern Ireland) 2012

9. DHSSPSNI Safer Management of Controlled Drugs: A guide to good practice in Primary Care (Northern Ireland) 2013
10. DHSSPSNI The Controlled Drugs (Supervision of Management and Use) Regulations (NI) 2009
11. DHSSPSNI Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Northern Ireland 2009
12. DHSSPSNI Managing and Sharing Concerns 2013
13. DHSSPSNI Safer Management of Controlled Drugs: A guide to strengthened governance arrangements in Northern Ireland 2013 (version 3)
14. DHSSPSNI The Misuse of Drugs Regulations (Northern Ireland) 2002
15. DHSSPSNI Misuse of Drugs (Safe Custody) Regulations 1973
16. NMC Standards for Medicines Management 2010
17. DOH Misuse of Drugs Act 1971
18. DOH The Health Act 2006
19. DOH The Human Medicines Regulations 2012

8.0 CONSULTATION PROCESS

BHSCT Accountable Officer Controlled Drugs

9.0 APPENDICES / ATTACHMENTS

Apendix 1: Reporting of unresolved controlled drug discrepancies in a ward/department/pharmacy

Appendix 2**:** Appendix 2: CD Accountable process for dealing with suspected or confirmed unlawful activity

10.0 EQUALITY STATEMENT

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 this policy/proposal has potential impact and if it should be subject to a full impact assessment. This process is the responsibility of the policy or service lead - the template and guidance are available on the Belfast Trust Intranet. Colleagues in Equality and Planning can provide assistance or support.
The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact ☒

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 **link.**
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

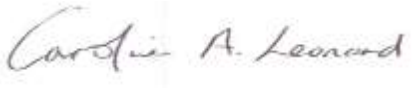
Under the Disability Discrimination Act 1995 (as amended), the Trust has a duty to make reasonable adjustments to ensure any barriers disabled people face in gaining and remaining in employment and in accessing and using goods and services are removed or reduced. It is therefore recommended the policy 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).

07/08/2019

_____ **Date:** _____

Authors

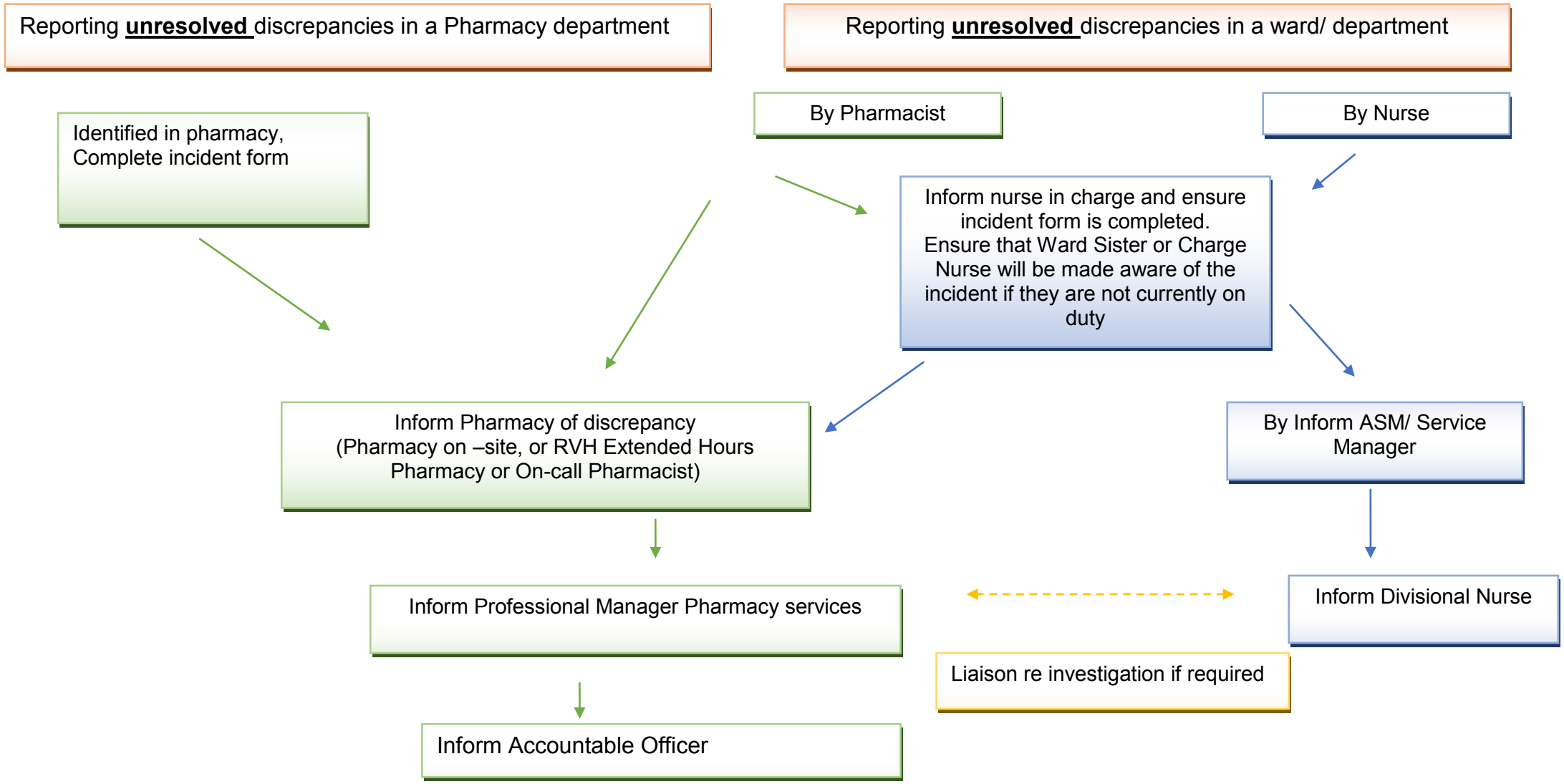


07/08/2019

_____ **Date:** _____

Director

Appendix 1: Reporting of unresolved controlled drug discrepancies in a ward/department/pharmacy



Appendix 2: CD Accountable process for dealing with suspected or confirmed unlawful activity

Identification of Concern

↓

Discuss concern with member of Senior Pharmacy team,
Professional Manager Pharmacy Services,
Lead Pharmacist Controlled Drugs,
Patient Services Manager,
Clinical Pharmacy Lead

↓

Discuss the following with Ward Sister or Charge Nurse

Do Not make any changes to current ward practice

Do Not return stock to pharmacy

Do Not reduce stock holding of medication

Do Not move medication to another location, e.g. controlled drug cupboard

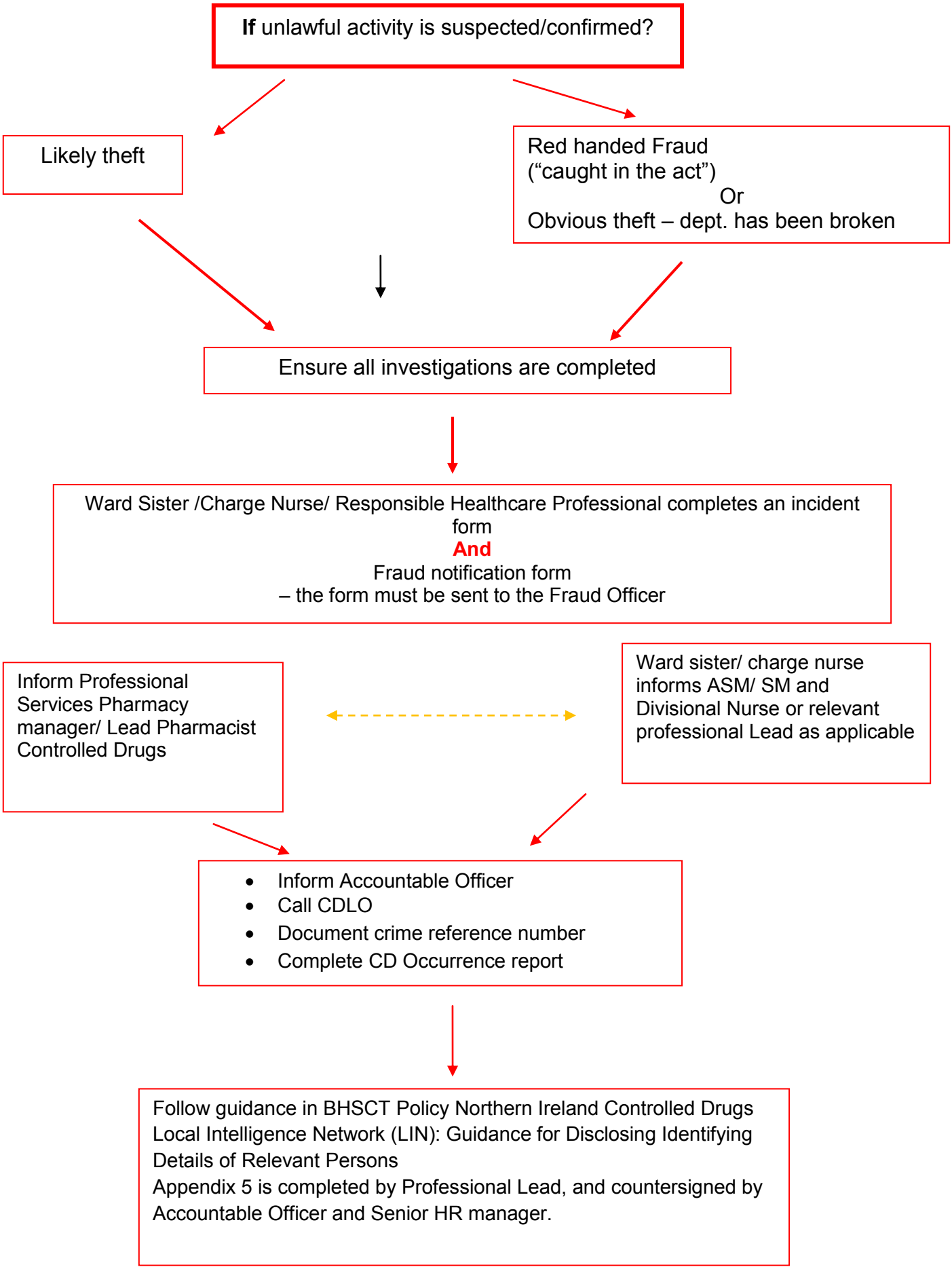
Do Not make any changes to key holding arrangements

↓

Liaise with Assistant Services Manager/ Service Manager/Divisional Nurse for investigation into the concern

The investigation process may include

- Installation of CCTV cameras
- Completing stock check balances on medication concerned
- Reviewing if access was given to drug stocks by staff other than the usual staff in that area
- Reviewing shift patterns for the day of the incident(shift patterns of surrounding days
- Interviewing relevant staff & taking statements
- Asking staff if another member of staff has shown signs of substance misuse
- Reviewing previous incidents to establish if there is a link


If unlawful activity is suspected/confirmed?
Likely theft
Red handed Fraud
("caught in the act")
Or
Obvious theft – dept. has been broken
Ensure all investigations are completed
Ward Sister /Charge Nurse/ Responsible Healthcare Professional completes an incident form
And
Fraud notification form
– the form must be sent to the Fraud Officer
Inform Professional Services Pharmacy manager/ Lead Pharmacist Controlled Drugs
Ward sister/ charge nurse informs ASM/ SM and Divisional Nurse or relevant professional Lead as applicable
Inform Accountable Officer
Call CDLO
Document crime reference number
Complete CD Occurrence report
Follow guidance in BHSCT Policy Northern Ireland Controlled Drugs Local Intelligence Network (LIN): Guidance for Disclosing Identifying Details of Relevant Persons
Appendix 5 is completed by Professional Lead, and countersigned by Accountable Officer and Senior HR manager.

Belfast Health and Social Care Trust
caring supporting improving together

Reference No: SG 03/21

Title:	**Controlled Drugs – Use of Automated Dispensing Cabinets in Clinical Areas**		
Policy Author(s)	Aideen O'Kane, Lead Pharmacist, Controlled Drugs Tel: [redacted]		
Responsible Director:	Caroline Leonard, Director of Surgery and Specialist Services		
Policy Type: (tick as appropriate)	*Directorate Specific ☐	Clinical Trust Wide ☒	Non Clinical Trust Wide ☐
If policy type is confirmed as ***Directorate Specific** please list the name and date of the local Committee/Group that policy was **approved**			
Date:			

Approval process:	Drugs and Therapeutics Committee Standards and Guidelines Committee Executive Team Meeting	**Approval date:**	04/12/2020 02/02/2021 17/02/2021
Operational Date:	February 2021	**Review Date:**	February 2026

Version No.	1	**Supercedes**	New policy
Key Words:	Automated Dispensing Cabinets, Controlled drugs		
Links to other policies	BHSCT Controlled Drugs policy – Inpatient Areas SG 01/15 (2017) BHSCT Dealing with discrepancies or concerns involving controlled drugs (2019) SG 18/11 BHSCT Clinical monitoring of patients prescribed controlled drugs (2019) SG 64/16		

Date	Version	Policy Author	Comments
11/05/2017	0.1	A O'Kane	Initial Draft
17/06/2019	0.2	A O'Kane	Review and inclusion of standard operating procedures in appendices
22/08/2019	0.3	A O'Kane	Review
29/11/2019	0.4	A O'Kane	DIPA screening
16/03/2020	0.5	A O'Kane	Updated following review of Health Building Note
28/07/2020	0.6	A O'Kane	Updates from D&T Committee 4.2.5 & 4.2.9

1.0 INTRODUCTION / SUMMARY OF POLICY

1.1 Background

Controlled drugs (CDs) are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care.

The Misuse of Drugs Regulations permits the use of controlled drugs in a clinical environment: the current version came into operation in 2002 and is periodically revised and amended. The Misuse of Drug Regulations categorises controlled drugs into schedules, which dictate how their use should be regulated. The schedules balance therapeutic use with potential for harm through misuse or abuse.

Following the Shipman Inquiry there have been significant changes in both governance and legislation surrounding the use and management of controlled drugs. The 2006 Health Act introduced regulations to strengthen governance and monitoring arrangements for CDs. The regulations in Northern Ireland are The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. All healthcare organisations are accountable, through the Accountable Officer, for ensuring the safe management of CDs.

The Accountable Officer (AO) for controlled drugs for the BHSCT is the Head of Pharmacy and Medicines Management.

Automated dispensing cabinets incorporates software into a drug storage system, which records the movement of medication, e.g. receipt of medication into cabinet and removal of medication for the purposes of administration.

The benefits of automated dispensing cabinets include:

- Strengthened governance and accountability in relation to the management of controlled drugs
- Increased patient safety
- Increased security
- Improved productivity
- Improved efficiencies
- Improved stock control
- Generation of reports on use of stock and access

1.2 Purpose

The purpose of this policy is to ensure the safe and effective use and management of controlled drugs when using automated dispensing cabinets within BHSCT. This policy should be read in conjunction with:

BHSCT Controlled Drugs policy – Inpatient Areas (2017) SG 01/15
BHSCT Dealing with discrepancies or concerns involving controlled drugs (2019) SG 18/11
BHSCT Clinical monitoring of patients prescribed controlled drugs (2019) SG 64/16

This policy is for staff working within BHSCT who may be involved in the operation of a controlled drug – automated dispensing cabinet. The policy aims, to provide clear instructions for storing, supplying, administering, recording, monitoring and disposing safely of controlled drugs in accordance with legislation, professional standards and best practice standards including:

- Misuse of Drugs Act 1971
- Misuse of Drugs Regulations (NI) 2002 and associated amendments
- The Controlled Drugs (Supervision of Management and Use) Regulations (NI) 2009 and associated amendments
- Safer Management of Controlled Drugs, A guide to Good Practice in Secondary Care (Northern Ireland) updated August 2019

1.3 Objectives

To ensure:

1.3.1 Controlled drugs – automated dispensing cabinets (CD-ADC) are used, and managed safely and securely whilst ensuring patients have timely access to the controlled drugs prescribed for them.

1.3.2 All staff involved in the use and operation of the CD-ADC are aware of their roles and responsibilities in relation to the management of controlled drugs.

2.0 SCOPE OF THE POLICY

2.1 This policy applies to BHSCT staff who may be involved in the use or operation of controlled drug –automated dispensing cabinets. Including nursing, midwifery, operating department practitioners, medical and pharmacy staff.

2.2 This policy will apply to controlled drugs in schedules 2, 3,4 and 5 of the Misuse of Drug Regulations (MDR).

2.3 This policy may also apply to medications deemed high risk of misuse that are not controlled by the Misuse of Drug Regulations and which may be stored in the CD-ADC.

3.0 ROLES AND RESPONSIBILITIES

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

3.2 The Accountable Officer – Controlled Drugs
The BSHCT Accountable Officer (AO) for controlled drugs is the Head of Pharmacy and Medicines Management. The AO is responsible for all aspects of the safe and secure management of controlled drugs and is accountable to the Chief Executive in this regard. This includes:

- Ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigation of concerns and incidents related to controlled drugs and reports to BHSCT Medicines Optimisation Committee in this regard
- To ensure that members of staff who are involved in prescribing, supplying, administering, clinically monitoring or disposing of controlled drugs receive appropriate training to enable them to carry out their duties
- Attendance at the Northern Ireland Local Intelligence Network (LIN) and to submit quarterly occurrence reports identify concerns and incidents relating to controlled drug management in BHSCT and annual declaration and self-assessment

3.3 All staff involved in the operation of CD-ADCs are accountable for properly discharging their duties and responsibilities in relation to controlled drugs as detailed in this policy and the BHSCT Controlled Drugs Policy – In patient areas.

3.4 System Administrator(s)
System Administrator(s) are responsible for:

- Liaising with the CD-ADC provider for onsite maintenance, service and support
- Liasing with BHSCT IT with colleagues to ensure CD-ADC server software updates are enabled
- Design and provide reports on CD management
- Inform the Accountable Officer of any unresolved discrepancies and corrective action taken
- Management of the drug database
- Provision of training to super-users and users of the CD-ADC

- Addition of new users and super-users to the Omnicell database (via a completed user request form – available on the intranet)

3.5 Super- User(s)
Super-Users are senior ward based team members (nursing and pharmacy staff) and are responsible for:

- Ensuring that all standard operating procedures for the CD-ADC are followed correctly
- Provision of training to users of the CD-ADC
- Addition of temporary access rights to the CD-ADC

3.6 User(s)
Users are ward based team members (who may be nursing, pharmacy or medical staff or Operating Department Practitioners (ODPs)).
Users are responsible for:

- Adhering to standard operating procedures outlined in this policy
- Attend any training updates provided by Omnicell, System Administrators or Super-users

3.7 BHSCT IT Department
The System administrators will liaise with BHSCT IT department to ensure compliance with relevant ICT policies.
System administrators will liaise with BHSCT IT department in relation to ongoing server maintenance and updates, archiving and storage arrangements and any other issues, which may arise.
Users of the CD-ADC cabinets will active directory details as logon credentials

3.8 BHSCT Information Governance
The System administrators will liaise with BHSCT Information Governance department to ensure compliance with relevant Information Governance policies

3.9 CD-ADC Cabinet Providers
CD-ADC Cabinet providers are responsible for:

- Installation and maintenance of the CD-ADC
- Adhering to BHSCT IT and Information Governance policy requirements
- Provison of support and service as documented in service agreements with individual areas (all ward areas should have copies of support and maintenance agreements)
- Provision of training to system administrators and super-users
- Assurance that hardware and software is compliant with relevant Misuse of Drugs legislation
- Contacting system administrators to arrange site visits for maintenance and any other matters in advance of visit
- Informing system administrators of calls logged by departments including requests for repairs and solutions provided

- Provide a 24-hour helpline for maintenance and support
- The 24 –hour helpline is **0161 413 5333**

4.0 CONSULTATION

Pilot Project Team Group
BHSCT Accountable Officer

5.0 POLICY STATEMENT/IMPLEMENTATION

5.1 Definitions

5.1.1 Controlled Drugs: Controlled Drugs are “dangerous or otherwise harmful drugs” which are subject to strict legal controls to prevent them being misused; being obtained illegally; or causing harm. The Misuse of Drugs Regulations includes five schedules that classifies all medicines and the associated legal controls.

5.1.2 Local Intelligence Network (LIN): A Local Intelligence Network (LIN) for Northern Ireland was established as per the legislative requirements of the Controlled Drugs (Supervision of management and Use) Regulations (Northern Ireland) 2009. This legislation imposed a statutory duty of collaboration on healthcare organisations, police forces, social services authorities and the relevant inspection and regulatory bodies. This enables information to be shared about potential controlled drug offences and potential or actual system failures.

5.1.3 Standard Operating Procedures (SOPs): Under the terms of the Health Act (2006), Standard Operating Procedures (SOPs) are required for any service that handles controlled drugs.

5.1.4 ADC: Automated Dispensing Cabinets, which are used to automate dispensing, and administration of medications

5.5.5 E-CDR: Electronic Controlled Drug Register, an electronic register (Home Office approved), which records CD entries which are attributable and auditable.

5.2 Key Policy Statement(s)

5.2.1 Any area or department wishing to install an automated dispensing system should identify potential locations and liaise with ADC system administrators as to feasibility.

5.2.2 Automated dispensing cabinets should be located in areas that easily accessible by authorised staff and near patients to support safe and efficient workflow. There should be adequate space around the cabinet to allow safe opening of drawers and bins.

4.2.3 Any area wishing to install an automated dispensing system must have completed the necessary service request processes with IT and estates departments as applicable. Minimum requirements include a internet point with allocation of a static IP address andan electrical power source which should be on the critical supply source.

5.2.4 Any estates and IT requirements must be considered prior to procurement of the ADC to allow suitable time for works requests to be completed.

5.2.5 Areas using a CD-ADC must adhere to the BHSCT CD policy – inpatient areas, except for the following sections which are no longer applicable due to using an electronic CD register:

- CD SOP A (1) – Storage of CDs – all category A CDs are stored in ADC
- CD SOP A (2) – Key holding and access to Category A CDs – ADCs do not have CD keys, access is via authorised biometric access
- CD SOP A 95) – Ordering CDs for ward stock – wards with ADCs have defined days ordering ward stock via a web portal to print a list of CD stock items required (CD requisition books retained for adhoc ordering).
- CD SOP A (7) Record Keeping – receipt of stock, administration and waste of CDs is recorded in the electronic CD register.

NB Wards with ADC must still use the POD CD register

5.2.6 Areas using a CD-ADC must have completed the necessary training and follow the standard operating procedures document.

5.2.7 All staff using a CD-ADC will be issued with a unique user name and password.

5.2.8 All staff using the CD-ADC will have biometric access permissions.

5.2.9 Temporary staff working in an area with a CD-ADC will be issued with a unique user name and password, which will expire after a defined period. Temporary nurses profile expiry dates are customisable from 12 hours to a maximum of 5 days.

5.2.10 Access to controlled drug medications will be defined and restricted to appropriate designated and legally authorised personnel.

5.2.11 The use of medications stored within the CD-ADC is audited and action taken as necessary.

5.2.12 Areas using a CD-ADC will be subject to a quarterly controlled drug audit check.

5.2.13 Designated staff from each area will receive additional training to become super-users. Super-users will be responsible for cascade of training to new staff members, in addition to investigating and resolving discrepancies on the ADC.

4.2.14 New staff members must complete the Omnicell Access request form (appendix 1) available on the controlled drugs section of the medicines management intranet page. Completed formsmust be countersigned by ward sister or deputy and sent to PharmacyIT@belfasttrust.hscni.net
Link to the request form is available here

5.2.14 Each Ward Sister/ Charge Nurse/ Senior Nurse in Charge will be given a set of emergency override keys for the ADC. The emergency override keys must be stored securely at ward level and access to the keys restricted.

5.2.15 Only designated super-users will be trained in the emergency override procedures.

5.2.16 The standard operating procedures are available to ward areas as a separate operational document. The operational procedures are updated by the system administrators.

5.3 Policy Principles

5.3.1 Medications belonging to schedules 2 and 3 and certain medications belonging to schedules 4 and 5 of the Misuse of Drug Regulations will be stored and managed in the CD-ADC.

5.3.2 Medications not controlled by Misuse of Drug Regulations but deemed to be high risk may be stored in the CD-ADC.

5.4 Dissemination

This policy is relevant to registered trust staff with involvement in the operation of CD- ADCs

The lead author should be notified if there are significant barriers to implementation of this policy

5.5 Resources

The policy will be accessible via the intranet.
The policy will be disseminated through the relevant service groups and implementation will include local training events led by the policy authors.

5.6 Exceptions

Patient's own controlled drugs may be stored in the CD-ADC but will require documentation in the BHSCT CD POD register.

6.0 MONITORING AND REVIEW

Ordering, administration and usage patterns for controlled drugs will be monitored in accordance with the Health Act and under the Controlled Drugs (Supervision of Management and Use) regulations 2009.

All errors and near misses involving controlled drugs will be reported in line with local reporting procedures and will include notification to the Accountable Officer/designated Officer or other as nominated.

7.0 EVIDENCE BASE/REFERENCES

1. NICE Controlled drugs: safe use and management NG 46 2016
2. BHSCT Controlled Drugs Policy – Inpatient Areas 2017
3. BHSCT Dealing with Discrepancies or Concerns involving Controlled Drugs 2015
4. DOH The Health Act 2006
5. DHSSPSNI The Controlled Drugs (Supervision of Management and Use) Regulations (NI) 2009
6. DHSSPSNI Safer Management of Controlled Drugs: A guide to Strengthened Governance Arrangements in Northern Ireland 2015 (V4)
7. DHSSPSNI Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Northern Ireland 2009
8. DHSSPNI Safer Management of Controlled Drugs: A guide to good practice in Secondary Care (Northern Ireland) 2012
9. NHS England & NHS Improvement Health Building Note 14-02 Medicines Storage in Clinical Areas Technical Engagement Draft November 2019

8.0 APPENDICES

Appendix 1: Staff User Access Request form

9.0 NURSING AND MIDWIFERY STUDENTS

Nursing and/or Midwifery students on pre-registration education programmes, approved under relevant 2018/2019 NMC education standards, must be given the opportunity to have experience of and become proficient in the **Controlled Drugs – Use of Automated Dispensing Cabinets in Clinical Areas** where required by the student's programme. This experience must be under the appropriate supervision of a registered nurse, registered midwife or registered health and social care professional who is adequately experienced in this skill and who will be accountable for determining the required level of direct or indirect supervision and responsible for signing/countersigning documentation.

Direct and indirect supervision

- Direct supervision means that the supervising registered nurse, registered midwife or registered health and social care professional is actually present and works alongside the student when they are undertaking a delegated role or activity.

- Indirect supervision occurs when the registered nurse, registered midwife or registered health and social care professional does not directly observe the student undertaking a delegated role or activity. (NIPEC, 2020)

This policy has been developed in accordance with the above statement.

Wording within this section must not be removed.

10.0 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 **link**.

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 equalityscreenings@belfasttrust.hscni.net

The outcome of the equality screening for the policy is:

Major impact ☐
Minor impact ☐
No impact ☐

Wording within this section must not be removed

11.0 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 ☐

Wording within this section must not be removed.

12.0 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.

13.0 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).

04/12/2020

_____ **Date:** _____

Policy Author

17/02/2021

_____ **Date:** _____

Director

Appendix 1: Staff User Access Request form

Belfast Health and Social Care Trust

P:\My Pictures\Royal Victoria Hospital_files\BHSCT_Logo_Colour_outlines.png

Omnicell
Inspired by Care™

Omnicell Access Request Form

Please complete and send this form to PharmacyIT@Belfastttrust.hscni.net if you would like access to Omnicell across the Belfast Trust. Any forms that are not authorised below by a senior member of staff will not be processed.

Once access has been granted you will be notified by Pharmacy/Senior Ward Staff and fingerprint enrolment instructions will follow.

Please complete the following details as fully as possible in BLOCK capitals.

New User Details

Full Name: _____

Job Title: _____

Band: _____

Site/Ward/Department: _____

Trust E-mail: _____

JAC Login (Pharmacy only): _____

Super User Access: Y / N **Reason For Access:** _____

Temporary Access required (max 5 days): Y / N **Reason:** _____

Authorised by Senior Staff

Full Name: _____

Signature: _____ **Date:** _____/_____/_____

Pharmacy Use Only

Added to Omni Centre: Y / N **Date Added:** _____/_____/_____

Added By: _____

Belfast Health and Social Care Trust

Reference No: SG 38/14

Title:	**Lithium Policy**		
Author(s)	Stephen Guy, Lead Mental Health Pharmacist, Pharmacy, Knockbracken Dr Michael Doherty, Consultant Psychiatrist		
Ownership:	Dr Cathy Jack, Medical Director		
Approval by:	Drugs and Therapeutics Standards and Guidelines Policy Committee Executive Team Meeting	**Approval date:**	26/11/2014 10/12/2014 15/12/2014 17/12/2014
Operational Date:	December 2014	**Next Review:**	December 2017
Version No.	1	**Supersedes**	
Key words	Safer Lithium		
Links to other policies	Admission Discharge Policy for Mental Health and Learning Disability		

Date	Version	Author	Comments
15/08/13	0.1	Michael Doherty & Stephen Guy	Sections widely shared and developed with comments from Consultant Psychiatrists, Nursing staff and management. Also discussed at Psychiatry D&T committee.
23/1013	0.2	Michael Doherty	Reviewed in Detail by selection of consultant Psychiatrists, Nursing staff and Management.
19/03/14	0.3	Michael Doherty & Stephen Guy	Reformatting and error correction
29/4/14	0.4	Michael Doherty & Stephen Guy	Incorporation of comments from Hilary Rea (clinical Pharmacist), Roan McClean (Consultant with responsibility for lithium). Update to Appendix 7, actions on response to notification of High lithium levels by labs
11/6/2014	0.5	Stephen Guy	Correction of typos and incorporation of comments from D&T Committee 6th June 2014
25/9/2014	0.6	Stephen Guy	Incorporation of arrangements for updating patient held record book and checks on lithium bloods when dispensing lithium discharge prescriptions. Incorporation of all Appendices into one document.

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

The National Patient Safety Agency (NPSA) issued an alert for "Safer Lithium Therapy" in December 2009 (2009/PSA005). This alert arose from the agency's monitoring of patient safety incidents, with regards to lithium, over a five year period from November 2003 to December 2008. During the 5 year period the NPSA received reports of 567 incidents through the National Reporting and Learning System (NRLS). The majority were from mental health services (55%) and from acute hospitals (28%). There were only 5 reports from general practice. The vast majority of these incidents were "No Harm" (82%). There were 36 moderate/severe harm reports (0.067%). An analysis of all 567 incidents revealed that medication error in administration and supply of medication was the most common cause (49%) especially in the area of dose and frequency, prescribing errors (20%) e.g. mismatching between patient and medication, preparation of medication and dispensing in pharmacy (19%). In addition to these reports the NPSA took into account the Royal College of Psychiatrists, Prescribing Observatory for Mental Health (POMH –UK) lithium audit reports.

The patient safety alert called on all frontline mental health services to ensure that patients prescribed lithium are monitored in accordance with the National Institute of Clinical Excellence (NICE) guidelines. The guidelines for the management of lithium are described in the NICE report on Bi-Polar Disorder (July 2006). Also that the managerial system for the clarification of responsibility, decision making and communication systems for the safe management of patients, who are prescribed lithium are put in place. A "Patient Safety Alert " was issued by the Northern Ireland, Department of Health, Social Services and Public Safety (DHSS&PS) in January 2010. This stated that the recommendations had to be in place for December 2010.

The response to the NPSA alert in Northern Ireland was addressed by an expert group established by the DHSS&PS and chaired by Dr Christopher Kelly, consultant psychiatrist. This multidisciplinary group also included Stephen Guy, senior Pharmacist from the Belfast Trust. The group developed lithium Shared Care Guidelines (2011) to be introduced throughout Northern Ireland.

A regional group representing General Practitioners and all five Trusts was established under the chair of Dr Richard Orr, from the GP Integrated Care department of Health and Social Care Board for Northern Ireland (HSCNI). This group had two main tasks. First to co-ordinate the introduction of the NPSA recommendations in Northern Ireland and also to develop and implement a Local Enhanced Service (LES) for lithium based on the Shared Care Guidelines for Lithium and the "Northern Ireland Secondary Care Pathway for lithium Initiation and monitoring'. (Appendix 4)

1.2 Purpose

The NPSA alert of December 2009 (2009/PSA005) has stated that the expected standards in the management of patients on lithium are not being met in many Trusts and many patients have been seriously harmed by lithium. It states that the implementation of the NICE guidelines (Bi-Polar Disorder Report, July 2006) as well as the managerial, decision making and communication systems for the safe

management of patients, who are prescribed lithium should be put in place by December 2010. A Patient Safety Alert, NI DHSS&PS (Jan 2010) has restated this priority for Northern Ireland.

The purpose of this Policy is to implement these guidelines based on the recommendations of the Northern Ireland, Regional Expert Group (2011), which has developed the "Lithium Shared Care Guidelines" and "Northern Ireland Secondary Care Pathway for lithium Initiation and monitoring'.

1.3 Objectives

The main objective is to ensure the Trust's compliance with the mandatory requirements arising from the NPSA Alert (2009) concerning safe lithium prescribing, dispensing and monitoring. These are

- Patients prescribed lithium are monitored in accordance with NICE guidance
- There are reliable systems to ensure blood test results are communicated between laboratories and prescribers
- At the start of lithium therapy and throughout their treatment patients receive appropriate ongoing verbal and written information and a record book to track lithium blood levels and relevant clinical tests.
- Prescribers and pharmacists check that blood tests are monitored regularly and that it is safe to issue a repeat prescription and/or dispense the prescribed lithium.
- Systems are in place to identify and deal with medicines that might adversely interact with lithium Therapy.

In order to implement this in Northern Ireland a regional group developed "Lithium Shared Care Guidelines" (2011) for Northern Ireland and the "Northern Ireland Secondary Care Pathway for lithium Initiation and monitoring. In order to implement this in the Belfast Trust the following are required:

- All patients attending the Trust will be allocated to a specific lithium Pathway (Appendix 9) identified by the Northern Ireland "Shared Care Guidelines (2011)".
- Clarity of responsibility and good communication between Secondary and Primary Care in both directions and use of the regionally developed documents.
- A Trust Lithium Patient List will be developed and maintained with up to date information on the patients attending the Trust.
- Ensure that Patients are fully involved and informed.
- Ensure that this policy links with other Trust policies (Admission /Discharge Policy for Mental Health and Learning Disability).

2.0 SCOPE OF THE POLICY

- This policy applies to all patients who are attending the Belfast Trust who are prescribed lithium. Certain sections are specific to Mental Health and Learning Disability Services.
- Management of lithium in Acute units (non mental health) is covered in Appendix 10
- The Policy is applicable to patients of all ages.
- The "Monitoring Section" (section 4.6) applies to patients on Pathway 1 (where the Trust is responsible for the monitoring of the out- patients on lithium).
- Arrangements for checking lithium levels when a prescription is dispensed by a Trust Pharmacy are included in Section 4.10.1(Mental Health Units) and Section 4.10.2 (Acute Units). The same checks apply irrespective of source of the prescription

3.0 ROLES/RESPONSIBILITIES

- The Medical Director, will ensure that all medical staff will adhere to this policy.
- Associate Medical Director, for the Adult Social and Primary Care Directorate will ensure safe and effective Implementation of the policy, and will also ensure adequate monitoring and regular audit.
- The Director of the Adult Social and Primary Care Directorate will ensure the provision of adequate staffing and training of staff.
- The Service Manager for the Lithium/Clozapine service will be responsible for the day to day management of the Lithium Service and ensuring adherence to this policy.
- There are also specified roles and responsibilities described in the Policy for:
  - Medical Staff
  - Nursing Staff
  - Pharmacy Staff
  - Community Team managers
  - Lithium Nursing Staff
  - Laboratory Staff
  - Administrative and Secretarial Staff

4.0 KEY POLICY PRINCIPLES

4.1 Lithium

Lithium is an Amber Listed Medication and has been the subject of an NPSA Alert (2009). Initiation is normally by a consultant Psychiatrist. The indications for use, features of toxicity, medication interactions and use of lithium are outlined in the Northern Ireland Shared Care Guideline 2011. (Appendix 4)
Detailed prescribing information on lithium can be found in the current edition of the British National Formulary (BNF) or the Summary of Product Characteristics (SPC) for the brand of lithium used (www.medicines.org.uk)

4.2 Definitions

4.2.1 Patient Pathways

The Pathways are those described in the Northern Ireland Regional *"Lithium Therapy Pathway - communication Information from consultant psychiatrist to general practitioner*" (Appendix 3) and "*Lithium Care Flow Chart* "(Appendix 9). The Pathways define who is responsible between secondary and primary care for the monitoring of the patients lithium, the related physical health assessments and their mental health.

- **Pathway 1:** Secondary Care services will be monitoring both the patient's blood and physical assessments in accordance with the Shared Care Guidelines, as well as reviewing them at a psychiatry outpatient clinic. The GP will prescribe lithium on the recommendation of secondary care. Pathway 1 is appropriate for patients starting lithium and for the first few months of treatment.
- **Pathway 2**: The GP will monitor the patient's blood and physical assessments in accordance with the Shared Care Guidelines and prescribe lithium as recommended by secondary care. The patient will continue to attend the psychiatry out-patient clinic. Transfer to Pathway 2 can only occur with the agreement of both the GP and the Consultant Psychiatrist.
- **Pathway 3:** The GP will monitor the patient's blood and physical assessments, in accordance with the Shared Care Guideline. The GP will also review the patient's mental health and prescribe lithium accordingly. There is no contact with secondary care services. Transfer to Pathway 3 can only occur with the agreement of both the GP and the Consultant Psychiatrist.

4.3 Key Policy Statement(s):

- All consultants and prescribers who commence patients on lithium and/or monitor patients on lithium must adhere to this policy.
- All patients' names will be placed on a Data List which will be kept up to date.
- The Lithium Service Manager will ensure safe and efficient running of the Lithium service.
- All Communication Documentation will be carefully adhered to.
- Patient education and involvement in decision making about their care underlies all aspects of this policy.
- There will be regular staff updates within the Trust.
- There will be regular local audits and also participation in the bi-annual lithium audits organised by the Royal College of Psychiatrist's Prescribing Observatory for Mental Health (POMH –UK).

4.4 Recommendation and Registration for Lithium:

The consultant psychiatrist is responsible for the recommendation that lithium is initiated and the Patient Registration Form (Appendix 1) is completed. The completed Registration Form is sent to the Lithium Nurse who will record the patient on the Lithium Patient List (Section 4.9) and make arrangements for attendance at lithium clinics in the community

The referral should be accompanied by a Risk management form and any relevant clinical details. If the patient is in hospital the lithium nurse will make arrangements for clinic appointments at the time of discharge.

4.5 Pre- Lithium Assessments and lithium initiation Process:

4.5.1 Location:

Patients attending the generic Recovery teams will have their pre-assessment tests for lithium initiation completed at one of the Trust lithium clinics. Those attending specialist teams or are inpatients will have their pre assessment and initiation checks completed by nursing and medical staff from those teams, or through agreement with the Lithium Nurse, at the Lithium clinic. These teams include for example

- Home Treatment Team
- Mental Health Inpatient Wards
- Acute Day Treatment team
- Forensic Team
- Psychiatry of Old age team
- Early Intervention Team
- CAMHS services
- Learning Disability Services
- Self Harm Team

4.5.2 Pre-assessments and assessments during initiation of Lithium:

The assessments must be conducted as outlined in the “Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway” (Appendix 2). The assessments include

- Current medication, including over the counter medication (use Emergency Care Record or contact GP or community pharmacy if necessary)
- Blood test results
- Physical assessments
- Mood assessment
- Side-effect assessment

The Consultant initiating lithium must be aware of all results before recommending the initiation of lithium.

4.5.3 Initiation Process and Practitioners Roles and Responsibilities During Initiation Process

This initiation process applies irrespective of location of initiation including mental health inpatient wards. Who performs the assessments must be clarified depending on the setting where the lithium is being commenced. The main roles are identified below with the responsible practitioner in brackets if not stated explicitly. There must

be good communication amongst professionals involved. The designated responsibilities include:

- The Lithium initiation Protocol (Appendix 2) is commenced for all patients (Consultant Psychiatrist, Lithium Nurse, and Key Worker).
- The patient is given an NPSA Patient Education Pack and it is explained to them and documented in the Care Pathway (any practitioner).
- An NPSA Record Card is given to the patient in which their lithium levels can be recorded and the patient can retain. This may be needed for the community pharmacist (any practitioner).
- The Consultant Psychiatrist must review all of the patient's medication both prescribed by the GP and obtained over the counter from community pharmacies, for potential interactions. This will include obtaining a list of medication from the general practitioner using for example, ECR.
- The Consultant Psychiatrist makes the decision if the patient is to start lithium, after reviewing all of the assessments
- The Consultant Psychiatrist will inform the GP by letter when a decision to start lithium treatment is made. A completed "*Lithium Therapy Pathway - communication Information is sent from consultant psychiatrists to general practitioner*" (Appendix 3) and a copy of "*Lithium Shared Care Guidelines*" (Appendix 4) are sent to the GP
- If patient is being commenced on lithium as an inpatient then the General Practitioner is informed at time of discharge, when they take over lithium prescribing responsibilities. The Consultant Psychiatrist will send to the G.P. a completed "*Lithium Therapy Pathway - communication Information from consultant psychiatrists to general practitioner*" (Appendix 3) and a copy of "*Lithium Shared Care Guidelines*" (Appendix 4).
- If a patient transfers between teams during the initiation of lithium, it is the responsibility of the transferring Consultant Psychiatrist to ensure all relevant documentation is passed to the new team and the lithium nurse informed.

4.5.4 Prescribing Lithium

Prescribers must be aware of potential drug interactions as outlined in the "Lithium Shared Care Guideline" (Appendix 4) and the British National Formulary (BNF).

The Consultant Psychiatrist must be aware of all medication that the patient is taking at time of initiation of lithium and check for medication interactions.

Lithium must be prescribed by brand name e.g. Priadel, Liskonum or Camcolit. Patients prescribed other brands of lithium must be maintained on the same brand, unless there is a good reason to change and this must be documented.

Initiation dose should be low, 400mg or equivalent of lithium carbonate 200mg or equivalent in older people or those with reduced renal function.

4.5.5 Non Attendance at Clinic

If the patient does not attend the policy on "Guidelines for patients who do not attend (DNA) and who cannot attend (CNA)" (Appendix 6) should be followed.

4.6 Regular Monitoring for Pathway 1 Patient

Regular Monitoring should be carried out as outlined in the "*Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway*" (Appendix 2). Patients should remain on Pathway 1 until stabilised on lithium which should take about 2 to 3 months. When stable, the patient may be transferred to Pathway 2 and monitoring transferred to the G.P. with their agreement (section 4.8).

4.6.1 Location

The location for monitoring will be agreed as outlined in Section 4.5.1

4.6.2 Assessments

Assessments will be conducted as outlined in the "*Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway*" (Appendix 2). Monitoring includes blood and physical assessments, a mood check and side-effect profile.

4.6.3 Monitoring Process and Specific Practitioners roles and responsibilities

- Enter the blood assessments taken, side-effects and Mood check results into
    1. The Lithium Monitoring Record in the *Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway*" (Appendix 2)
    2. *Ongoing Lithium Monitoring Communication Proforma' (Appendix 5) (Clinic Nurse)*
- Send the partially completed "*Ongoing Lithium Monitoring Communication Proforma'* (Appendix 5) to the Lithium Nurse, for those attending the Lithium clinic. For other situations the proforma is sent directly to the responsible consultant. (Clinic nurse).
- Download and **screen** results of bloods taken, within 5 days, or earlier if clinically indicated (Lithium Nurse).
- If there are any significant concerns when the blood results are screened the lithium nurse will inform the consultant immediately (lithium nurse)
- Attach the downloaded blood results to the partially completed "*Ongoing Lithium Monitoring Communication Proforma"* and send to the respective consultant within one week of the assessment (Lithium Nurse).
- The consultant psychiatrist will check and sign the blood assessments and complete and sign the *"Ongoing Lithium Monitoring Communication Proforma"* and to include any specific recommendations (Consultant Psychiatrist or deputy).
- The original completed and signed *"Ongoing Lithium Monitoring Communication Proforma"* is sent to the GP within 2 weeks of the clinic attendance. A copy is sent to the Lithium secretary and a copy kept for the clinical notes. (Consultant's secretary).
- When the signed copy of blood results and *"Ongoing Lithium Monitoring Communication Proforma"* is returned to the lithium secretary the lithium nurse will populate the Lithium Monitoring Form with the results and any variance is recorded and acted on (lithium Nurse).

- If the lithium dose is changed, especially if it is increased the consultant psychiatrist should inform the lithium nurse when the next blood sample should be taken to check the effects of the change of dose.
- The consultant psychiatrist should copy any clinic correspondence with the G.P. to the lithium nurse as well as any updates with the Risk Management form.
-

4.6.4 NPSA Patient Education Book:

The NPSA recommends that "at the start of lithium therapy and throughout their treatment, patients receive appropriate ongoing verbal and written information and a record book to record lithium blood levels and relevant clinical tests."

- The Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway (Appendix 2) require the Education Book and Record to be supplied to all patients.
- When the education book is given to patients the lithium nurse or other professional, will go through the book with the patient and explain the contents in a manner that the patient will understand.
- The lithium nurse or other professional will record (sign and date) in the Initiation Pathway that this has been done
- Initially this education booklet will be given to all new patients starting on lithium and then it will be extended to patients already established on Pathways 1 and 2.
- During the monitoring process and attendance at the lithium clinic, patients will be reminded about the important aspects of being safe on lithium.

4.6.5 NPSA Record Book

The purpose of the record book is to more fully involve patients in their own care and to make them aware of their lithium level and the frequency of blood monitoring. It also enables the patient to have the information about their serum lithium levels and related assessments and to provide it for the community pharmacist if it is needed for verification that they are attending their lithium clinic appointments. The patient will be largely responsible for keeping this up to date, although it will be checked at the lithium clinic reviews. Because of the delay between blood sampling and communication of results to the patient the Lithium Record Book may not be fully up to date. All clinicians involved with a patient prescribed lithium should verify the latest lithium level using clinical charts and/or information from the ECR or Trust laboratory systems. Lithium dose should be verified with the patient, and their GP or Consultant psychiatrist.

The NPSA record book will be used with some alterations to make it more applicable to Northern Ireland.

- A sticky label with relevant information will be put over the page 2 concerning "Your mental Health providers information…Your community Health providers information…..Personal contact".

4.6.6 Operational use of NPSA Lithium record book.

The patient will be asked to bring their lithium record book to the lithium review clinic. This is to enable the lithium nurse to check that the patient has put in the most up to date information. The lithium card should also accompany the patient if they are admitted to a psychiatric unit and it should be updated during the admission. Always check the most recent Record Book is being used and verify the lithium levels and dose using clinical charts and/or information from the ECR or Trust laboratory systems The following is how the different aspects of the information are recorded.

- **Blood Test Results**: Serum lithium level, thyroid and renal function, from the patient's most recent appointment will be sent to the patient, by the lithium nurse, after the "*Ongoing Lithium Monitoring Communication Proforma"* (Appendix 5) has been signed by the consultant psychiatrist or deputy and returned to the lithium nurse. This information will be sent to the patient in the form of a letter (Appendix 14) and the patient will be asked to insert the results in their record card.
- **Weight/B.M.I.**: This will be inserted during the consultation.
- **Record Card**: The patient's record card will be checked at each lithium clinic appointment to ensure it is up to date and accurate. It should accompany the patient into hospital and be updated during the admission. If the patient has lost their card or misplaced it, they will be given a new card with the results of the last two sets of bloods recorded on it. Tell the patient to destroy the old book if it is found later

4.6.7 Monitoring of Trends

Every 6 months a copy of the Lithium monitoring form is sent to the consultant psychiatrist by the lithium service secretary to help monitor the trends in blood results and side effect profiles.

4.6.8 Non-attendance at clinic

If the patient does not attend the policy on "Guidelines for patients Who Do Not attend (DNA) and Who Can Not attend (CNA)" (Appendix 6) should be followed.

4.7 Abnormal Lithium Result and Related Bloods and Action to be taken

Lithium samples can be processed by Link Labs, Belfast Trust or Ulster Hospital Labs, South Eastern Trust. An alerting process for urgent communication of lithium levels over 1.0mmol/ to the relevant medical team and the Lithium Service has been agreed with both labs and is described in Appendix 7 *(Guideline for Laboratory Technician Contact with Psychiatry and the Response to Raised Lithium Levels).*

This should be used in conjunction with "*Acute Lithium Toxicity Guide*" (Appendix 8).

4.8 Transfers to General Practitioner for Monitoring

This is the process for the transfer of patients from hospital monitoring (Pathway 1) to GP monitoring (Pathway 2 or 3), and is in keeping with the Shared Care

Guidelines and local enhanced service agreement (LES) which started to be introduced in March 2013. The pathways are described in "*Lithium Care Flowchart*" (Appendix 9).

4.8.1Transfer to Pathway 2

This would occur when the consultant Psychiatrist is satisfied that the patient has achieved stability. This would normally be about 4 to 6 months after having started on lithium. The psychiatrist would continue to review the patient at the outpatient clinic.

- The consultant Psychiatrist or the Lithium Nurse will discuss the transfer proposal with the patient, the patient must be in agreement with this.
- The consultant psychiatrist writes to the General Practitioner and requests that he takes over the regular Monitoring of the Patient in line with the Shared Care Guidelines.
- A copy of the Shared Care Guidelines (Appendix 4) is included.
- A completed *"Lithium Therapy Pathway - communication Information from consultant psychiatrists to general practitioner"* is included with Pathway 2 ticked (Appendix 3).
- The General Practitioner then has to confirm that they are taking over the patient's monitoring and states the date and time of their appointment.
- The Consultant Psychiatrist will then inform the Lithium Nurse.
- The Lithium Nurse will make the changes on the Lithium Patient List, cancel further appointments for the Lithium Clinic and send a copy of all of the lithium documentation to the consultant psychiatrist, including the Lithium Monitoring Form which had been completed while the patient was on Pathway 1
- By agreeing to the LES the General practitioner will send a copy of the assessments carried out as per the LES and Shared Care Guideline to the consultant psychiatrist using the "*Ongoing Lithium Monitoring Communication Proforma"* (Appendix 5).
- The consultant psychiatrist will then enter the results in the Lithium Monitoring Form which they will have received from the Lithium Nurse. This is to enable them to monitor trends and to have the information for when the patient is next seen at the clinic.
- The General Practitioner can request transfer of the patient back to Pathway 1 at any time.

4.8.2 Transfer to Pathway 3

This occurs when both the consultant psychiatrist and the General Practitioner are agreed that the patient is stable and that both the clinical reviews and the monitoring assessments can all be done by the General Practitioner. The patient also has to be in agreement with this. Normally the patient will already have been on Pathway 2 for some time. It would not be envisaged that there would be a transfer to Pathway 3 from Pathway 1.

- The procedure is the same as **section 4.8.1** except Pathway 3 is indicated on the "*Lithium Therapy Pathway - communication Information from consultant psychiatrists to general practitioner"* (Appendix 3).
- The GP agrees the Transfer and sends the details of their next appointment for the patient.
- The patient is discharged from the outpatient clinic.
- No results are sent to the consultant from the General Practitioner.
- The Lithium Nurse will make the changes on the Lithium Patient List.
- By accepting the patient onto Pathway 3 the General Practitioner is taking over full care of the patient and there will be no further follow-up from secondary care.
- The General Practitioner can request the transfer of patients from pathway 3 to either Pathway 2 or Pathway 1 at any time, by making a referral which will be dealt with promptly.

4.9 Maintaining the Lithium Patient List

The Lithium Patient List maintained by the Trust will apply to patients on Pathway 1 and Pathway 2. It will only apply to patients on Pathway 3 if they had been on Pathway 1 or 2 in the Belfast Trust, previously.

It will contain the following Information:

- Name, Address, Date of Birth, H&C number,
- Consultant Psychiatrist, Key Worker (if applicable).
- Where lithium and related assessments are carried out,
- Lithium Pathway, Lithium Pathway History.

It is important that the Lithium Nurse, who will be responsible for keeping the database up to date, is always informed of:

- New patients starting on lithium
- Any change of lithium pathway
- Any Transfer of patients e.g. consultant, general practitioner
- Any Transfer to another Trust
- Admissions and Discharges from Acute Psychiatric Care.

4.10 Admission/Discharge Hospital

The Lithium Pathway monitoring refers to the process which identifies responsibility for the patient's monitoring in the community.

While an inpatient or with the Home Treatment Team responsibility for lithium monitoring passes to the respective Consultant. The following outlines the procedure for keeping the community lithium team informed of admission and prepared for resuming responsibility when the patient is discharged. It is also to ensure clarity about Pathway at time of discharge.

4.10.1 Admission/Discharge Inpatient Psychiatry Unit and Home Treatment Team

This covers all types of General Adult Mental Health, Child and Adolescent Services and Learning Disability inpatient Units. The patient's lithium level needs to be checked and the recommended adjustment made to the lithium as decided by the consultant psychiatrist.

- The Lithium Nurse needs to be informed at time of admission and discharge
- The patient's Lithium Record Book should be kept up to date during the admission
- It must be clarified with the General Practitioner and the patient who is responsible for the monitoring of the lithium when the patient is discharged from hospital.
- At discharge from hospital the following should be in place.
    1. Appointment for the next lithium assessment and location is given to patient and recorded. This is irrespective of which Lithium Pathway the patient is on
- The discharge prescription must have details of the most recent lithium level. The date of sample and lithium level must be added to the discharge prescription. As part of the clinical check by a pharmacist on discharge prescriptions, a check will be made to ensure the necessary details have been provided or can be obtained. The Discharge prescription for lithium will not be dispensed until this information has been confirmed. An urgent serum lithium may be required with follow up action agreed between the pharmacist and doctor requesting the test.
    2. The follow up arrangements should be incorporated into the Discharge Plan and copied to the relevant services and GP in the community.
    3. *"Lithium Therapy Pathway - communication Information from Consultant psychiatrists to general practitioner*" form (Appendix 3) needs to be completed and sent to the GP at time of Discharge even if it is to confirm the previous Pathway which the patient was on.

4.10.2 Admission and Discharge, Acute Medical or Surgical inpatient units:

The guidance for the "Advice for medical staff with regards Patients who are taking lithium and are admitted to Non-Psychiatric Inpatient Units" (Appendix 10) should be followed. The psychiatry liaison teams (General adult and Elderly Care) will be main points of contact as per the Policy.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination:

- All consultant Psychiatrists in Belfast Trust
- Inpatient Mental Health, Learning Disability and CAMHS managers
- All Community Mental Health, Learning Disability and CAMHS Team Managers.
- Home Treatment Team

- Acute Day Treatment Team (Mental Health).
- All consultant medical staff and Junior Doctors in the Trust (Policy on Admission /Discharge in non-psychiatric wards).
- Head of Pharmacy and Medicines Management
- GP practices. Four educational meetings have been held with GPs and Practice Nurse in Belfast.

Visual flow Charts will be circulated:

- Outlining the key aspects of the lithium process (Appendix 11).
- Outlining what should happen when a patient is admitted to hospital on lithium or is being commenced on lithium in hospital (Appendix 12).

The full implementation of this policy will take at least one year, summer of 2015. This is because the implementation of the Local Enhanced Service (LES) for lithium has also been introduced this year and has involved a lot of staff time and co-ordination. This involved a large transfer of patients from Pathway 1 to Pathway 2 as well as developing a joint working pattern with General practitioners and Practice Nurses.

Dr. O' Kane, Associate Medical Director, should be notified if there are significant barriers or timescales are not being met.

5.2 Resources

The current resources required for this process are 1 Band 6 Nurse, 1 Band 5 Nurse and secretarial support. There is cross support available from the clozapine team to help cover leave arrangements and emergencies.

There will be an identified consultant psychiatrist who will be the "lithium lead"

It will take some time to clarify how many patients will be attending the lithium clinic (Pathway 1 patients) and how successful the new LES for lithium is. The Lithium Nurse needs additional support from another nurse and to have appropriate secretarial support.

The Lithium nurse will enable the ongoing training and awareness raising with a range of staff, on an ongoing basis. The Lithium nurse will also be a focus of information for the important interface between primary Care and secondary care services.

Mental Health Staff: There is a need for ongoing training and awareness raising among all staff in mental Health. This will be carried out by the Lithium Nurse.

Primary Care: There is a need for intermittent meetings with Primary care in particular Practice Nurses to ensure there is a good flow of appropriate information and clarification of the processes in place. The Lithium Nurse will co-ordinate this.

Induction of new medical staff concerning lithium services will be carried out by the lithium nurse.

Currently the "*Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway"* (Appendix 2) forms are in use. New forms containing the important elements of these forms and developing them further will shortly be piloted with a view to introducing them later this next year.

5.3 Exceptions

When this policy is fully implemented (envisaged by the summer of 2015) there should be no exceptions unless agreed with the lithium service manager.

6.0 MONITORING

The Lithium Nurse will monitor patients who do not attend (DNA) and who cannot attend (CNA) and will adhere to the DNA/CNA policy.

Every month, the Lithium Nurse will identify any patient who has not attended at the clinic within the past 4 months. It will then be clarified what action is being taken. This is a form of a "double check".

The Trust will participate in the Prescribing Observatory for Mental Health (POMH) lithium audits when these are running.

The operation of the Appendix 5, Lithium Monitoring Proforma will be audited to ensure appropriate communication between primary and secondary care in both directions.

The lithium process will also be subject to clinical audit regionally and locally.

7.0 EVIDENCE BASE / REFERENCES

- Bipolar Disorder: The management of bi-polar Disorder in adults in primary and secondary Care. Nice Clinical Guideline 38: July 2006.
- Safer Lithium Therapy: National Patient Safety Alert: 2009(2009/RSA005): Dec 2009.
- Lithium: Mental Health Shared Care Guidelines. Health and social Care Board (N.I.) June 2011

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8.0 CONSULTATION PROCESS

The GP integrated Care Team co-ordinated the introduction of the lithium LES and Lithium Secondary Care Pathway throughout Northern Ireland.

The Belfast Trust has organised meetings with local General Practitioners and Practice Nurses for the introduction of the protocol.

There has been consultation with, Lithium Team Manager and Lithium Nurse, Consultant Psychiatrists, Mental Health Team Managers, Learning Disability Services and CAMHS services.

9.0 APPENDICES / ATTACHMENTS

Appendix 1	Patient Registration Form
Appendix 2	Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway (link)
Appendix 3	Lithium Therapy Pathway - communication Information from consultant psychiatrists to general practitioner"
Appendix 4	Lithium, Shared Care Guideline (link)
Appendix 5	Ongoing Lithium Monitoring Communication Proforma
Appendix 6	Guidelines for patients who do not attend (DNA) and who cannot attend (CNA)
Appendix 7	Guideline for Laboratory Technician Contact with Psychiatry and the response to raised lithium Levels
Appendix 8	Acute Lithium Toxicity Guide
Appendix 9	Lithium Care Flowchart (Pathways Definition).
Appendix 10	Advice for medical staff with regards patients who are taking lithium and are admitted to non-psychiatric inpatient unit.
Appendix 11	Summary Lithium Care Pathway
Appendix 12	Summary Lithium Pathway in Acute Care
Appendix 13	NPSA Record Book (link)
Appendix 14	Letter to patient with details of latest result

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. ☐

SIGNATORIES

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

Stephen Guy

_____ **Date: _____December 2014_____**

Author

_____ **Date: _____December 2014_____**

Director

Belfast Health and Social Care Trust

Lithium Registration Appendix 1

Please complete ALL sections of this form to the best of your knowledge. This helps determine the most appropriate monitoring pathway for the patient

Name: Address: Landline: Mobile:	DOB: H&C Number: Ethnic Origin: Patient consent: YES/NO
Next of Kin: Relationship: Address: Landline: Mobile:	GP: Address: Cypher Code: Tel No:
Key Worker: Address: Work No: Mobile:	Consultant Psychiatrist: Address: Tel No:
Clinical Indication For Lithium: If new to lithium – Date commenced: Current Dose: Next sample date:	Lithium Care Pathway document commenced on: Lithium Therapy Pathway Communication Proforma completed by sent to GP on: Where are bloods being checked currently?
Are you requesting a referral to a lithium Clinic? YES/NO If 'NO' – Where will they be monitored?	Patient given information/education on lithium YES/NO Next Medical/Psych review date:
List of current medications: Drug interactions checked? YES/NO Please specify any interactions identified & recommendations:	Any known relevant medical conditions? E.g. Heart, kidney, thyroid problems. (If yes please specify) Any Special requirements? Referred By: Tel No: Date of Referral: Signature of Referrer:

This form must be completed for any person being started on lithium within the BHSC Trust, regardless of where they will be monitored. The form should be sent to the Lithium Service.

Appendix 2

Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway

The Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway can be found on the Trust Hub using the link below

http://intranet.belfasttrust.local/directorates/css/MedicinesManagement/Documents/Lithium%20Initiation%20and%20Monitoring%20Care%20Pathway%20-%20HSC%20May%202012.pdf

Belfast Health and Social Care Trust

Appendix 3

Lithium Therapy Pathway

NI Regional NPSA Lithium Working Group June 2011

Communication Information from Consultant Psychiatrist to Primary Care (Must be completed at lithium initiation, and when pathway changes.)

Name: …… DOB…../…../….. H&C number……
Address: …… has been/is attending Dr……
at……hospital.
Consultant's Contact telephone number: ……... & Lab Code……..
Add patient to or update Primary Care Lithium Register according to pathway below

Pathway 1	**Remain in Secondary Care for review and monitoring*** Secondary Care is responsible for informing the patient's GP of **all** blood monitoring results (using 'copy to' GP cipher number on lab request form). The GP should be informed **immediately** of abnormal lithium levels and action taken.	Please insert ✓ to indicate pathway patient will follow
Pathway 2	**Remain in Secondary Care for review, AND monitoring passes to Primary Care with GP agreement*.** Primary Care is responsible for informing Secondary Care of **all** blood monitoring results- using 'copy to' Consultant's name (and Lab Code if known) and hospital on lab request form. Secondary care should be informed **immediately** of abnormal lithium levels and action taken.	
Pathway 3	**Review and monitoring passes to Primary Care with GP agreement.** • Lithium blood results will not be copied to Secondary Care in this instance • If patient is persistently non compliant with monitoring – consider change to another treatment and discuss with, or refer back to, Secondary Care	

*Refer to Lithium Shared Care Guideline

Indication for treatment						
Recent blood results ……//……//……	Serum Lithium	freeT4	TSH	eGFR	Creatinine	Other
	Target Lithium Level					
Lithium	Current Dose & Brand:					
Lithium monitoring requirement:	As per Shared Care Guideline ☐				Other: (Please specify)	
Educational information	Patient has: Received Lithium book/pack □ Provided with information on Lithium therapy □ Confirmed they understand information □					
Signed (Consultant) **Date ……//……//……**						

Appendix 4

Northern Ireland Regional Shared Care Guidelines for Lithium

The Northern Ireland Regional Shared Care Guidelines for lithium can be accessed using the link below

http://www.hscboard.hscni.net/medicinesmanagement/Prescribing%20Guidance/Lithium/index.html

Appendix 5

Health and Social Care in Northern Ireland

Ongoing Lithium Monitoring

Communication Proforma

The Trust or GP practice responsible for a patient's ongoing lithium monitoring must use this proforma to communicate lithium monitoring results:

- **From Consultant to GP – for patients following Pathway One or**
- **From GP to Consultant - for patients following Pathway Two *(See Lithium Flowchart on reverse)***

To (name of GP/Consultant): ……..……..…..

Address (GP Practice/Trust site) ……..…

Patient Name:……..... **DOB**…./…../…… **H&C number**……

Address: …… **attended for lithium monitoring* on** …….. (date) **at** …….. (Name of GP Practice/Trust site).

Medical Lead** …… **Tele No:** …… **Cipher No/Lab Code……**

This patient is following Pathway …… (One/Two)

* As per Regional Lithium Shared Care Guideline
**Name of GP/Consultant responsible for the patient's monitoring, their contact details and their GP cipher no or consultant lab code

Monitoring	Results	Comments	Monitoring	Results	Comments
Serum Lithium *0.4 – 1.0 mmol/l* *(elderly 0.4 –0.8)*			Side-effects		
FreeT4 *12 – 22 pmol/l*					
TSH *0.3 – 4.2mU/l*			Interactions		
eGFR					
Urea 2.5 -7.8 mmol/L			Mood Check		
Creatinine Females: 45-84 umol/L Males: 59-104 umol/L					
BMI					
If monitoring above is not carried out, a valid reason for this must be documented eg not due					

A copy of the blood results may be attached to this proforma (rather than inserting manually).
Please note: If lithium levels are abnormal or toxicity is suspected, medical staff must inform the patient's GP/consultant immediately (by telephone), in addition to sending this proforma.

The above lithium monitoring results have been reviewed:

by:……. (name of GP/ Consultant#) **on** …… (date)

Action taken (if no action, please state):

……

Treatment plan:

Appendix 6

Guidelines for patients who Do Not Attend (DNA) and who Can Not Attend (CNA) at Lithium Clinic

1.0 Purpose

This policy applies to patients on **Pathway 1** for lithium monitoring. This is the patient group who are prescribed lithium and where it is agreed that they have their mental health review as well as blood and physical assessments completed by the secondary care services. It describes the actions to be taken by the lithium nurse if a patient does not attend (DNA) or cannot attend (CNA). There are several potential reasons why a patient does not attend an appointment and it must be borne in mind that they may have become unwell (Appendix 6.1)

It is essential that a patient on lithium has regular Blood tests for serum, thyroid function and renal function and this underpins the need for this protocol which is to ensure that:

- The patient is not experiencing side-effects,
- The patient's physical health is not affected by the medication
- The medication is at a level that is optimal for the treatment of the patient's illness.
- The patient's mental state is stable.

Thus if a patient cannot attend an appointment or does not attend an appointment it is important that this is followed up by the lithium nurse.

2.0 Response to DNA/CNA

The response to a DNA/CNA will vary depending on what the purpose for the appointment at the clinic is. Although this is based on attendance at the lithium clinic the same principles apply if the Community Team is for example, carrying out the assessments. The three main situations are:

- **Routine Monitoring Attendance** where there is no indication that there is a significant problem and the appointment is a routine assessment.
- **Non-Routine Attendance:** This is normally where there is a reason the patient is attending with regards their mental state, their physical health or an issue with the lithium levels.
- **CNA** this is where the patient or their representative has contacted the clinic to state that they cannot attend (CNA)

Clinical concern for the patient overrides any aspect of this protocol

2.1 Routine Monitoring Attendance

2.1.1 First DNA

Step 1	Contact patient, if possible by phone and arrange appointment within **two to three weeks**. Confirm appointment by Letter (Appendix 6.2), If they can't be contacted then go to Step 2
Step 2	Send a second appointment to the patient by letter (Appendix 6.2) for a date within the next **two to three weeks.** Provided there are no clinical concerns.

In **both** Steps 1 and 2 copy the letter to the patient's GP, Consultant Psychiatrist and Key Worker (if appropriate).

2.1.2 Second DNA

Step 1	**Contact the Patient** on the day of the missed appointment or the following day by phone, if possible. Clarify reason for the two missed appointments and if everything is stable - Arrange appointment within the **following one to two weeks.** Confirm arrangements in letter to patient and copy to the General Practitioner, consultant psychiatrist and CMHT member if involved (Appendix 6.3). If there any concerns ring the consultant psychiatrist. If unable to contact patient go to Step 2
Step 2	**Contact next of Kin by phone** (if consent previously given by patient) on the day of the missed appointment or the following day- Clarify how patient is and why they have not been attending their appointments. If possible, also speak to the patient directly. A**rrange an appointment within the following one to two weeks**, if there are no concerns. Confirm in Letter to patient and copy to the General Practitioner, Consultant Psychiatrist and CMHT member if involved. (Appendix 6.3). If there any concerns ring the consultant psychiatrist. If unable to contact the patient or next of Kin go to Step 3.
Step 3	**If contact remains unsuccessful**, **Send** 2nd DNA letter to Patient with an appointment within 2 weeks, copied to Consultant Psychiatrist, General Practitioner and CMHT member, if involved (Appendix 6.3). **And** **Inform the consultant psychiatrist**, by phone or at a meeting, of difficulties in contacting the patient and suggest that they arrange a face to face assessment either themselves, with a CMHT member (if they are involved) or the General Practitioner, to assess the patient, as soon as possible. It is the consultant's

	responsibility to arrange this. The consultant should also be informed of the proposed third appointment at the lithium clinic which can be re-arranged at their request or postponed if they make other arrangements for having the patient's bloods checked and mental health assessment carried out (e.g. CMHT member if involved or General Practitioner). **And** **Inform the Lithium Nurse** of the outcome of the assessment and the arrangements for the lithium monitoring, if changed from what is proposed. They also need to be to be informed of the reason for non-attendance

2.1.3 Third DNA
This arises when the patient has not attended the appointment as arranged after the second DNA.

- **The Lithium Nurse:** should inform the consultant psychiatrist by phone and follow this up by letter.

- **The Consultant Psychiatrist** needs to:
  - **Ensure:** Patient is assessed and bloods checked. This may involve directly contacting the patient or the next of kin, discussion with the Team Leader, if a key worker is involved with the patient or with the GP.
  - **Agree:** With General Practitioner whether the patient should remain on lithium and what the future arrangements for the monitoring of lithium are to be. This will involve weighing up the balance between the risks associated with stopping the lithium therapy against those of continuing the lithium therapy with less than the recommended frequency of assessments.
  - **Inform the Lithium Nurse**: whatever the outcome of the decision and the future recommendations for the Patient's monitoring.
  - **Future Appointments:** The Lithium Clinic will continue to send further appointments to the patient even if the patient has not attended, unless advised otherwise by the consultant psychiatrist. The consultant psychiatrist should recommend the frequency, which will depend on the outcome of the joint decision with the General Practitioner. The consultant psychiatrist needs to be informed of any further DNAs.
  - **Consultant Psychiatrist** will clarify in writing to the GP what has been agreed between them with regards the ongoing prescribing arrangements and copy to the Lithium Nurse.

2.2 Non-Routine Monitoring Attendance
Patients may be attending the lithium clinic for other reasons than routine monitoring. This might include

- **Initiating Therapy**
- **Abnormal result**, being followed up.

- **Adjusting Therapy** because of changes in mental state or side-effects being experienced.

In these situations there is greater risk for the patient if they have not attended. Action needs to be quick depending on the reason for attendance.

2.2.1 First DNA

Contact the Patient or the agreed Next of Kin if necessary:

- **Clarify** what has happened and how patient is. Make arrangements for the blood tests at a lithium clinic, Depending on clinical need, It may be required **that day**.
- **Inform consultant psychiatrist** of what is happening. The Consultant psychiatrist must decide what the appropriate action is, in conjunction with the General Practitioner, depending on the circumstances
- Document the action in the patient's notes.

If the patient can't be contacted

- **The Lithium Nurse will inform the Consultant Psychiatrist** by phone. The consultant should make arrangements for the patient to be contacted and seen. This could be by themselves, by the general practitioner or CMHT key worker. This may involve an urgent **Assessment** or **Home Visit** or **Outpatient clinic appointment**. This depends on the urgency of the clinical situation

2.2.2 Second DNA

If the patient does not attend for their second appointment after having been contacted after the first DNA through 2.2.1 guideline as above

- **Consultant Psychiatrist** should arrange to see the patient, request the General Practitioner or CMHT member, to see the patient urgently, that same day if appropriate.
- Arrange for Next Appointment as recommended by consultant psychiatrist.
- **An appointment will always be sent to the patient unless the consultant states otherwise.**

2.3. Patient has notified the clinic that they will not be attending (CNA)

The response depends on the purpose for the appointment and is summarised in the box below.

	1st CNA	**2nd CNA**
Routine Monitoring	Send for again in 2 to 3 weeks, if no clinical	Treat as per **2ND DNA** Routine Monitoring

	concerns identified	Attendance Response (section 2.1.2) as above and as 3rd DNA if 3rd CNA response (section 2.1.3)
Non-Routine Monitoring	Treat as 1st DNA response for Non-Routine monitoring Response (section 2.2.1) depending on clinical situation.	Treat 2nd and 3rd CNA as per DNA policy for Non-Routine Monitoring (sections 2.2.2).

3.0 Monthly Monitoring

The Lithium Service will keep a record of last attendance at appointments. This will be reviewed every month to identify patients who have not been assessed within the past four months in order to clarify why this is the case.

Appendix 6.1

Potential Reasons for non-attendance

There are several explanations as to why a patient may not attend their clinic appointment. It is important to identify these reasons for a particular patient in order to try and ensure future attendance. Reasons for non-attendance include:

- Simply forgot the appointment.
- The patient has phoned to cancel the appointment but the message was not passed to the clinic staff.
- A last minute alternative reason for the patient.
- Lack of appreciation by the patient of the importance of the monitoring.
- The patient has become unwell either physically or mentally.

Irrespective of the reason for the non-attendance there is a need for a consistent response in order to ensure the patient's safety and their continued prescription of lithium.

Belfast Health and Social Care Trust

Appendix 6.2

1st DNA Letter to Patient

Lithium Service
Woodstock Lodge
1-15 Woodstock Link
Belfast
BT6 8DD
Tel: 028 95044837

Date:

Lithium Clinic
1st DNA

Dear,

According to our records you did not attend for lithium monitoring on__ I hope that you are well and that this was just an oversight.

It is very important that you come for the lithium blood tests and I have arranged an appointment for you on__.

If this appointment does not suit or you have any concerns please do not hesitate to contact the team on the numbers provided.

I have informed your GP and Consultant Psychiatrist as they need to know if and why there would be any delays in reading your blood results.

Yours sincerely,

Lithium Clinic Nurse
CC. G.P –
Consultant Psychiatrist –
Key Worker

Belfast Health and Social Care Trust

Appendix 6.3

2nd DNA Letter to Patient

Lithium Service
Woodstock Lodge
1-15 Woodstock Link
Belfast
BT6 8DD
Tel: 028 95044837

Date:

Lithium Clinic
2nd DNA

Dear ,

According to our records you have missed two appointments with the Lithium Clinic. As you know it is very important that your bloods are checked every three months in order to ensure that you are on the appropriate level of lithium and that you are not experiencing any medical problems from the medication.

It is very important that you come for the lithium blood tests and we have arranged another appointment for you on ___

If you cannot attend or you have any concerns please do not hesitate to contact the team on the numbers provided. Our priority is your health and wellbeing, so we will do our best to accommodate changes in appointments to ensure your lithium treatment is being monitored.

I have informed your GP and Consultant Psychiatrist as they need to be aware of overdue tests.

It is extremely important that you come for this appointment.

Yours sincerely,

Lithium Clinic Nurse

CC.
G.P
Consultant
Key Worker

Belfast Health and Social Care Trust

Appendix 6.4

Letter to Consultant Psychiatrist
2nd DNA

Lithium Service
Woodstock Lodge
1-15 Woodstock Link
Belfast
BT6 8DD
Tel: 028 95044837

Date:

Dear Doctor

Re

The above patient has missed two consecutive appointments at the lithium clinic. You will already have received a copy of the letter sent to the patient concerning their first DNA and will have been informed directly concerning the second DNA. This patient is on Pathway 1 for lithium monitoring, which means that secondary care services are responsible for the monitoring. I have sent for the patient again to attend on / / at Clinic.

There is a possibility that the patient has become unwell and in keeping with the DNA protocol, I would appreciate if you would advise me of what your plan is for the assessment of the patient. You may need to consider arranging this through an outpatient appointment or the Mental Health Team if there is a key worker involved in the patient's care or by contacting the patient's GP. Please let me know of the outcome of the assessment and if you want the patient to have an alternative appointment to the one given above.

If you need to discuss this patient please contact me.

Yours Sincerely

Lithium Clinic Nurse

Cc GP
Key Worker

Appendix 7

Guideline for Laboratory Technician Contact with Psychiatry and the Response to Raised Lithium Levels

1.0 Background

Urgent contact with the responsible clinician is essential if a patient has a serum lithium level above 1.0 mmol/l because of the potential acute toxic effects and underlying causes. The Biochemistry laboratories, which analyse lithium and related bloods for patients attending the Belfast Trust, are

- Link-Labs, Belfast Trust (contact Peter Auld)
- Ulster Hospital Labs, South Eastern Trust (contact Derek Stirling)

Both Laboratories have a policy of informing the clinical source about a raised lithium level as soon as it is possible but sometimes they have difficulties identifying who should be contacted. The purpose of this protocol is to:

- Clarify who should be contacted when abnormal blood samples originate from the Belfast Trust.
- Ensure a decision can be made as soon as possible about what immediate action is required.
- Ensure information is passed on to the appropriate clinician, when they are available.

2.0 Clarification of sample source

It is important that the laboratory technician clarifies the source of the sample as this will determine who needs to be contacted. The source will be identified on the blood sample form.

2.1 General Practice is source of blood test

If the source of the lithium test is from General Practice, and it is during working hours, the laboratory technician should contact the GP practice directly. Outside working hours the out of hours GP service for that particular practice is contacted. This is the current arrangement. The GP can obtain advice or help from the Trust by contacting the relevant consultant or lithium nurse during working hours or on-call medical staff outside working hours.

2.2 Belfast Trust is source of blood test

If the source is from any 24hr. department, for example if it is A&E dept., medical ward, inpatient psychiatric ward etc., then these departments should be phoned directly and the information passed over to the relevant clinician verbally. The date, time and name of the person to whom the information is given should be recorded.

2.3 Belfast Trust Lithium Clinic is source of Blood test

There are two parts to this section.

1. Action required if the abnormal result is reported during working hours (working days 9am to 5pm).
2. Action required if the result is reported outside working hours. This is necessary because the results of laboratory analysis may become available during the evening.

2.3.1 Within Working Hours (9am to 5pm)

The Lab technician should go down the list below until they can contact a doctor or nurse to whom they can verbally give the information. They should give the information as stated in section 2.3.3 below

1. The Lithium Nurse (if on leave follow the advice of the telephone message). The telephone numbers and staff will be updated.
2. The Consultant Psychiatrist responsible for the patient or a member of the Medical Team (See Appendix 7.1)
3. The manager of the lithium Service, Martina Elliott (if on leave follow the advice of the telephone message).

2.3.2 Outside Working Hours (5pm to 9am and at weekends / Bank holidays)

Contact Second on-call psychiatrist through the Knockbracken Healthcare Park, Switchboard number (02890565656) or any Belfast Trust Switchboard. Ask to speak to the second on-call psychiatrist, and give the information as stated above 2.3.3. If second on-call psychiatrist is not available ask to speak with the Consultant Psychiatrist on-call.

2.3.3 Information to be transferred by the Laboratory Technician

If the lithium level is >1.0mmol/l the laboratory technician should take the action below

The patient information that needs to be communicated verbally from the laboratory technician to a clinician should include:

- Name, Date of Birth, H&C number
- Address of patient and /or telephone number
- Source of Blood sample
- Date and Time of sample
- Lithium Level
- Name of the consultant
- Name of technician

3.0 Action to be taken by staff informed of raised lithium level

The person who receives the abnormal lithium level needs to inform the consultant and the Lithium Nurse during working hours or if outside working hours the laboratory staff will have contacted the second On Call doctor. If necessary, more patient information can be obtained through the PARIS system or the lithium database list which is placed in the filing cabinet in the HTT office. The on-call unscheduled care staff can assist with this. Work will be taken forward to covert the Lithium Patient List into a formal Register

3.1 Action during Working Hours

The patient should be contacted by Phone (if not contactable by phone, the General Practitioner or Key Worker should be asked to visit them) or arrangements made for them to see a lithium nurse, the same day. The patient should be asked about

- Signs of Toxicity
- Possible causes for abnormal result including clarifying if there was an issue with blood sampling or time of patient taking lithium.
-

The "Acute lithium toxicity Guide" can be consulted for guidance on management (Appendix 8).

3.2 Action outside Working Hours

The patient should be contacted by phone and assessed as in section 3.1. If the patient cannot be contacted and the serum lithium level is lower than 1.2mmol/l, contact can wait until the next day, although it would be preferable to contact that evening. If the serum lithium level is greater than 1.2mmol/l the patient must be contacted directly that evening and the relevant action in Appendix 8. If there are difficulties contacting the patient then the contact can be made through either the Home Treatment team or the relevant GP out of hours unit.

The patient's consultant and the Lithium Nurse need to be contacted the next workday morning by the on-call psychiatrist.

3.2.1 Urgent Weekend assessments

This is envisaged as being a rare occurrence as the last lithium clinic is on a Thursday and the results will be available by Friday morning. If the patient needs to be seen and bloods taken, over the weekend, this can be done on Ward K, Mater Hospital. However the person making arrangements (usually lithium nurse) for the assessments needs to inform the Nurse in Charge of the ward beforehand, and the second on-call psychiatrist who will be seeing the patient on the day the assessment is being carried out. There are two main situations where this may occur:

1. An already identified raised lithium level, which needs to be followed up on a Saturday, Sunday or bank holiday. In this case the consultant psychiatrist or Lithium Nurse requesting the assessment will contact the second on call psychiatrist for the appropriate weekend day and describe what needs to be

done and pass on the relevant clinical details and contact information for the patient including next of kin details.

2. A new raised lithium level is notified to the second on-call psychiatrist on a Friday night or over the weekend, and depending on the assessment carried out that night, the patient needs to be seen the following day. The second on-call psychiatrist makes the arrangements as detailed above or passes the information onto the second on-call psychiatrist for the next morning, who will then make the arrangement.

4.0 Contact Details

The lithium nurse will keep the contact telephone number sheet up to date and ensure that the laboratory staff at Link Labs Belfast Trust (Peter Auld) and Ulster hospital labs (Derek Stirling) are kept informed.

5.0 Reviews

There will be regular contact between the Lithium Nurse and the laboratory to review any communication issues.

Appendix 7.1

Contact Telephone Numbers

Lithium Nurse: **Kathy Parker:** [redacted]

Lithium Service Manager: **Martina Elliott**: [redacted]

Consultant Psychiatrists Belfast Trust Contact Details

ID:	GMC2642505
NAME:	DR P. BELL(P AUL)
JOB TITLE:	CONSULTANT PSYCHIATRIST
MEDICAL FACILITY:	KNOCKBRACKEN MENTAL HEALTH SERVICES
FACILITY TYPE:	HOSPITAL
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FAX:	[redacted]
E-MAIL:	[redacted]

ID:	GMC2644394
NAME:	DR G. LOUGHREY(G ERARD)
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FAX:	[redacted]
E-MAIL:	[redacted]

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NAME:	DR P. DEVINE(P AUL)
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E-MAIL:	[redacted]

ID:	GMC6051738
NAME:	DR R.J. MCCLEAN(R OWAN JAMES)
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FAX:	[redacted]
E-MAIL:	[redacted]

ID:	GMC3450392
NAME:	DR A.P. MCDONNELL(A NNE)
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E-MAIL:	[redacted]

ID:	GMC2854885
NAME:	DR F.A. O'NEILL(F RANCIS ANTHONY)
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FAX:	[redacted]
E-MAIL:	[redacted]

ID:	GMC2736536
NAME:	DR P. MCGARRY(P HILIP)

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ID:	GMC6074415
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ID:	GMC3488982
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ID:	GMC4709406
NAME:	DR A.J. TURKINGTON(A IDAN JOSEPH)
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FAX:	[redacted]
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ID:	GMC3485673
NAME:	DR E.M. O' KANE (MA RIA)
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ADDRESS:	OLD SEE HOUSE, 603 ANTRIM ROAD, BELFAST, BT15 4DX
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CONTACT PHONE FOR PATIENTS:	[redacted]
FAX:	NOT AVAILABLE

ID:	GMC4538510
NAME:	DR R.S. BARR(R UTH)
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CONTACT PHONE FOR PATIENTS:	[redacted]
FAX:	[redacted]
E-MAIL:	[redacted]

ID:	GMC3257874
NAME:	DR J. LYNCH(J ANINE)
JOB TITLE:	CONSULTANT PSYCHIATRIST
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FAX:	[redacted]
E-MAIL:	[redacted]

ID:	GMC4094757
NAME:	DR P. MCGUCKEN(P AMELA)
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CONTACT PHONE FOR PATIENTS:	[redacted]
FAX:	[redacted]
E-MAIL:	[redacted]

ID:	GMC3548482
NAME:	DR A. THAMPI(A NNETTE)

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MEDICAL FACILITY:	BELFAST CITY HOSPITAL
FACILITY TYPE:	HOSPITAL
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TELEPHONE:	[redacted]
CONTACT PHONE FOR PATIENTS:	[redacted]
FAX:	[redacted]
E-MAIL:	[redacted]

Appendix 8

Acute Lithium Toxicity Guide

Introduction

Lithium is a medication with a narrow therapeutic index and must be regularly monitored in line with NICE guidelines. In most patients on lithium the aim is to have the blood lithium level between 0.6 and 0.8mmol/l. but if patients continue to have symptoms or relapse they may need to be stabilized at a higher level up to 1.0mmol/l. The normal adult range is 0.4 to 1.0mmol/l and for >65yrs age 0.4 to 0.8mmol/l.

At the beginning of treatment it is necessary that patients are educated about the symptoms of lithium toxicity as well as being given written information about this i.e. the NPSA guide for patients. This advice needs to be reiterated through review appointments. Patients must be advised if they are experiencing toxic symptoms that they contact a doctor that day.

Signs and Symptoms of toxicity

Dizziness, stomach pains along with nausea/vomiting, and diarrhoea, muscle weakness are common signs of lithium toxicity. Development of CNS signs indicate a worsening situation and include severe hand tremors, inco-ordination of the limbs, ataxia, muscle twitches, confusion, seizures, slurred speech (either self report or observed), metallic taste, nystagmus and feeling unusually sleepy.

Any one of these symptoms needs to be assessed urgently with both a physical assessment and bloods for lithium level and U&E. The blood samples should be sent urgently to the laboratories who should be phoned in advance to alert them and arrange for the results to be communicated to a specified member of medical staff later that day.

Remember lithium toxicity can occur even with normal lithium levels (especially with low sodium levels) – Immediate Clinical Assessment is essential for any of these symptoms and if significant direct consultation with and referral to nearest A&E department.

Urgent Lithium Bloods

Samples requested are **serum lithium level, U&E and Creatinine**. The laboratory should be informed by phone that urgent bloods are being sent urgently and arrangements put in place to ensure that the results are accessed by phone or by computer, **later that day**. The clinician taking bloods has to clarify who is taking responsibility for accessing these results, communicating them to the patient and putting into place appropriate clinical care.

Communication and Responsibility

It is the responsibility of the clinician who first becomes aware of or is informed about a raised serum lithium level to ensure that the patient and GP are informed and that the protocol below is implemented. There is a system established with the Laboratory that if a patient has a lithium level above 1.0mmol/l that the technician will phone a clinician as outline in "*Guideline for Laboratory Technician Contact with Psychiatry and the response to raised Lithium Levels*" (Appendix 7) about this result. This may be to an out of hours General Practitioner or on-call doctor. If they are not the appropriate person then they need to make sure that the relevant information is handed over verbally and a record kept to the appropriate person who agrees to take on the responsibility. Generally for patients on **Pathway 1** this will be the consultant Psychiatrist and the Lithium Nurse, who need to communicate rapidly with each other and the patient's GP. For patients on **Pathway 2 and 3** the general practitioner will be responsible but can seek advice from the consultant psychiatrist or lithium nurse. However if the lithium level is significantly raised the general practitioner can request that the consultant/Lithium nurse takes over responsibility. This must be done verbally and agreed.

Raised Lithium level: When a raised lithium level is obtained consider the guidelines below. However it is also important to find explanations or causes for the raised lithium level, such as medication interaction (prescribed or bought over the counter).

- **Blood Sample issues**: Check that the blood sample was taken 12 hours after the lithium. Sometimes patients will have changed from taking medication at night to first thing in the morning, which would lead to an artificially high serum lithium level. Also consider that there may have been a mis-labeling of the blood samples or results and another patient's level is in fact high.

- **Lithium Medication Issues:** Look at and check with the patient their lithium tablets/syrup and what they are actually taking. Patients can get medication mixed up especially if on multiple medication. A change in the medication colour, type of packaging or strength could lead to a misunderstanding. Check also that the patient is taking the named brand of lithium prescribed as changes between brands may affect lithium levels. Also consider that there could have been a prescribing or dispensing error.

- **Other medication Issues:** There are a number of medicine interactions that can lead to an increase in serum lithium level. This is especially significant for medication which reduces renal excretion and can result in a significant increase in serum lithium levels. The most common are covered in the "*Lithium Shared Care Guidelines*" (Appendix 4) and include:
    a) Non-steroidal anti-inflammatory medication (including COX-2 selective inhibitors) as these medications can be bought over the counter it is very important that patients are specifically made aware of this risk.
    b) Diuretic Medication (particularly thiazides)
    c) ACE Inhibitors (including angiotensin II antagonists)

d) Medications with significant sodium as a chloride or bi-carbonate (e.g. antacids, urinary alkalinisers and effervescent analgesics) can lower serum lithium levels if taken regularly. Thus if this medication stopped by a patient who was stabilized on lithium while taking them could lead to a raised lithium level.
e) Check with the BNF if there is any doubt about medication interactions.

- **Other Medical Reasons:** Febrile illness, acute renal infection, any condition leading to dehydration such as vomiting and /or diarrhoea, confusion leading to taking the wrong lithium dose, reduced sodium levels.

- **Psychiatric Reasons:** Patient has become unwell and is getting mixed up because of poor concentration.

Always consider the patient has overdosed or is taking a rolling overdose.

Appendix 8.1

Action required when dealing with actual or suspected lithium toxicity

General Practitioners and Consultant Psychiatrist must keep each other Closely informed irrespective of who is taking the lead role

Toxicity suspected clinically (either during interview or patient/carer ringing in)	1) Patient to be seen that day for assessment urgently either by Psychiatric Team or by General Practitioner. If toxicity suspected, and already at clinic they should not leave until they have had a physical and psychiatric assessment and blood results have been reported and reviewed. 2) If clinically symptoms are significant, refer to A&E should and contact A&E staff. 3) Remember there may be something else wrong with the patient experiencing symptoms similar to lithium toxicity – clinical decision making and treatment are paramount. 4) Urgent bloods (see above) for serum lithium, U&E and Creatinine need to be sent.
Lithium Level **0.8 - 1.0 mmol/l** (This is more significant if > 65yrs.)	1) Check from Treatment plan if this is their target lithium level. 2) Check that there were no toxicity symptoms during the assessment. 3) Inform consultant and /or general practitioner
Lithium Level **1.0 – 1.2 mmol/l** (This is more significant if > 65yrs.)	1) Patient contacted by phone and asked about toxicity symptoms. 2) Clarify dose of medication and timing of taking medication and blood sample. 3) Go through other reasons for raised lithium levels (see above). 4) **If no concerns**, ask to attend for repeat blood tests (lithium and renal function) the next morning, to be sent urgently so that result is back that day. Also to bring up their medication so this can also be checked. **If concerns** send urgent bloods or refer to and contact A&E department. 5) Inform consultant psychiatrist or general practitioner and make arrangements for them to receive the blood results the next day. 6) If repeat blood sample is under 1.0 repeat again within one week and continue weekly, with if necessary medication alteration, overseen by the consultant/general practitioner until within the therapeutic range that is required for that patient. <u>Again try and clarify why the level went so high.</u> 7) If repeat level is still in the range 1.0 to 1.2 with no explanation, and no toxic symptoms reduce the lithium dose by 200mg and repeat level again in two to three days. Keep assessing for toxic symptoms. Continue lithium and renal bloods

	every two to three days until maintained within the target range for that patient. 8) Will need more regular follow-up bloods until stabilization is maintained.
Lithium Level **1.2** to **1.5 mmol/l** (This is more significant if> 65yrs.)	1) Contact patient by phone and asked about toxicity symptoms, if present the patient requires immediate assessment and possible transfer to A&E. If the symptoms are severe they may need to go directly to A&E. 2) Clarify dose of medication and timing of taking medication and blood sample. 3) Go through other reasons for raised lithium levels (see above). 4) If no concerns clinically ask patient to stop lithium that night. 5) Ask patient to attend for repeat blood tests the next morning, to be sent urgently so that result is back that day. Request patient to bring up their medication with them in order that the medication and dosing can be checked. Reassess patient clinically for mental state and side-effects. 6) Inform consultant psychiatrist and GP and make arrangements for them to receive the repeat blood levels and develop the response to the raised lithium level. 7) If repeat blood level is **within the target range** for the patient - try and clarify why there was such a high result. Also consider that there may have been a mis-labeling of the blood samples or results and another patient's level is in fact high. Recommence lithium at 400mg lower than the previous dose and check blood results every two to three days with medication adjustment as necessary until stabilization at the required level. More regular lithium levels will be required for a period of time, after stabilization, to ensure that it is maintained. 8) If repeat blood level **remains high or is increasing** despite missing the one night's dose then: a. Stop lithium entirely b. Patient will need ongoing physical assessments to assess the degree of impact of the raised lithium level, and possible referral to an A&E department c) Check bloods daily and don't start re-titration until lithium level is low and underlying reason for toxic level has been established.

	Consultant and GP should communicate with each other urgently by phone and followed up in writing
Lithium Level >1.5mmol/l (This is more significant if > 65yrs.)	1) The patient needs to be contacted that day and seen that day in order to assess the degree of toxicity, conduct a physical examination and if necessary referred to the A&E department. Direct referral to A&E may be appropriate. A&E doctor will need to be informed so that there is no undue delay when the patient arrives. 2) If level is approaching 2.0mmol/l the patient is at risk of serious neurological damage or cardiovascular and renal collapse. The patient should be referred to an A&E department for a full physical examination and assessment. 3) Stop lithium and check daily bloods for lithium, U&E and creatinine. 4) Identification for reason of raised serum lithium levels is essential before recommencing lithium. 5) Re-titration should not restart until lithium level is reduced to a low level and the cause for the raised lithium level has been established. Consultant and G.P. should communicate with each other urgently by phone and followed up in writing

Health and Social Care in Northern Ireland

Appendix 9

LITHIUM CARE FLOWCHART

Lithium Initiation Preferably in Secondary Care.
Psycho-education included

Patients added to Lithium Register in both Secondary Care and Primary Care
Lithium Blood Results Copied to Primary Care

Pathway 1
Patient remains in Secondary Care for review and monitoring. Lithium blood monitoring results copied to Primary Care.*

Pathway 2
Patient remains in Secondary Care for review but, with agreement between GP and Secondary Care, monitoring passes to Primary Care. Lithium blood monitoring results copied to Secondary Care.*

Pathway 3
If patient stable or strong patient preference, with agreement between GP and Secondary Care, review and monitoring passes to Primary Care. Lithium blood monitoring results not copied to Secondary Care.*

*A communication proforma from secondary care to primary care will advise of the pathway the patient will follow and responsibilities for review and monitoring. Primary and secondary care lithium registers should be updated using this information.

Appendix 10

Advice for medical staff with regards Patients who are taking Lithium and are admitted to Non-Psychiatric In-Patient Units

1.0 Rational

This advice aims to ensure that patients admitted to general hospital wards while on lithium treatment have their lithium managed appropriately during their inpatient care and that appropriate follow-on care in the community, on discharge is arranged. Advice from Liaison Psychiatry Services is readily available.

2.0 Acute Medical or Surgical Admissions

If the patient is admitted acutely ill it should be borne in mind that lithium toxicity symptoms may be contributing to the symptomatology. This is especially true if there has been dehydration, due to vomiting, diarrhoea, blood loss or lack of fluid intake. Also the patient may start to become lithium toxic secondary to the acute physical illness. This is particularly important in elderly patients. It is safer to stop lithium and seek advice from Liaison Psychiatry than to continue it in an acutely physically ill patient. Even after the lithium has been stopped the lithium levels and renal function tests still need to be carefully monitored. In cases of acute medical or surgical conditions it is important to:

- **Stop** lithium
- **Send** Urgent bloods immediately for serum lithium level, renal function and thyroid Function. It is important to identify low sodium levels as this can contribute to lithium toxicity
- **Contact** Liaison Psychiatry for advice about restarting, continuing or keeping the patient off lithium.

If lithium is restarted, follow liaison psychiatry's advice about dose of lithium and frequency of checking serum lithium levels. Always be aware that the patient's level of hydration is important and needs to be maintained otherwise the lithium may need to be stopped.

3.0 Surgical procedures and lithium

Lithium levels can be altered during surgery as a result of fluid imbalance and electrolyte disturbance and toxicity may occur. Follow the recommendations in the Trust Preperative Policy and discontinue lithium when there is a risk of fluid imbalance. Ensure any fluid imbalance and electrolyte disturbance is corrected before lithium is restarted. To avoid any effect on mental state, lithium should be restarted at the previous dose as soon as possible. Lithium levels should be checked frequently after surgery to avoid unexpected toxicity. Steady state levels may not be

reached for 5-7 days. Ensure a follow up appointment to recheck levels is made (section 6.0)

4.0 Routine Admissions

Advice may be needed about lithium in general or in specific situations, including the following:

- Procedures for which the lithium has to be stopped and then restarted promptly e.g. planned surgery, refer to the Trust Preoperative assessment Polic for further information
- Abnormally low or high lithium levels being identified through routine testing necessitating appropriate action. (Normal Range 0.4 to 1.0mmol/l, the upper limit is 0.8mmol/l for >65yrs of age).
- Side effects of lithium may be identified and adjustments to medication may be needed.
- There may be symptoms suggesting lithium toxicity, which is a medical emergency.
- Possible drug interactions may be identified, always check BNF.
- There may be concerns about the patient's mental state.

It is important that lithium is managed properly, that medical staff know where to seek advice and any identified issues are communicated to the General Practitioner and Consultant Psychiatrist at time of discharge.

4.1 Basic Assessment:

This should be carried out on **every patient** who is admitted to hospital and is on lithium.

- Ensure that the lithium is at the correct dose, this should be checked with the patient's General Practitioner using for example ECR.
- A serum lithium level **MUST** be taken as soon as possible after admission. In the situations stated above in **section 2.0** or if toxicity is suspected, the serum level should be sent **immediately** and results checked urgently by computer or phoning labs. Laboratory staff will need to have been informed of the urgent lithium blood.
- Routine Serum Level must be taken 12 hours after taking the medication. (Lithium is normally taken at night and serum level in the morning, if patient is on liquid lithium which is normally taken twice each day the Serum sample should be taken before the morning dose).
- Renal function with particular attention to sodium level.
- Thyroid function
- Routine Results should be checked by computer with the Labs the following day and not await the arrival of the paper copy of the results.

4.2 LithiumToxicity

Symptoms such as severe tremor, severe diarrhoea, confusion, ataxia or convulsions, could indicate serious lithium toxicity. This is a medical emergency and can lead to cerebro-vascular and renal collapse as well as permanent neurological damage. The actions below are required

- Discontinue lithium on the patient's Kardex, even if toxicity is only suspected.
- Take an urgent lithium Level and U&E immediately and contact the Physicians. This should not be left to the following day. This is a medical emergency.
- If in doubt treat as lithium toxicity and seek the relevant advice.
- Even when the lithium has been discontinued it is important to continue monitoring serum lithium, renal function and electrolytes until advised to stop.
- Toxicity can occur in some people with lithium levels in the normal range and should also be treated as an emergency. This occurs especially if sodium levels are low.
- The relevant psychiatry liaison team should also be contacted for advice about recommencing lithium. See section 4.0.

5.0 Advice Needed

If there are any concerns or advice is needed this can be obtained through the relevant Hospital Psychiatry liaison service. If there are any suggestions of lithium toxicity or a serum lithium level > 1.0mmol/l this should be considered as Urgent and advice is required urgently. How to obtain advice depends on the age of the patient and if it is within or outside working hours. This is outlined below.

5.1 During Working Hours

5.1.1 Under 65yrs of age

Contact the One Point of Referral at Woodstock Lodge, telephone number: 02890737547, state the issue and the degree of urgency.

5.1.2 Over 65yrs of age:

Make a referral to the Psychiatry of Old Age Liaison Service using the e-referral available on The HUB (search Psychiatry Referral Form), if necessary mark URGENT.

5.2 Out of Hours and weekends for all Patients:

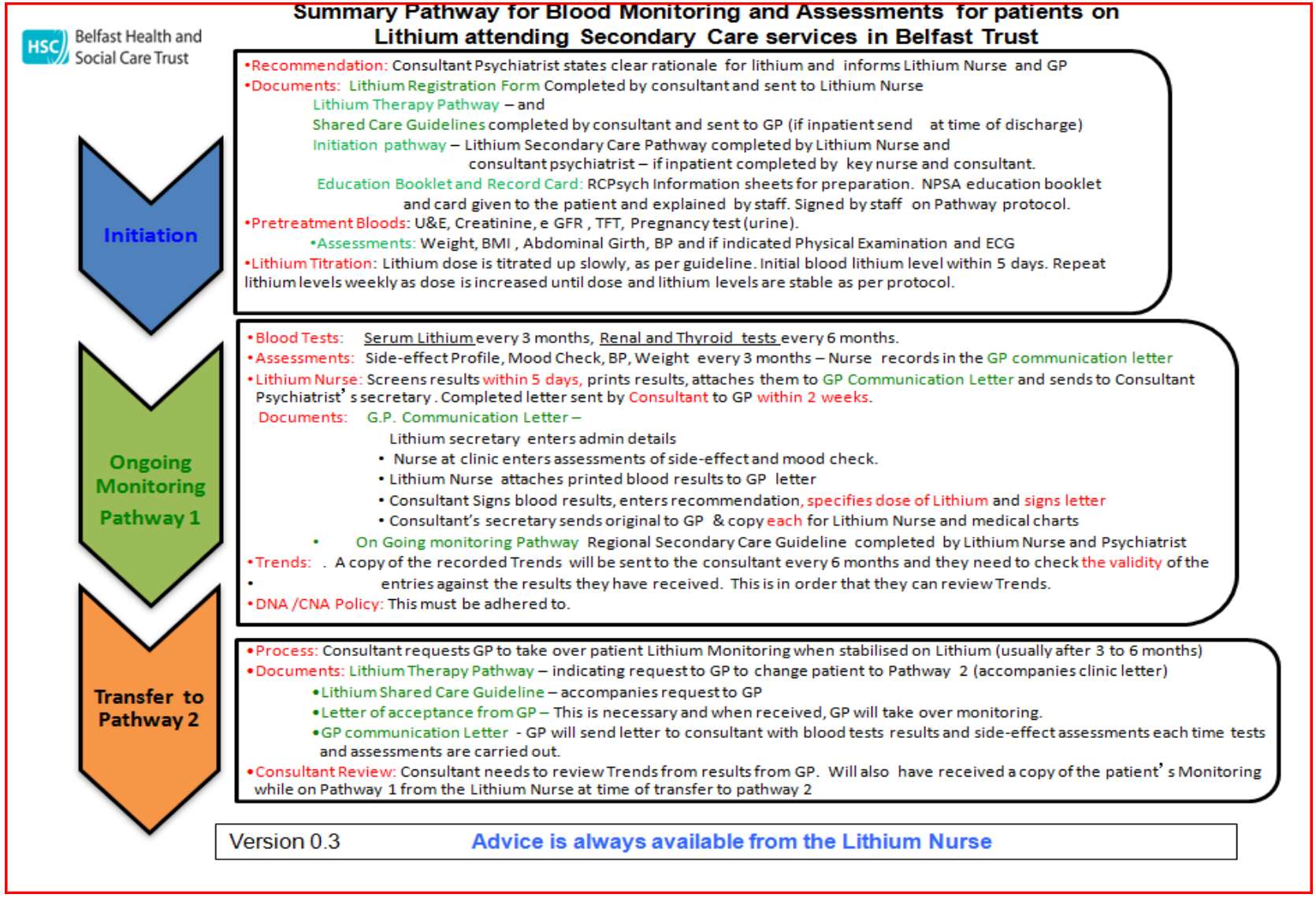
Contact Knockbracken Health Care Park Switchboard 02890565656 or Belfast Trust general switchboard and ask for second On Call Psychiatrist. If the second on call psychiatrist cannot be contacted, ring the on call consultant psychiatrist.

6.0 Arrangements at Discharge

It is very important that any issues or modifications to lithium during an admission are communicated to both the patient's General Practitioner and Consultant Psychiatrist. There must be clear arrangements for the on-going follow-on of the lithium monitoring, in the community after discharge.

- There should be a **date** and **location** arranged and recorded for the next lithium monitoring appointment after discharge. This may be earlier than the next routine appointment if any issue has arisen during the admission. For example any change in dose of lithium, commencing any medication that interacts with lithium (BNF) a significant change in renal function or lithium was stopped prior to surgery. Ensure patient is informed of this date.
- Even if the Liaison team has coordinated the new appointment this needs to be checked at time of Discharge.
- The discharge prescription must have details of the most recent lithium level. The date of sample and lithium level must be added to the discharge prescription. As part of the clinical check by a pharmacist on discharge prescriptions, a check will be made to ensure the necessary details have been provided or can be obtained. The Discharge prescription for lithium will not be dispensed until this information has been confirmed. An urgent serum lithium may be required with follow up action agreed between the pharmacist and doctor requesting the test.
- Copy Discharge letter to relevant Consultant Psychiatrist with either routine or new lithium Monitoring appointment included.

Appendix 11


Belfast Health and Social Care Trust
Summary Pathway for Blood Monitoring and Assessments for patients on Lithium attending Secondary Care services in Belfast Trust
Initiation
•Recommendation: Consultant Psychiatrist states clear rationale for lithium and informs Lithium Nurse and GP
•Documents: Lithium Registration Form Completed by consultant and sent to Lithium Nurse
Lithium Therapy Pathway – and
Shared Care Guidelines completed by consultant and sent to GP (if inpatient send at time of discharge)
Initiation pathway – Lithium Secondary Care Pathway completed by Lithium Nurse and consultant psychiatrist – if inpatient completed by key nurse and consultant.
Education Booklet and Record Card: RCPsych Information sheets for preparation. NPSA education booklet and card given to the patient and explained by staff. Signed by staff on Pathway protocol.
•Pretreatment Bloods: U&E, Creatinine, e GFR , TFT, Pregnancy test (urine).
•Assessments: Weight, BMI , Abdominal Girth, BP and if indicated Physical Examination and ECG
•Lithium Titration: Lithium dose is titrated up slowly, as per guideline. Initial blood lithium level within 5 days. Repeat lithium levels weekly as dose is increased until dose and lithium levels are stable as per protocol.
Ongoing Monitoring Pathway 1
•Blood Tests: Serum Lithium every 3 months, Renal and Thyroid tests every 6 months.
•Assessments: Side-effect Profile, Mood Check, BP, Weight every 3 months – Nurse records in the GP communication letter
•Lithium Nurse: Screens results within 5 days, prints results, attaches them to GP Communication Letter and sends to Consultant Psychiatrist's secretary . Completed letter sent by Consultant to GP within 2 weeks.
Documents: G.P. Communication Letter –
Lithium secretary enters admin details
• Nurse at clinic enters assessments of side-effect and mood check.
• Lithium Nurse attaches printed blood results to GP letter
• Consultant Signs blood results, enters recommendation, specifies dose of Lithium and signs letter
• Consultant's secretary sends original to GP & copy each for Lithium Nurse and medical charts
• On Going monitoring Pathway Regional Secondary Care Guideline completed by Lithium Nurse and Psychiatrist
•Trends: . A copy of the recorded Trends will be sent to the consultant every 6 months and they need to check the validity of the entries against the results they have received. This is in order that they can review Trends.
•DNA /CNA Policy: This must be adhered to.
Transfer to Pathway 2
•Process: Consultant requests GP to take over patient Lithium Monitoring when stabilised on Lithium (usually after 3 to 6 months)
•Documents: Lithium Therapy Pathway – indicating request to GP to change patient to Pathway 2 (accompanies clinic letter)
•Lithium Shared Care Guideline – accompanies request to GP
•Letter of acceptance from GP – This is necessary and when received, GP will take over monitoring.
•GP communication Letter - GP will send letter to consultant with blood tests results and side-effect assessments each time tests and assessments are carried out.
•Consultant Review: Consultant needs to review Trends from results from GP. Will also have received a copy of the patient's Monitoring while on Pathway 1 from the Lithium Nurse at time of transfer to pathway 2
Version 0.3
Advice is always available from the Lithium Nurse

Appendix 12

Summary Pathway of Care for Lithium Patients under Acute Care

Developed by Nora Curran

ACUTE ADMISSION – ALREADY ON LITHIUM

On Admission

1) Contact Lithium Service. Inform of admission & ascertain patient's current pathway.
2) Check prescribed Brand & Dose with GP.
3) Check Serum Lithium, U&E, TFT.

During Admission

1) If Inpatient longer than 3 months remember to recheck serum level on 3rd month & TFT, U&E on 6th month. Unless increased monitoring required.
2) If any changes to lithium treatment check serum lithium on day 5, then weekly until level is stable.

Prior To Discharge

PATHWAY 1	PATHWAY 2
1) Consultant to complete ***Lithium Therapy Pathway Proforma*** & attach copy of ***Shared Care Guidelines.*** This should be included in the discharge plan with original to GP and copy to Lithium Service. 2) Contact Lithium Service & get ***Date, Time & Location*** of next appointment. This ***MUST*** be included in the discharge documentation including on the discharge prescription	1) Contact GP to check if they are still agreeable to Pathway 2. 2) If yes, Consultant to complete ***Lithium Therapy Pathway Proforma*** as per agreement. 3) Get appointment date & time for next lithium monitoring at GP Practice. This ***MUST*** be included in discharge documentation. 4) If GP no longer agreeable – follow Pathway 2 section.

NB If Lithium therapy discontinued during admission – Lithium Service MUST be informed for purpose of updating BHSCT

PTO for Starting Lithium flowchart

Appendix 12

Summary Pathway of Care for Lithium Patients under Acute Care

Developed by Nora Curran

ACUTE ADMISSION - STARTING LITHIUM

Starting Lithium

1) Contact Lithium Service.
2) Using Lithium Care Pathway – Do work up/Initiation Section.
3) When definitely starting Lithium – ***REGISTER THE PATIENT*** – Using the BHSCT Registration form – to be completed by doctor.
4) Complete patient information section of Care Pathway, ensuring ***NPSA patient information booklet, record book & alert card*** are given & explained to the patient.
5) On commencement – follow the Initiation & Monitoring Section of Care Pathway.

Prior To Discharge

1) As agreed with Primary Care – New patients to follow Pathway 1 for at least the first 6 months.
2) Consultant to complete ***Lithium Therapy Pathway Proforma*** & attach a copy of ***Shared Care Guidelines.*** Send original to GP and copy to Lithium Service.
3) Contact Lithium Service to arrange ***Date, Time & Location*** of 1st Lithium Clinic appointment. This ***MUST*** be included in discharge documentation.

NB Remember to send the following to Lithium Service –

- ***Registration Form***
- ***Original Care Pathway***
- ***Copy of Discharge Plan***
- ***Copy of Risk Assessment***
- ***Copy of Lithium Therapy Pathway Form***

PTO for Flowchart of Patient Already on lithium

Appendix 13
National Patient Safety Agency Lithium Record Book

The National Patient Safety Record Book can be access using the link below

http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=65430&type=full&servicetype=Attachment

Appendix 14

Letter to Patient to Advise Result of Lithium Level

Lithium Service
Woodstock Lodge
1 -15 Woodstock Link
Belfast
BT6 8DD

Tel.No

Dear _____,

Thank you for attending your recent appointment at the lithium clinic. The results from your assessments are included below. Please record these in your Lithium Record Book and bring it with you when collecting your next prescription from the chemist and also to your next appointment at the psychiatry or Lithium Clinic. Not all of the assessments below are carried out at each appointment. The normal values are recorded on your Lithium Record Book

If you have any difficulties or have any concerns please do not hesitate to contact me at the above number.

Name	**H&C no.**	**Date of Assessment**

Date of Next Assessment	**Location**	**Time**

Results

Blood Lithium Level mmol/l	**Kidney Function Test (eGFR)**	**Weight (kg)/BMI**	**Thyroid Function Tests**	
			Free Thyroxine	**TSH**

Yours Sincerely

Lithium Nurse

Belfast Health and Social Care Trust

Reference No: SG 38/14

Title:	**Lithium Policy**			
Author(s)	Stephen Guy, Lead Mental Health Pharmacist, Pharmacy, KHCP Dr Michael Doherty, Consultant Psychiatrist			
Ownership:	Dr Cathy Jack, Medical Director			
Approval by:	Drugs and Therapeutics Committee Standards and Guidelines Committee Trust Policy Committee Executive Team Meeting		**Approval date:**	07/09/2018 03/10/2018 04/10/2018 10/10/2018
Operational Date:	October 2018		**Next Review:**	October 2023
Version No.	2	**Supersedes**	Version 1	
Key words	Safer Lithium			
Links to other policies	Admission Discharge Policy for Mental Health and Learning Disability Guidance on the Administration of Medications in Perioperative Adult patients: Elective Surgery, 2017 (SG 43/15)			

Date	Version	Author	Comments
15/08/2013	0.1	Michael Doherty Stephen Guy	Sections widely shared and developed with comments from Consultant Psychiatrists, Nursing staff and management. Also discussed at Psychiatry D&T committee.
23/10/2013	0.2	Michael Doherty	Reviewed in Detail by selection of consultant Psychiatrists, Nursing staff and Management.
19/03/2014	0.3	Michael Doherty Stephen Guy	Reformatting and error correction
29/04/2014	0.4	Michael Doherty Stephen Guy	Incorporation of comments from Hilary Rea (clinical Pharmacist), Roan McClean (Consultant with responsibility for lithium). Update to Appendix 7, actions on response to notification of High lithium levels by labs
11/06/2014	0.5	Stephen Guy	Correction of typos and incorporation of comments from D&T Committee 6th June 2014
25/09/2014	1	Stephen Guy	Incorporation of arrangements for updating patient held record book and checks on lithium bloods when dispensing lithium

			discharge prescriptions. Incorporation of all Appendices into one document.
08/10/2017	2	Stephen Guy	Two year review. Change include Updates to NICE CG185, Lithium Shared care Guideline. Removal of duplication and unnecessary details.
06/04/2018	2.1	Stephen Guy Rowan McClean Kathy Parker	Update to include new Regional Lithium Care Pathway
15/07/2018	2.2	Stephen Guy Rowan McClean	Update to reflect new Divisional Structures
26/09/2018	2.3	Stephen Guy	Addition of comments after equality impact screen

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

The safe prescribing and monitoring of lithium is outlined in a number of National and Regional alerts and guidelines.

- The National Patient Safety Agency (NPSA) "Safer Lithium Therapy" December 2009 (2009/PSA005)
- HSC (SQSD) 84-09 Safer lithium Therapy (Jan 2010) Bipolar Disorder: NICE Guideline CG185 assessment and management (2014 updated 2016)
- Lithium Regional Shared Care Guideline (Interface Pharmacy Group June)
- Regional Care Pathway for initiation of Lithium (January 2018)

This policy incorporates these various documents into Trust Policy.

1.2 Purpose

The purpose of this Policy is to implement various National and Regional guidelines into Trust Policy to ensure safe and effective prescribing and monitoring of lithium.

1.3 Objectives

The objectives of this policy are

1. To ensure the Trust's compliance with the mandatory requirements arising from the NPSA Alert (2009) and HSC (SQSD) 84-09 Safer Lithium Therapy concerning safe lithium prescribing, dispensing and monitoring. These are

    - Patients prescribed lithium are monitored in accordance with NICE guidance.
    - There are reliable systems to ensure blood test results are communicated between laboratories and prescribers.
    - At the start of lithium therapy and throughout their treatment, patients receive appropriate ongoing verbal and written information and a record book to track lithium blood levels and relevant clinical tests.
    - Prescribers and pharmacists check that blood tests are monitored regularly and that it is safe to issue a repeat prescription and/or dispense the prescribed lithium.
    - Systems are in place to identify and deal with medicines that might adversely interact with lithium Therapy.

2. To comply with the recommendations of the Lithium Shared Care Guideline and the Northern Ireland Care Pathway for lithium Initiation and monitoring. In order to implement this in the Belfast Trust the following are required:

    - All patients attending the Trust will be allocated to a specific lithium Pathway (Appendix 9) identified by the Northern Ireland "Shared Care Guidelines (2017)".
    - Clear responsibility and good communication between Secondary and Primary Care in both directions and use of the regionally developed pathway documents.

- A Trust Lithium Patient List will be maintained with up to date information on the patients attending the Trust for monitoring.
- Patients prescribed lithium are fully involved and informed.
- Links to other Trust policies (Admission /Discharge Policy for Mental Health and Intellectual Disability).

2.0 SCOPE OF THE POLICY

- This policy applies to all patients attending the Belfast Trust who are prescribed lithium.
- Management of lithium in Acute units (non-mental health) is covered in Appendix 10
- The Policy applies to patients of all ages.
- The "Monitoring Section" (section 4.6) applies to patients on Lithium Pathway 1 (Where the Trust is responsible for the monitoring of the outpatients on lithium).

3.0 ROLES/RESPONSIBILITIES

- The Medical Director, will ensure that all medical staff adhere to this policy.
- The Chair of Division for Mental Health and Child and Adolescent Mental Health, The Chair of Division for Intellectual Disability and the Clinical Director, Psychiatry of Old Age will be responsible for implementation in their respective areas.
- The Service Manager for the Lithium/Clozapine service will be responsible for the day-to-day management of the Lithium Service and ensuring adherence to this policy.
- The Policy describes specific roles for :
  - Medical Staff
  - Nursing Staff
  - Pharmacy Staff
  - Community Team managers
  - Lithium Nursing Staff
  - Laboratory Staff
  - Administrative and Secretarial Staff

4.0 KEY POLICY PRINCIPLES

4.1 Definitions

4.1.1 Patient Pathways

There are three regionally agreed Patient Pathways. The Pathways set out responsibilities of secondary and primary care for monitoring a patients lithium, the related physical health assessments and their mental health. More details on the operation of the pathways are described in the "*Lithium Care Flow Chart* "(Appendix 9).

- **Pathway 1:** Patient remains in Secondary Care for review and monitoring. Lithium blood monitoring results copied to Primary Care. Transfer to Pathway 2 or 3 can only occur with the agreement of both the GP and the Consultant Psychiatrist.
- **Pathway 2**: Patient remains in Secondary Care for review but, with agreement between GP and Secondary Care, monitoring passes to Primary Care. Lithium blood monitoring results copied to Secondary Care.
- **Pathway 3:** If patient stable or strong patient preference, with agreement between GP and Secondary Care, review and monitoring passes to Primary Care. Lithium blood monitoring results not copied to Secondary Care.

4.2 Key Policy Statement(s):

- All prescribers who commence patients on lithium and/or monitor patients on lithium must adhere to this policy.
- Details of patients prescribed lithium will be maintained on the Trust Lithium Patient List.
- The Lithium Service Manager will ensure safe and efficient running of the Lithium service.
- Patient education and involvement in decision making about their care underlies all aspects of this policy.
- There will be regular staff updates on lithium within the Trust.
- There will be regular local audits and also participation in audits organised by the Royal College of Psychiatrist's Prescribing Observatory for Mental Health (POMH-UK).

4.3 Recommendation and Registration for Lithium:

The consultant psychiatrist is responsible for the recommendation that lithium is initiated.

The referral should be accompanied by a Risk Management Form and any relevant clinical details. If the patient is in hospital, the ward nurse must make arrangements for clinic appointments at the time of discharge and inform the patient.

4.4 Lithium Work-Up and Patient Information

The same actions are required for inpatients and outpatients including informing the Trust Lithium Nurse.

Patients attending Community Mental Health Services will have their pre-assessment tests for lithium initiation completed at one of the Trust lithium clinics. Patients in acute services or any mental health inpatient ward will have their pre-assessment and initiation checks completed by nursing and medical staff from those teams or wards

Lithium work-up must be conducted according to the Regional Lithium Care Pathway" (Appendix 2). The actions and responsibilities are:

Consultant Psychiatrist

- Send a Patient Registration Form (Appendix 1) to the Lithium Nurse who will record the patient on the Lithium Patient List (Section 4.11).
- Commence the Lithium Care Pathway (Appendix 2).
- Provide the patient with information on the risks and benefits of taking lithium
- Review current medication for potential interactions. Use Emergency Care Record (ECR), GP or Community Pharmacy Records as appropriate. Check for Over the Counter Medicines.
- Inform the GP by letter and include a completed Pathway Communication Performa (Appendix 5) and a copy of the Regional Lithium Shared Care Guidelines (Appendix 4). For inpatients, do this at point of discharge and copy to the Lithium Nurse.
- If a patient transfers between teams during the initiation of lithium, it is the responsibility of the transferring Consultant Psychiatrist to ensure all relevant documentation is transferred to the new team and the lithium nurse informed.
- Review all tests completed by nurse.

Nursing

- Physical observation as outlined in the Regional Shared Care Guideline
- Blood Tests as outlined in the Regional Shared Care Guideline
- Provide the Lithium Patient Information (NPAS) and Choice and Medication Patient Information Leaflet for Lithium. There are versions of the Choice and Medication leaflet available in a range of languages and levels of reading ability.
- Baseline side effect check.
- Mood Check.

4.5 Prescribing Lithium

Prescribers must be aware of potential drug interactions outlined in the Lithium Shared Care Guideline (Appendix 4) and the British National Formulary (BNF).

Lithium must be prescribed by brand name e.g. Priadel, Liskonum or Camcolit. Patients must be maintained on the same brand, unless there is a good reason to change and this must be documented.

Initiation dose should be low, 400mg or equivalent of lithium carbonate. Even lower doses should be considered in older people or those with reduced renal function.

4.6 Regular Monitoring for Pathway 1 Patient

Regular Monitoring should be carried out as outlined in the Monitoring Section of the Regional Lithium Care Pathway (Appendix 2). Patients should remain on Pathway 1 until stabilised on lithium. When stable, the patient may be transferred to Pathway 2 and monitoring transferred to the GP with their agreement (section 4.10).

4.6.1 Monitoring Process and Specific Practitioners roles and responsibilities

Nursing

- Take blood tests according to the Long-Term Monitoring section of the Lithium Regional Shared Care Guideline and Care Pathway.
- Complete a side-effect and Mood check and record in the relevant section of the Regional Lithium Care Pathway (Appendix 2) and on the Lithium Monitoring Communication Proforma (Appendix 5)
- The Lithium nurse must screen results of all bloods taken within 5 days. If there are any significant concerns when the blood results are screened the lithium nurse will inform the consultant immediately.
- Print all blood test results and attach to the Lithium Communication proforma and send to the patient's consultant for review.
- Record the blood test results on the Monitoring Form in the Regional Care Pathway.

Consultant Psychiatrist or Senior Doctor.

- Review and sign the blood results and complete and sign the Lithium Communication Proforma. Clearly document any changes to dose or monitoring frequency.
- Retain the original Lithium Communication Proforma for the clinical records and send a copy to
    - The patient's GP
    - The Lithium Nurse
    - NOTE: If a dose change is required, this should be confirmed to the GP on a Trust Treatment Advice Note
- When the signed copy of blood results and Ongoing Lithium Monitoring Communication Proforma is returned to the lithium secretary the lithium nurse will populate the Lithium Monitoring Form with the results and any variance is recorded and acted on (lithium Nurse).
- If the lithium dose is changed, especially if it is increased, the consultant psychiatrist should inform the lithium nurse when the next blood sample should be taken to check the effects of the change of dose.

4.7 NPSA Patient Education Book:

The NPSA recommends, "At the start of lithium therapy and throughout their treatment, patients receive appropriate ongoing verbal and written information and a record book to record lithium blood levels and relevant clinical tests."

- The Regional Lithium Care Pathway (Appendix 2) requires the Education Book and Record to be supplied to all patients.
- The Choice and Medication Lithium Patient Information Leaflet. There are versions of the Choice and Medication leaflet available in a range of languages and levels of reading ability
- A nurse or other professional will go through the book with the patient and explain the contents in a manner that the patient will understand.
- The nurse or other professional will record (sign and date) in the Initiation Pathway that this has been done
- During the monitoring process and attendance at the lithium clinic, patients will be reminded about the important aspects of being safe on lithium.

4.7.1 NPSA Record Book

The Lithium Therapy Record book promotes patients involvement in their own care Patients should be encouraged to bring the book to every clinical appointment when it will be updated by the Lithium Nurse.

Clinicians making prescribing or treatment decisions must not rely on the Lithium Record Book for the most recent test results. Always confirm tests results on ECR or Trust Laboratory systems. Lithium dose should be verified with the patient, and their GP or Consultant psychiatrist

The NPSA record book will be used with some alterations to make it more applicable to Northern Ireland.

- A label with relevant local information will be placed over the section on page 2 concerning "Your mental Health providers information…Your community Health providers information…… Personal contact".

4.8 Non-attendance at clinic

Regular blood tests as outlined in the Regional Shared Care Guideline are important for patient safety and should take place at the agreed intervals for all patients. The frequency of checks may need to be increased at certain times e.g.

- During the initiation of lithium or when doses are changed
- The patient is physically unwell.
- The patient's mental state is unstable.
- There are signs of toxicity.

The lithium nurse must review patients who do not attend the Lithium Clinic for whatever reason, paying particular attention to patients who repeatedly do not attend. Patients should be contacted (Copies of DNA letters in Appendix 6) and a new clinic appointment made. The Lithium Nurse should liaise closely with the patient's consultant psychiatrist to ensure they are aware of a patient's failure to attend for blood tests and other monitoring and agree an action plan, which may include stopping lithium.

Reasonable adjustments will be made for disabled clients when reviewing response to non-attendance at clinic. This might include taking blood samples at a different location or in the clients own home.

4.9 Abnormal Lithium Result and Related Bloods and Action to be taken

Lithium samples can be processed by Belfast Labs. An alerting process for urgent communication of lithium levels over 1.0mmol/ to the relevant medical team and the Lithium Service has been agreed with labs and is described in Appendix 7 *(Guideline for Laboratory Technician Contact with Psychiatry and the Response to Raised Lithium Levels).*

This should be used in conjunction with "*Acute Lithium Toxicity Guide*" (Appendix 8).

4.10 Transfers to General Practitioner for Monitoring

The process for transferring patients from Pathway 1 to Pathway 2 or 3 is described in the Regional Shared Care Guidelines. All parties should agree before the transfer takes place.

4.10.1Transfer to Pathway 2

This can occur when the patient is stable on lithium and with agreement between the patient, the consultant and the GP.

- The consultant psychiatrist writes to the GP and requests moving the patient to Pathway 2 (GP monitoring).
- Consultant sends a completed Pathway communication proforma to the GP and Lithium Nurse (Appendix 3).
- The patent may be transferred back to Pathway 1 at any time following agreement between the GP and Consultant Psychiatrist.

4.10.2 Transfer to Pathway 3

This occurs when both the consultant psychiatrist and the GP agree the patient is stable and that both the clinical reviews and the monitoring can all be done by the General Practitioner. Follow the steps in 4.10.1 above.

4.11 Maintaining the Lithium Patient List

The Lithium Patient List maintained by the Trust will apply to patients on Pathway 1 and Pathway 2.

It will contain the following Information:

- Name, Address, Date of Birth, H&C number,
- Consultant Psychiatrist, Key Worker (if applicable).
- Where lithium and related assessments are carried out.
- Lithium Pathway, Lithium Pathway History.

It is important that the Lithium Nurse, who will be responsible for keeping the database up to date, is always informed of:

- New patients starting on lithium
- Any change of lithium pathway
- Any Transfer of patients e.g. consultant, general practitioner
- Any Transfer to another Trust
- Admissions and Discharges from Acute Psychiatric Care.

4.12 Admission/Discharge Hospital

For patients admitted to Home Treatment Team or an acute mental health ward, responsibility for lithium monitoring passes to the respective Consultant. The community lithium team should be informed of the admission and when the patient is discharged. Current Lithium monitoring Pathway must be confirmed on discharge.

4.12.1 Admission/Discharge Inpatient Psychiatry Unit and Home Treatment Team

This applies to General Adult Mental Health Wards, Home Treatment Team Child and Adolescent Services and Intellectual Disability inpatient Units.

- Check lithium level and other blood tests as outlined in the Regional Shared Care Guidelines on admission
- The Lithium Nurse should be informed at time of admission and discharge
- Update the patient's Lithium Record Book during the admission
- At discharge, the following should be in place.
    1. Date and location for the next lithium assessment for Pathway 1 patients is given to patient and recorded in discharge letter.
    2. For Pathway 2 Patients, confirm this to the GP in the discharge letter and suggest when follow up tests are required.
    3. Details of the most recent lithium level (date & value) must be added to the discharge prescription. A pharmacist clinical screen of the discharge prescription includes a check to ensure the necessary details have been provided or can be obtained. The Discharge prescription for lithium will not be dispensed until this information has been confirmed. An urgent serum lithium may be required with follow up action agreed between the pharmacist and doctor requesting the test. The follow up arrangements should be incorporated into the Discharge Plan and copied to the relevant community services and GP.
    4. For patients newly commenced on lithium during the admission send the GP a copy of the Regional Shared Care Guidelines and the Pathway Communication Proforma (Appendix 3)

4.12.2 Admission and Discharge to Acute Medical or Surgical inpatient units:

The guidance for the "Advice for medical staff with regards Patients who are taking lithium and are admitted to Non-Psychiatric Inpatient Units" (Appendix 10) should be followed. The psychiatry liaison teams (General adult and Elderly Care) will be main points of contact..

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination:

- All consultant Psychiatrists in Belfast Trust
- Inpatient Mental Health, Intellectual Disability and CAMHS managers
- All Community Mental Health, Intellectual Disability and CAMHS Team Managers.
- Home Treatment Team
- Acute Day Treatment Team (Mental Health).
- All consultant medical staff and Junior Doctors in the Trust (Policy on Admission /Discharge in non-psychiatric wards).
- Head of Pharmacy and Medicines Management
- Visual flow Charts that summarise aspects of the Policy are included:

- Outlining the key aspects of the lithium process (Appendix 11).
- Outlining what should happen when a patient is admitted to hospital on lithium or is being commenced on lithium in hospital (Appendix 12).

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5.2 Resources

The current resources required for this process are 1 Band 6 Nurse, 1 Band 5 Nurse and secretarial support. There is cross support available from the clozapine team to help cover leave arrangements and emergencies.

There will be an identified consultant psychiatrist who will be the "lithium lead"

The Lithium nurse will enable the ongoing training and awareness raising with a range of staff, on an ongoing basis. The Lithium nurse will also be a focus of information for the important interface between primary Care and secondary care services.

Mental Health Staff: There is a need for ongoing training and awareness raising among all staff in mental Health. This will be carried out by the Lithium Nurse.

Details of the Trust Lithium Clinics, he Regional Pathways, Regional Shared Care Guidelines and Care Pathway will be included in psychiatry induction.

Currently the Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway (Appendix 2) forms are in use.

5.3 Exceptions

There are no exceptions.

6.0 MONITORING

The Trust will participate in the Prescribing Observatory for Mental Health (POMH) lithium audits when these are running.

The operation of the Appendix 5, Lithium Monitoring Proforma will be audited to ensure appropriate communication between primary and secondary care in both directions.

The lithium process will also be subject to clinical audit regionally and locally.

7.0 EVIDENCE BASE / REFERENCES

- Bipolar Disorder: Assessment and Management. Nice CG 38: July 2014.
- Safer Lithium Therapy: National Patient Safety Alert: 2009(2009/RSA005): Dec 2009.
- Lithium: Mental Health Shared Care Guidelines V3.0. Health and social Care Board (N.I.) June 2017

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8.0 CONSULTATION PROCESS

This reviewed policy was circulated for Consultation to the following

- All Consultant Psychiatrists in Belfast Trust
- The Lithium nurse and members of the Lithium team

9.0 APPENDICES / ATTACHMENTS

Appendix 1	Patient Registration Form
Appendix 2	Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway (link)
Appendix 3	Lithium Therapy Pathway - communication Information from consultant psychiatrists to general practitioner"
Appendix 4	Lithium, Shared Care Guideline (link)
Appendix 5	Ongoing Lithium Monitoring Communication Proforma
Appendix 6	Guidelines for patients who do not attend (DNA) and who cannot attend (CNA)
Appendix 7	Guideline for Laboratory Technician Contact with Psychiatry and the response to raised lithium Levels
Appendix 8	Acute Lithium Toxicity Guide
Appendix 9	Lithium Care Flowchart (Pathways Definition).
Appendix 10	Advice for medical staff with regards patients who are taking lithium and are admitted to non-psychiatric inpatient unit.
Appendix 11	Summary Lithium Care Pathway
Appendix 12	Summary Lithium Pathway in Acute Care
Appendix 13	NPSA Record Book (link)

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. ☒

SIGNATORIES

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

28/09/2018

_____ **Date:** _____

Author

28/09/2018

_____ **Date:** _____

Director

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Lithium Registration Appendix 1

Please complete ALL sections of this form to the best of your knowledge. This helps determine the most appropriate monitoring pathway for the patient

Name: Address: Landline: Mobile:	DOB: H&C Number: Ethnic Origin: Patient consent: YES/NO
Next of Kin: Relationship: Address: Landline: Mobile:	GP: Address: Cypher Code: Tel No:
Key Worker: Address: Work No: Mobile:	Consultant Psychiatrist: Address: Tel No:
Clinical Indication For Lithium: If new to lithium – Date commenced: Current Dose: Next sample date:	Lithium Care Pathway document commenced on: Lithium Therapy Pathway Communication Proforma completed by sent to GP on: Where are bloods being checked currently?
Are you requesting a referral to a lithium Clinic? YES/NO If 'NO' – Where will they be monitored?	Patient given information/education on lithium YES/NO Next Medical/Psych review date:
List of current medications: Drug interactions checked? YES/NO Please specify any interactions identified & recommendations:	Any known relevant medical conditions? E.g. Heart, kidney, thyroid problems. (If yes please specify) Any Special requirements? Referred By: Tel No: Date of Referral: Signature of Referrer:

This form must be completed for any person being started on lithium within the BHSC Trust, regardless of where they will be monitored. The form should be sent to the Lithium Service.

Appendix 2

Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway

The Northern Ireland Secondary Care Initiation and Monitoring Lithium Care Pathway can be found using the link below

http://www.medicinesgovernance.hscni.net/download/primary/secondary_care/medicines_safety_documents/lithium/Lithium-Care-Pathway.pdf

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Appendix 3

Communication Information from Consultant Psychiatrist to Primary Care
(Must be completed by consultant when pathway changes.)

Consultant name: _____ **Contact Number:** _____	**Write in CAPITAL LETTERS or use addressograph** **Surname:** ..... **First name:** ..... **Hosp No. / H&C:** ..... **DOB:** .....

Dear Dr _____ your patient is now stabilised on lithium. Please continue to prescribe lithium as below:

Lithium target range	
Lithium brand	
Lithium dose	

Please update your practice Primary Care Lithium Register as below

		Please insert ✓ to indicate pathway patient will follow
Pathway 1	**Remain in Secondary Care for review and monitoring** Secondary Care is responsible for informing the patient's GP of **all** blood monitoring results (using 'copy to' GP cipher number on lab request form). The GP should be informed **immediately** of abnormal lithium levels and action taken.	
Pathway 2	**Remain in Secondary Care for review, AND monitoring passes to Primary Care with GP agreement*.** Primary Care is responsible for informing Secondary Care of **all** blood monitoring results- using 'copy to' Consultant's name (and Lab Code if known) and hospital on lab request form. Secondary care should be informed **immediately** of abnormal lithium levels and action taken.	
Pathway 3	**Review and monitoring passes to Primary Care with GP agreement.** • Lithium blood results will not be copied to Secondary Care in this instance • If patient is persistently non-compliant with monitoring – consider change to another treatment and discuss with, or refer back to, Secondary Care	

Signed (Consultant): ..... **Date** ...../...../.....

Regional Lithium Care Pathway January 2018 8

Appendix 4

Northern Ireland Regional Shared Care Guidelines for Lithium

The Northern Ireland Regional Shared Care Guidelines for lithium can be accessed using the link below

http://www.ipnsm.hscni.net/download/shared_care_guidelines/LithiumSCGMar2018.pdf

Appendix 5

Health and Social Care in Northern Ireland

Appendix 4: Ongoing Lithium Monitoring Communication

The Trust or GP practice responsible for a patient's ongoing lithium monitoring must use this proforma or another locally agreed mechanism to communicate lithium monitoring results:

- From Consultant to GP – for patients following Pathway One or
- From GP to Consultant - for patients following Pathway Two *(See Lithium Flowchart appendix 1)*

To (name of GP/Consultant): .....

Address (GP Practice/Trust site) .....

Write in CAPITAL LETTERS or use addressograph Surname: ..... First name: ..... Hosp No. / H&C: ..... DOB:	**Medical Lead****	
	Tele No:	
	Cipher No/Lab Code	
	This patient is following Pathway (one or two)	

Attended for lithium monitoring* on ..../..../.... (Date) **at** ..... (GP Practice / Trust site).

* As per Regional Lithium Shared Care Guideline
**Name of GP/Consultant responsible for the patient's monitoring, their contact details and their GP cipher number or consultant lab code

Current Lithium dose	
Serum lithium & date (0.6 – 0.8mmol/l & elderly 0.4 - 0.8mmol/l)	
Current mental status / mood check	
Side effects and monitoring	

Please note: If lithium levels are abnormal or toxicity is suspected, medical staff must inform the patient's GP/consultant immediately (by telephone), in addition to sending this proforma.

The above lithium monitoring results have been reviewed:

by:..... (Name of GP/ Consultant#) **on** ..... (Date)

Action taken (if no action, please state):

.....

Treatment plan:

.....

Additional comments:

.....

Signed (GP/ Consultant#)..... **Date**.....

#Name and role of staff must be specified if not GP or Consultant

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Appendix 6

Lithium Service
Community Mental Health Team
Woodstock Lodge
1-15 Woodstock Link
Belfast
BT6 8DD
Tel: 02895 044888
02895 044476
Date:

Lithium Clinic

1st DNA

Dear

According to our records you did not attend for lithium blood test on

We hope you are well and that this was just an oversight.

It is very important that you come for the lithium blood tests and we have arranged an appointment for you on

If this appointment does not suit or you have any concerns please do not hesitate to contact the team on the numbers provided.

We have informed your GP and Consultant Psychiatrist as they need to know if and why there would be any delays in reading your blood results.

Yours sincerely,

Kathy Parker
Lithium Clinic Nurse

CC. **G.P** –

Consultant Psychiatrist –

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Appendix 6

Lithium Service
Community Mental Health Team
Woodstock Lodge
1-15 Woodstock Link
Belfast
BT6 8DD
Tel: 02895 044888
02895 044476
Date:

Lithium Clinic

2nd DNA

Dear ,

As you know it is very important that your bloods are checked every three months in order to ensure that you are on the appropriate level of lithium medication and that you are not experiencing any medical problems from the medication. According to our records you have not attended for lithium blood tests on two occasions on and.

It is very important that you come for the lithium blood tests and we have arranged another appointment for you on

If you cannot attend I would appreciate if you would contact us in advance so that we can arrange another appointment.

We have informed your GP and consultant psychiatrist that we do not have a recent blood result for you. If you have any concerns please do not hesitate to contact us or talk with your general practitioner.

It is extremely important that you come for this appointment.

Yours sincerely,

Kathy Parker
Lithium Clinic Nurse

CC. **G.P** –

Consultant –

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Appendix 6

Lithium Service
Woodstock Lodge
1-15 Woodstock Link
Belfast
BT6 8DD
Tel: 028 95044888
028 95044476
Date:

Lithium Clinic
3rd DNA

Dear ,

According to our records you have missed **3** appointments with the Lithium Clinic. As you know it is very important that your bloods are checked every three months in order to ensure that you are on the appropriate level of lithium medication and that you are not experiencing any medical problems from the medication.

It is very important that you come for the lithium blood tests and we have arranged another appointment for you on

at in .

If you cannot attend or you have any concerns please do not hesitate to contact the team on the numbers provided. Our priority is your health and wellbeing, so we will do our best to accommodate changes in appointments to ensure your lithium treatment is being monitored.

We have informed your GP and Consultant Psychiatrist as they need to be aware of overdue tests.

It is extremely important that you come for this appointment.

Yours sincerely,

Lithium Clinic Nurse

CC.
G.P
Consultant

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Appendix 6

Lithium Service
Woodstock Lodge
1-15 Woodstock Link
Belfast
BT6 8DD
Tel: 028 95044888
028 95044476
Date:

Dear Dr.

Re :

DOB:

The above patient has DNA'd the Lithium clinic on three consecutive occasions. You will already have received a copy of the letters sent to the patient concerning their first and second DNA. This patient is on Pathway 1 for Lithium monitoring, which means that secondary care services are responsible for the monitoring. We have sent for the patient again to attend on

There is a possibility that the patient has become unwell and in keeping with the DNA protocol, I would appreciate if you would advise me of what your plan for the assessment of the patient is. You may need to consider arranging this through an outpatient appointment, or the Mental Health Team, as well as contacting the General practitioner. Please let me know of the outcome of the assessment and if you want the patient to have an alternative appointment to the one given above.

If you need to discuss this patient please contact me on 028 95044476 .

Yours Sincerely

Kathy Parker

Lithium Clinic Nurse

Cc GP:

Appendix 7

Guideline for Laboratory Technician Contact with Psychiatry and the Response to Raised Lithium Levels

1.0 Background

Due to potential acute toxic effects urgent contact with the responsible clinician is essential if a patient has a serum lithium level above 1.0 mmol/l

The purpose of this protocol is to:

- Clarify who is contacted when abnormal blood samples are reported.
- Ensure information is passed to the appropriate clinician.
- Ensure appropriate action is taken in light of the abnormal result.

2.0 Source of Sample

Samples may come from hospital wards or community facilities. The action required will vary accordingly.

2.1 Sample from a GP

During working hours, the laboratory technician should contact the GP practice directly. Outside working hours, contact the out of hours GP service for the practice.. The GP can obtain advice from the Trust by contacting the relevant consultant or lithium nurse during working hours or on-call medical staff outside working hours.

2.2 Sample from a Belfast Trust 24hr facility

If the sample is from any 24hr. department, e.g. ED dept., medical ward, inpatient psychiatric ward etc., contact the department directly by phone and give the information to the relevant clinician verbally. Record the date, time and name of the person to whom the information is given.

2.3 Sample from a Belfast Trust Community Facility

The action will vary if the result is reported during working hours (weekdays 9am to 5pm) or outside these times.

2.3.1 Within Working Hours (Weekday 9am to 5pm)

Contact the Lithium Nurse on 95044476 or 07825915253

2.3.2 Outside Working Hours (5pm to 9am and at weekends / Bank holidays)

Contact Second on-call psychiatrist using the Golden Number 90454999 or Belfast Trust Switchboard. Ask to speak to the second on-call psychiatrist, and give the information outlined in Section 2.3.3. If second on-call psychiatrist is not available, ask to speak with the Consultant Psychiatrist on-call.

2.3.3 Information to be provided by the Laboratory Technician

If the lithium level is >1.0mmol/l (over 0.8mmol/l in over 65's) the laboratory technician should verbally communicate the information below to the relevant nurse or doctor.

- Name, Date of Birth, H&C number
- Address of patient and /or telephone number
- Source of Blood sample
- Date and Time of sample
- Lithium Level
- Name of the consultant
- Name of Lab technician

3.0 Action to be taken by staff informed of raised lithium level

3.1 Action during Working Hours

Follow the advice in the "Acute lithium toxicity Guide" (Appendix 8).

3.2 Action outside Working Hours by Second On-Call Psychiatrist.

The patient should be contacted by phone and assessed as in section 3.1. If the patient cannot be contacted and the serum lithium level is lower than 1.2mmol/l, contact can wait until the next day, although it would be preferable to contact that evening. If the serum lithium level is greater than 1.2mmol/l the patient must be contacted directly that evening and the relevant action in Appendix 8. If there are difficulties contacting the patient then the contact can be made through either the Home Treatment team or the relevant GP out of hours unit.

The patient's consultant and the Lithium Nurse should be informed the next workday morning by the on-call psychiatrist.

3.2.1 Urgent Weekend assessments

This is envisaged as a rare occurrence as the last lithium clinic is on a Thursday and the results will be available by Friday morning. If the patient needs to be seen and bloods taken, over the weekend, this can be done on Ward K, Mater Hospital. However, the person arranging (usually lithium nurse) for the assessments needs to inform the Nurse in Charge of the ward beforehand, and the second on-call psychiatrist who will be seeing the patient on the day the assessment is being carried out. There are two main situations where this may occur:

1. An already identified raised lithium level, which needs to be followed up on a Saturday, Sunday or bank holiday. In this case, the consultant psychiatrist or Lithium Nurse requesting the assessment will contact the second on call psychiatrist for the appropriate weekend day and describe what needs to be done and pass on the relevant clinical details and contact information for the patient including next of kin details.

A new raised lithium level is notified to the second on-call psychiatrist on a Friday night or over the weekend, and depending on the assessment carried out that night,

the patient needs to be seen the following day. The second on-call psychiatrist arranges as detailed above or passes the information onto the second on-call psychiatrist for the next morning, who will then make the arrangement.

Appendix 8

Acute Lithium Toxicity Guide

Introduction

Lithium has a narrow therapeutic index and requires regular monitoring in line with NICE guidelines. The normal adult range is 0.4 to 1.0mmol/l and 0.4 to 0.8mmol/l for people over 65yrs age.

Signs and Symptoms of toxicity

Dizziness, stomach pains along with nausea/vomiting, and diarrhoea, muscle weakness are common signs of lithium toxicity. Development of CNS signs indicate a worsening situation and include severe hand tremors, incoordination of the limbs, ataxia, muscle twitches, confusion, seizures, slurred speech (either self-report or observed), metallic taste, nystagmus and feeling unusually sleepy.

Any one of these symptoms needs to be assessed urgently with both a physical assessment and bloods for lithium level and U&E

Remember lithium toxicity can occur with normal lithium levels (especially with low sodium levels) – Immediate Clinical Assessment is essential for any of these symptoms and if significant direct consultation with and referral to nearest A&E department.

Urgent Lithium Bloods

If a patient has signs or symptoms of toxicity but the lithium level is unknown

Request an urgent **serum lithium level, U&E.**. The clinician taking bloods has to clarify who is taking responsibility for checking the results and putting into place appropriate clinical care.

High Lithium Levels, Communication and Responsibility

It is the responsibility of the clinician who first becomes aware of or is informed about a raised serum lithium level to ensure that the relevant team is alerted and it is agreed who will take clinical responsibility.

- For inpatients in a 24hr. department, e.g. ED dept., medical ward, inpatient psychiatric ward the responsibility for action lies with the patient's medical team. If necessary, seek advice from psychiatry.
- For samples from a Trust Lithium Clinic the Lithium Nurse should follow the steps outlined in (Appendix 8.1)
- For samples from a GP Practice the general practitioner will be responsible.

Raised Lithium level: When a raised lithium level is reported, consider the guidelines below. It is important to identify possible causes for the raised lithium level.

- **Consider the possibility of a deliberate or accidental overdose of lithium**

- **Blood Sample issues**: Check that the blood sample was taken at least 10 hours after the last lithium dose. Samples should be taken 10 to 14hrs after last dose (ideally 12hrs). Arrange repeat sample if appropriate.

- **Lithium Medication Issues:** Check the patient is taking the correct medication and the correct dose. Mix ups can occur especially if the patient takes multiple medicines. Changes in the medication colour, type of packaging or strength could lead to a misunderstanding. Check the patient is taking the named brand of lithium as changes between brands may affect lithium levels. Consider the possibility of a prescribing or dispensing error.

- **Other medication Issues:** A number of medicines interact with lithium to increase lithium levels. Medication which reduces renal excretion can significantly increase serum lithium levels. The most common interactions are described in the "*Lithium Shared Care Guidelines*" (Appendix 4) and include:
  a) Non-steroidal anti-inflammatories. These can be bought over the counter so it is important to ask specifically about this possibility.
  b) Diuretic Medication (particularly thiazides)
  c) ACE Inhibitors (including angiotensin II antagonists)
  d) Medications with significant sodium content as chloride or bi-carbonate (e.g. antacids, urinary alkalinisers and effervescent analgesics) can lower serum lithium levels if taken regularly. Stopping these medicines by a patient stabilized on lithium while taking them could lead to raised lithium levels.
  e) Check with the BNF if there is any doubt about medication interactions.

- **Dehydration**: Inadequate fluid intake, infection, vomiting and/or diarrhoea, sunstroke. Alcohol misuse.

- **Other Medical Reasons:** Confusion leading to taking the wrong lithium dose. Reduced sodium levels.

- **Psychiatric Reasons:** Patient has become unwell and is getting mixed up because of poor concentration or lack of insight

Appendix 8.1

Action required when dealing with actual or suspected lithium toxicity

General Practitioners and Consultant Psychiatrist must keep each other Closely informed irrespective of who is taking the lead role

Lithium Level **1.0 – 1.2 mmol/l** Lithium Level 0.8 to 1.0 mmol/l over 65yrs	1) Review patient, contact outpatients by phone and ask about toxicity symptoms. 2) Clarify dose of medication and timing of sample. 3) Consider reasons for raised lithium levels 4) **If no clinical concerns**, arrange urgent repeat blood tests (lithium and renal function) the next morning. 5) **If there are clinical, concerns** send urgent bloods or refer to and contact ED department. 6) Inform consultant psychiatrist or GP and arrange for them to receive the blood results the next day. 7) If repeat lithium level is >1.0mmol/l, repeat within one week and continue weekly. Consider dose reduction overseen by the consultant/general practitioner until the patient is in their target range. 8) If repeat level is still in the range 1.0 to 1.2 with no explanation, and no toxic symptoms reduce the lithium dose by 200mg and repeat level in 2 – 3 days. Keep checking for toxic symptoms. Continue lithium every 2 -3 days until levels are stable in the target range for the patient.
Lithium Level **1.2** to **1.5 mmol/l** (This is more significant if> 65yrs.)	1) Review patient, contact outpatients by phone and ask about toxicity symptoms, if present, the patient requires immediate assessment and possible transfer to ED. If the symptoms are severe, they may need to go directly to ED. 2) Clarify dose of medication and timing of taking medication and blood sample. 3) Consider reasons for raised lithium levels 4) If no clinical concerns tell patient to omit lithium that night. Arrange urgent repeat blood tests (lithium and renal function) the next morning.. 5) Inform consultant psychiatrist or GP and arrange for them to receive the blood results the next day. 6) If repeat blood level is **within the target range** for the patient - try and clarify the reason for the high result. Recommence lithium but consider doing so at a lower dose and check blood results every two to three days with medication adjustment as necessary until stabilization at the required level. More regular lithium levels will be required for a period of time, after stabilization, to ensure that it is maintained. 7) If repeat blood level **remains high or is increasing** despite missing the one night's dose

	then: a. Stop lithium entirely b. Patient will need ongoing physical assessments to assess the degree of impact of the raised lithium level, and possible referral to an A&E department c) Check bloods daily and don't start re-titration until lithium level is low and underlying reason for toxic level has been established. Consultant and GP should communicate with each other urgently by phone and followed up in writing
Lithium Level >1.5mmol/l (This is more significant if > 65yrs.)	1) The patient must be assessed to determine the degree of toxicity. Consider referral to ED if appropriate. Contact ED department and advise patient will be attending 2) If level is approaching 2.0mmol/l the patient is at risk of serious neurological damage or cardiovascular and renal collapse. The patient should be referred urgently to an ED department for a full physical examination and assessment. 3) Stop lithium and check daily bloods for lithium, U&E and creatinine. 4) Identification for reason of raised serum lithium levels is essential before recommencing lithium. 5) Re-titration should not restart until lithium level is reduced to a low level and the cause for the raised lithium level has been established. Consultant and G.P. should communicate with each other urgently by phone and followed up in writing

Appendix 9

LITHIUM CARE FLOWCHART

Lithium Initiation Preferably in Secondary Care.
Psycho-education included
Lithium Work-up information (page 2) forwarded to GP

Patients added to Lithium Register in both Secondary Care and Primary Care
Lithium Blood Results Copied to Primary Care

Pathway 1
Patient remains in Secondary Care for review and monitoring. Lithium blood monitoring results copied to Primary Care.*

Pathway 2
Patient remains in Secondary Care for review but, with agreement between GP and Secondary Care, monitoring passes to Primary Care. Lithium blood monitoring results copied to Secondary Care.*

Pathway 3
If patient stable or strong patient preference, with agreement between GP and Secondary Care, review and monitoring passes to Primary Care. Lithium blood monitoring results not copied to Secondary Care.*

*A ccommunication proforma from secondary care to primary care will advise of the pathway the patient will follow and responsibilities for review and monitoring. Primary and secondary care lithium registers should be updated using this information.

Regional Lithium Care Pathway January 2018

Appendix 10

Advice for medical staff with regards Patients who are taking Lithium and are admitted to Non-Psychiatric In-Patient Units

1.0 Rational

To ensure that patients taking lithium who are admitted to general hospital wards have their lithium managed appropriately during their inpatient care and that appropriate follow-on care in the community, on discharge is arranged. Advice from Liaison Psychiatry Services is readily available.

2.0 Acute Medical or Surgical Admissions

If the patient is admitted acutely ill consider if lithium toxicity may be contributing to the symptomatology. Toxicity can arise due to dehydration, due to vomiting, diarrhoea, blood loss or lack of fluid intake. Lithium toxicity may develop secondary to an acute physical illness. This is particularly important in elderly patients. It is safer to stop lithium and seek advice from Liaison Psychiatry than to continue it in an acutely physically ill patient. Even after the lithium has been stopped the lithium levels and renal function tests still need to be carefully monitored. In cases of acute medical or surgical conditions, it is important to:

- Stop lithium
- Send Urgent bloods immediately for serum lithium level, renal function and thyroid Function. Check for low sodium levels as this can contribute to lithium toxicity
- Contact Liaison Psychiatry for advice about restarting, continuing or keeping the patient off lithium.

If lithium is restarted, follow liaison psychiatry's advice about dose of lithium and frequency of checking serum lithium levels.

3.0 Surgical procedures and lithium

Lithium levels can be altered during surgery as a result of fluid imbalance and electrolyte disturbance and toxicity may occur. Follow the recommendations in the Trust Guidance on the Administration of Medications in Perioperative Adult patients :and discontinue lithium when there is a risk of fluid imbalance. Ensure any fluid imbalance and electrolyte disturbance is corrected before lithium is restarted. To avoid any effect on mental state, lithium should be restarted at the previous dose as soon as possible. Lithium levels should be checked frequently after surgery to avoid unexpected toxicity. Steady state levels may not be reached for 5-7 days. Ensure a follow up appointment to recheck levels is made (section 6.0)

4.0 Routine Admissions

Advice may be needed about lithium in general or in specific situations, including the following:

- Procedures for which the lithium has to be stopped and then restarted promptly e.g. planned surgery, refer to the Trust Preoperative assessment Policy for further information
- Abnormally low or high lithium levels identified through routine testing. (Normal Range 0.4 to 1.0mmol/l, >65yrs of age 0.4 to 0.8mmol/l).
- Side effects of lithium may be identified and adjustments to medication may be needed.
- There may be symptoms suggesting lithium toxicity, which is a medical emergency.
- Possible drug interactions may be identified, always check BNF.
- There may be concerns about the patient's mental state.

4.1 Basic Assessment:

This should be carried out on **every patient** who is admitted to hospital and is on lithium.

- Verify the dose of lithium is correct. Use at least two information sources.
- Take lithium level as soon as possible after admission. In the situations stated above in **section 2.0** or if toxicity is suspected, the serum level should be sent **urgently** and results checked online by or phoning labs.
- Routine Serum Level must be taken 12 hours after taking the medication. (Lithium is normally taken at night and serum level in the morning, if patient is on liquid lithium which is normally taken twice each day the Serum sample should be taken before the morning dose).
- Renal function with particular attention to sodium level.
- Thyroid function

4.2 Lithium Toxicity

Symptoms such as severe tremor, severe diarrhoea, confusion, ataxia or convulsions, could indicate serious lithium toxicity. This is a medical emergency and can lead to cerebro-vascular and renal collapse as well as permanent neurological damage. The actions below are required

- Discontinue lithium on the patient's Kardex, even if toxicity is only suspected.
- Take an urgent lithium Level and U&E immediately
- If in doubt, treat as lithium toxicity and seek the relevant advice.
- Even when the lithium has been discontinued, continue to monitor serum lithium, renal function and electrolytes until advised to stop.

- Toxicity can occur in some people with lithium levels in the normal range and should be treated as an emergency. This occurs especially if sodium levels are low.
- The relevant psychiatry liaison team should also be contacted for advice about recommencing lithium. See section 4.0.

5.0 Advice Needed

Advice is can be obtained through the relevant Hospital Psychiatry liaison service. If there are any suggestions of lithium toxicity or a serum lithium level > 1.0mmol/l this should be considered as urgent. How to obtain advice depends on the age of the patient and if it is within or outside working hours. This is outlined below.

5.1 During Working Hours

5.1.1 Under 65yrs of age

Contact the Golden Number 90454999. State the issue and the degree of urgency.

5.1.2 Over 65yrs of age:

Make a referral to the Psychiatry of Old Age Liaison Service using the e-referral available on The HUB (search Psychiatry Referral Form), if necessary mark URGENT.

5.2 Out of Hours and weekends for all Patients:

Contact Golden Number 90454999 or any Belfast Trust switchboard and ask for second On Call Psychiatrist. If the second on call psychiatrist cannot be contacted, ring the on call consultant psychiatrist.

6.0 Arrangements at Discharge

Changes to lithium during an admission must communicated to both the patient's General Practitioner and Consultant Psychiatrist. There must be clear arrangements for the on-going follow-on of the lithium monitoring, in the community after discharge.

- There should be a **date** and **location** arranged and recorded for the next lithium monitoring appointment after discharge. This may be earlier than the next routine appointment if any issue has arisen during the admission. For example, any change in dose of lithium, commencing any medication that interacts with lithium (BNF) a significant change in renal function or lithium was stopped prior to surgery. Ensure patient is informed of this date.
- Even if the Liaison team has coordinated the new appointment this needs to be checked at time of Discharge.

- Details of the most recent lithium level (date & value) must be added to the discharge prescription. A pharmacist clinical screen of the discharge prescription includes a check to ensure the necessary details have been provided or can be obtained. The Discharge prescription for lithium will not be dispensed until this information has been confirmed. An urgent serum lithium may be required with follow up action agreed between the pharmacist and doctor requesting the test. The follow up arrangements should be incorporated into the Discharge Plan and copied to the relevant community services and GP
- Copy Discharge letter to relevant Consultant Psychiatrist with either routine or new lithium Monitoring appointment included.

Appendix 11

Belfast Health and Social Care Trust

Summary Pathway for Blood Monitoring and Assessments for patients on Lithium attending Secondary Care services in Belfast Trust

Initiation

- Recommendation: Consultant Psychiatrist states clear rationale for lithium and informs Lithium Nurse and GP
- Documents:
  - Lithium Registration Form Completed by consultant and sent to Lithium Nurse
  - Lithium Therapy Pathway – and
  - Shared Care Guidelines completed by consultant and sent to GP (For inpatient send, at time of discharge)
  - Initiation pathway – Lithium Secondary Care Pathway completed by Lithium Nurse and consultant psychiatrist– if inpatient completed by key nurse and consultant
  - Education Booklet and Record Card: NPSA education booklet and lithium card given to the patient and explained by staff. Signed by staff on Pathway protocol.
- Pretreatment Bloods: U&E, eGFR, serum calcium, TFT, Pregnancy test (urine).
- Assessments: Weight, BMI, BP and if indicated Physical Examination and ECG
- Lithium Titration: Start at low dose and increase slowly. Prescribe lithium by brand name. Initial lithium level after 5 days. Repeat lithium levels weekly as dose is increased until dose and lithium levels are stable as per shared care guideline.

Ongoing Monitoring Pathway 1

- Blood Tests: Serum Lithium every 3 months, U&E, eGFR, serum calcium and TFTs every 6 months.
- Assessments: Side-effect Profile, Mood Check, BP, Weight, BMI every 3 months – Nurse records in the GP communication letter
- Lithium Nurse: Screens test results within 5 days, prints results, attach to GP Communication Letter and send to Consultant Psychiatrist's secretary. Completed letter sent by Consultant to GP within 2 weeks.

Documents: G.P. Communication Letter –

- Lithium team secretary enters admin details.
- Nurse at clinic enters assessments of side-effect and mood check.
- Lithium Nurse attaches printed blood results to GP letter.
- Consultant reviews and signs blood results, enters any recommendations, specifies dose of Lithium and signs letter
- Consultant's secretary sends original to GP & copy each for Lithium Nurse and medical charts
- On Going monitoring Pathway Regional Secondary Care Guideline completed by Lithium Nurse and Psychiatrist
- Reduced Monitoring for Stable patients - see Shared Care Guideline for criteria for reduced frequency of monitoring for stable patients

Transfer to Pathway 2

- Process: Consultant may request GP to take over patient Lithium Monitoring when the patient is stabilised on lithium
- Documents: Lithium Therapy Pathway – indicating request to GP to change patient to Pathway 2 (accompanies clinic letter)
  - Lithium Shared Care Guideline – accompanies request to GP
  - Letter of acceptance from GP – This is necessary and when received, GP will take over monitoring.
  - GP communication Letter - GP will send letter to consultant with blood tests results and side-effect assessments each time tests and assessments are carried out.

Version 0.4 August 2018 **Advice is always available from the Lithium Nurse**

Appendix 12

Summary Pathway of Care for Lithium Patients under Acute Care

Developed by Nora Curran

ACUTE ADMISSION – ALREADY ON LITHIUM

On Admission

1) Contact Lithium Service. Inform of admission & ascertain patient's current pathway.
2) Check prescribed Brand & Dose with GP.
3) Check Serum Lithium, U&E, serum calcium and TFT.

During Admission

1) If Inpatient longer than 3 months remember to recheck serum level on 3rd month & TFT, U&E on 6th month. Unless increased monitoring required.
2) If any changes to lithium treatment check serum lithium on day 5, then weekly until level is stable.

Prior To Discharge

PATHWAY 1	PATHWAY 2
1) Consultant to complete ***Lithium Therapy Pathway Proforma*** & attach copy of ***Shared Care Guidelines.*** This should be included in the discharge plan with original to GP and copy to Lithium Service. 2) Contact Lithium Service & get ***Date, Time & Location*** of next appointment. This ***MUST*** be included in the discharge documentation including on the discharge prescription	1) Contact GP to check if they are still agreeable to Pathway 2. 2) If yes, Consultant to complete ***Lithium Therapy Pathway Proforma*** as per agreement. 3) Get appointment date & time for next lithium monitoring at GP Practice. This ***MUST*** be included in discharge documentation. 4) If GP no longer agreeable – follow Pathway 2 section.

NB If Lithium therapy discontinued during admission – Lithium Service MUST be informed for purpose of updating BHSCT

PTO for Starting Lithium flowchart

Appendix 12

Summary Pathway of Care for Lithium Patients under Acute Care

Developed by Nora Curran

ACUTE ADMISSION - STARTING LITHIUM

Starting Lithium

1) Contact Lithium Service.
2) Using Lithium Care Pathway – Do work up/Initiation Section.
3) When definitely starting Lithium – ***REGISTER THE PATIENT*** – Using the BHSCT Registration form – to be completed by doctor.
4) Complete patient information section of Care Pathway, ensuring ***NPSA patient information booklet, record book & alert card*** are given & explained to the patient.
5) On commencement – follow the Initiation & Monitoring Section of Care Pathway.

Prior To Discharge

1) As agreed with Primary Care – New patients to follow Pathway 1 until stable.
2) Consultant to complete ***Lithium Therapy Pathway Proforma*** & attach a copy of ***Shared Care Guidelines.*** Send original to GP and copy to Lithium Service.
3) Contact Lithium Service to arrange ***Date, Time & Location*** of 1st Lithium Clinic appointment. This ***MUST*** be included in discharge documentation.

NB Remember to send the following to Lithium Service –

- ***Registration Form***
- ***Original Care Pathway***
- ***Copy of Discharge Plan***
- ***Copy of Risk Assessment***
- ***Copy of Lithium Therapy Pathway Form***

PTO for Flowchart of Patient Already on lithium

Appendix 13

National Patient Safety Agency Lithium Record Book

The National Patient Safety Record Book can be access using the link below

https://www.sps.nhs.uk/wp-content/uploads/2018/02/2009-NRLS-0921-Lithium-patientet-2009.12.01-v1.pdf

Leaflet on Lithium in different languages and version for various levels of reading ability can be found on the Choice and Medication website at

www.choiceandmedication.org/hscni

Belfast Health and Social Care Trust
caring supporting improving together

Reference No: SG 10/19

Title:	**Clozapine Policy**		
Author(s)	Stephen Guy, Lead Mental Health Pharmacist Dr Michael Doherty, Locum Consultant Psychiatrist		
Ownership:	Caroline Leonard, Surgery and Specialist Services Director		
Approval by:	Drugs and Theraputics Committee Standards and Guidelines Committee Trust Policy Committee Executive Team Meeting	**Approval date:**	22/02/2019 10/05/2019 06/06/2019 12/06/2019
Operational Date:	June 2019	**Next Review:**	June 2024
Version No.	1	**Supersedes**	None
Links to other policies	• Empirical Antibiotic Prescribing in Hospitalised Adults (SG 27/12) http://intranet.belfasttrust.local/policies/Documents/Empirical antibioitic prescribing in hospitalised adults.pdf • Guidelines for the management of oncology/haematology adult patients (>18) with neutropenic sepsis (SG 48/10) http://intranet.belfasttrust.local/policies/Documents/Neutropenic Sepsis - Guidelines for the management of oncology haematology adult patients.pdf • The management of patients treated with clozapine who smoke and are admitted to inpatient units following the implementation of the hospital smoke-free policy (SG51/16) http://intranet.belfasttrust.local/policies/Documents/Smokers treated with clozapine admitted to inpatient units following the implementation of the hospital smoke-free policy -.pdf • Point of care testing Policy (SG 38/11) http://intranet.belfasttrust.local/policies/Documents/Point of Care Testing.pdf		

Date	Version	Author	Comments
01/02/2017	0.1	M Doherty S Guy	Initial drafting
30/08/2018	0.2	S Guy	Incorporation of comments from Consultation
09/09/2018	0.3	S Guy	Addition of all Appendices
10/12/2018	0.4	S Guy	Typing and grammar corrections after D&T review
21/02/2019	0.5	S Guy	Updated Community Pharmacy Script, Red Alert Guide and added new Clozapine Red Alert Information Sheet

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background:

Clozapine is an atypical antipsychotic drug used in the management of treatment resistant schizophrenia and psychosis associated with Parkinson's disease. Clozapine causes neutropenia with an incidence of 3% that may progress to agranulocytosis (high risk of sepsis) in 1% of patients. Treatment with clozapine requires mandatory registration with a clozapine haematological monitoring service and adherence to their monitoring protocol.

Careful attention must be paid to pre-clozapine checks, monitoring during clozapine titration and for the first few months of treatment, as the risks of adverse events are higher at this stage. In addition to haematological problems, clozapine is associated with increased rates of myocarditis and cardiomyopathy, constipation that can progress rapidly to life-threatening gastrointestinal hypomotility, increased risk of seizures and metabolic syndrome. Mortality due to severe gastrointestinal hypomotility is higher than that due to neutropenia and benign constipation can progress to life threatening hypomotility in less than 24 hours. Patient and carer education is a central aspect to the safe use of clozapine.

Due to the necessary level of monitoring, clozapine is categorised as a RED List Medicine by the Northern Ireland Regional Group on Specialist Medication. Prescribing and monitoring responsibility for RED List medicines must remain with the Hospital consultant and a Trust Pharmacy must supply clozapine.

1.2 Purpose

The purpose of this policy is to implement a system for prescribing, monitoring and communication of the physical and mental health of patients prescribed clozapine. This involves communication within the Trust, the Haematological monitoring service, the general practitioner and the patient and carer.

1.3 Objectives:

The main objective is to ensure a safe system for the treatment of patients with clozapine. This will include:

- Following the Integrated Care Pathway (ICP) for Assessment to ensure all baseline checks are completed. (Appendix 1: ICP for Clozapine Assessment)
- Following the Integrated Care Pathway for Clozapine Titration to ensure appropriate monitoring takes place during initiation. There are separate Pathways for Community and Inpatient clozapine initiation.(Appendix 2: ICP Hospital Titration Clozapine, Appendix 3: ICP Community Titration Clozapine)
- There is an effective system to check results, whether it is from the Trust laboratories, Point of Care Testing (PocHi) or the Clozapine Haematology monitoring service and only to supply clozapine to a patient against a valid blood result.
- Take appropriate action if Clozapine RED or AMBER alerts are reported. (Appendix 8: Red Amber Guide)
- Take appropriate action if myocarditis or cardiomyopathy are suspected.

2.0 SCOPE OF THE POLICY

- The policy applies to all patients attending the Belfast Trust, who are prescribed clozapine including clozapine patients from other Trusts.
- Specific sections will apply to those attending
    - Mental Health and Learning Disability Services.
    - General medical wards
- Applicable to patients of all ages.
- There are no exceptions.

3.0 ROLES/RESPONSIBILITIES

- The Medical Director, will ensure that all medical staff adhere to this policy.
- The Chair of Division for Mental Health and Child and Adolescent Mental Health, The Chair of Division for Intellectual Disability and the Clinical Director, Psychiatry of Old Age will be responsible for implementation in their respective areas.
- The Service Manager for the Lithium/Clozapine service will be responsible for the day-to-day management of the Clozapine clinics and ensuring adherence to this policy in clinics.

4.0 KEY POLICY PRINCIPLES

Definitions

- **GREEN, AMBER or RED Haematology result**: in Table 1 below

Table 1

	Total WCC x 10^9/l	**Neutrophil x 10^9/l**
GREEN	>3.5	>2.0
AMBER	3.0 to 3.5	1.5 to 2.0
RED	< 3.0	<1.5

(Note a lower range applies to initial sample, See ZTAS Manual)

- **Confirmed RED**: Normally occurs when a patient has two consecutive RED results but can occur in other sequences. The monitoring company is responsible for declaring a Confirmed RED result. All results of locally tested samples must be communicated to the haematology monitoring company.

- **Treatment Resistant Schizophrenia**: is defined as a lack of satisfactory clinical improvement despite the use of adequate doses of at least two different antipsychotic agents, including at least one atypical or second-generation antipsychotic medication, prescribed for an adequate duration of time**.**

4.1 Clozapine Initiation and Prescribing

Clozapine is a RED listed medication and can only be recommended and initiated by a consultant psychiatrist. Once commenced by a consultant

psychiatrist, ongoing prescriptions for inpatients and outpatients can be written by Trust recognised, medical and non-medical prescribers.

4.2 Haematological Monitoring

All patients prescribed clozapine must be registered with a haematological monitoring service and dispensing/supply of clozapine must be in accordance with the clozapine companies' guidelines. The Monitoring Company must be notified of changes to patient details e.g.

- A change of consultant e.g. on admission or discharge to hospital or transfer to another team.
- Change in blood sampling location.
- Change of Trust Pharmacy that dispenses clozapine.

Blood samples may be analysed as follows

- Locally in the Trust lab: Results MUST be communicated to the monitoring service.
- Centrally by the monitoring company.
- Point of Care testing (PocHi) supplied by the monitoring company.

The frequency of routine monitoring is shown in Table 2. The frequency of the blood samples may change depending on the clinical situation and the recommendation of the monitoring company must be followed.

Table 2

Time on Clozapine	Frequency of Tests
Week 1 to Week 18	Weekly Blood samples
Week 19 to Week 52	Fortnightly Blood Samples
Week 52 onwards	Monthly blood samples

The blood results are classified by the haematology monitoring service using a Traffic Light system based on the total white cell or the neutrophil count: (Table 1). Dispensing and supply of clozapine should be in accordance with the recommendations of the monitoring company and a check must be made by a nurse or pharmacist that a valid blood result is in place before dispensing or supplying clozapine. **NOTE:** Nurse and pharmacist review of blood test results is limited to confirming clozapine can be dispensed or supplied – other blood test parameters are not reviewed.

Responsibility for checking a valid blood result exists before dispensing or issuing clozapine is as follows

- Inpatients – a pharmacist must confirm a valid test result exists before issuing clozapine to the ward
- Community patients – A nurse must confirm a valid test result exists before clozapine is issued to a patient. The nurse may do this in advance and direct or provide a list of patients with a valid result to a Healthcare Assistant who may make the supply.

4.3 Point of Care Testing (PocHi)

The Trust Point of Care Testing Committee has approved the use of Point of Care Testing for clozapine blood tests. The Clozapine Team Manager should maintain a list of staff trained to operate PocHi and provide a copy of this to the Trust Point of Care Testing Committee.

The monitoring company, ZTAS will provide haematology analysers on long-term loan for use in the Trust. ZTAS will provide all reagents and materials required for operation of the machines and will be responsible for maintenance and repair of the machines including temporary replacement if required.

4.3.1 Staff training

Only trained staff are permitted to operate the PocHi machine and will require a User ID card issued by ZTAS to operate the PocHi machine.

ZTAS will train Trust staff to use the PocHi machines and will issue certificates to staff that are deemed competent. ZTAS trained users are permitted to train other local staff in accordance with ZTAS guidelines and these staff must register with ZTAS before operating the PocHi. These staff may not train other staff.
All staff must operate in line with the PocHi operator's Training Course and PocH-100i Operators' Manual.
All PocHi operators are required to complete an annual online revalidation process in order to demonstrate ongoing competence. ID cards will be revoked by ZTAS if the staff member does not successfully complete the annual online revalidation.

4.3.2 Quality Control

A daily Quality Control (QC) sample must be run and verified by ZTAS before patient samples can be analysed. These checks must be performed in accordance with the PocHi operator's Training Course and PocH-100i Operators' Manual. In addition, monthly external validation checks are sent by NEQAS and these must be tested by a trained staff member and the results reported to ZTAS. The results of these checks must be sent to the Trust point of Care Committee.

4.3.3 Sample Testing

The haematology lead for the Trust Point of Care Testing Committee has approved the use of the PocHi machine according to the following conditions.

- Routine blood tests taken in line with the patient's normal sampling frequency.
- Additional tests taken due to clinical concern about the patient e.g. suspicion of infection etc.
- After an AMBER result, the patient requires at least two tests per week. Retests after an AMBER result may be analysed in the PocHi machine.
- If a RED result is reported by PocHi at any time, then the same sample must be sent to Trust Local labs in order to activate existing internal haematology protocols on any necessary additional screening or action required by haematology. **The patient must stop taking clozapine.** If the Trust analysis is significantly different from the PocHi result, discuss the action required with ZTAS. Follow the RED AMBER Alert Guide (Appendix 8)
- Further testing after a RED result must be done in Trust Labs and not by PocHi. Daily testing is required after a RED result and must continue in line with ZTAS

guidelines. TWO consecutive RED results will block further use of clozapine. Daily testing in Trust labs is required until two GREEN results are obtained.

- After an unconfirmed RED alert, follow ZTAS guidance on restarting clozapine. Testing in PocHi may restart once a GREEN result has been obtained in Trust lab testing. Follow the RED AMBER Alert Guide (Appendix 8)

4.4 Clozapine Assessment Pathway:
The same Pathway is used for Inpatient and Community Initiations. The consultant psychiatrist is responsible for the recommendation that clozapine is initiated in a particular patient. The Integrated Care Pathway (ICP) for Clozapine Assessment (Appendix 1) should be followed. This Pathway does not replace clinical notes but all sections should be completed. Specific responsibilities are identified in the pathway for each profession. The assessment pathway contains several important Appendices that are noted below

- Appendix 11 Acute Clinical Issues
- Appendix 15 GP Information Leaflet
- Appendix 16 Pharmacy Medication Checklist

Patients should also be given a Patient Information leaflet on Clozapine available from http://www.choiceandmedication.org/hscni/. The leaflet is available in different languages and formats to suite different levels of reading ability including a pictorial version. Ensure the most recent version of the relevant leaflet is used. Consider the use of an interpreter to improve communication.

4.5 Clozapine Titration Pathways:
There are two titration Pathways:

- ICP Hospital Titration Pathway (Appendix 2)
- ICP Community Titration Pathway (Appendix 3).

These detail the required physical observations, blood tests and side effect assessments required during titration.

The Recommended titration schedule is slower for Community patients compared to an inpatient. The recommended schedules are:

- Hospital Inpatient Clozapine Titration Schedule (Appendix 5)
- Community Clozapine Titration Schedule (Appendix 6)

Patients should be seen weekly by a senior doctor and the pathway reviewed at weekly ward round or MDT. The pathway dose titration schedules can be altered depending on the clinical assessments and the clinical situation however, for patient safety the community titration should only be slowed down and not speeded up.

4.5.1 Specific Points about Hospital Inpatient Titration Pathway:

- Ideally, the patient should not be discharged during the first two weeks of the titration process.
- If the patient wishes to leave hospital, the Clozapine Pathway is transferred to the Home Treatment Team who are usually involved in the discharge process

and the rest of the titration process. The current clozapine dose should be mapped to the closest dose on the community titration.

4.5.2. Specific Points about Community Titration Pathway.

- During the first two days of a community titration, the patient will be based for 6 hours after taking the morning medication in a location where there will be trained nurses who will carry out the physical health and side-effect assessments.

4.6 Monitoring of Clozapine:
Patients on clozapine will require long-term monitoring.

4.6.1 Clozapine Outpatient Review:
Patients will be reviewed in line with blood monitoring frequency (Table 2) or according to clinical need. A routine side effect assement should be carried out and recorded at each visit for blood tests.

The result of samples analysed on a Point of Care machine will be automatically emailed to the Registered Consultant on the day of testing. The consultant should review all of the blood parameters, physical health observations and side-effect profiles regularly.

4.6.2 Annual physical health review:
The annual physical health review for patients on clozapine incorporates both the review required for people with severe mental illness (SMI) and specific reviews for clozapine. The GP may have carried out the annual assessment and bloods for people with SMI but there may be a wide variety in practice among GPs. It is important to ensure that duplication of tests is avoided where possible and good communication with the GP maintained. It is the responsibility of the mental health services to ensure that the assessments have been done and reviewed. In order to do this:

- A specified month (possibly a different month for each consultant's patients) will be identified for the annual reviews.
- As preparation, the Clozapine team nurse should send the Consultant a patient list with Health & Care Number to allow checking on ECR of tests already completed. The Consultant will request missing tests and return the list to the clozapine nurse.
- To avoid duplication, the Consultant will review each patients ECR record for results of test already completed by the GP. Ensure the following tests as assessment are completed at least once a year.
    - Fasting Blood Sugar or HbA1c
    - Lipids and Cholesterol
    - Liver Function Tests
    - U&E
    - Clozapine Plasma Level if indicated
    - ECG (if there is personal or family Hx of cardiac disease, High Dose Antipsychotics, other drugs affecting QT interval)
    - Weight/BMI
    - Blood Pressure
- The Consultant should review Haematological trends in FBC – available from Magna Labs using Consultants own user name and password.

- The consultant should review the physical observations and side-effect profile from the past years clinic records
- If applicable, the patient should be given written information leaflet about the issues of smoking cigarettes and clozapine.
- They patient should be given general health and dental advice.
- The GP should be kept up to date about reviews and any developments. They should be reminded regularly to enter clozapine on the patient's medication list so it appears as a Hospital Supplied Medicine on ECR.

4.7 Non Attendance at Clinic:
If a patient fails to attend for a routine blood test then the nurse must contact the patient that day to determine the reason. The nurse must ask about the patients physical and mental health to ensure there is no clozapine related issue that must be addressed. Arrangements must be made for a blood sample to be obtained in order to prevent a possible break in treatment. Clozapine must not be supplied until a new valid blood result is available for the patient.

If it is not possible to obtain a blood result and sufficient sample validity remains to allow a reduced supply, nursing staff cannot alter or amend dispensed medication supplied by pharmacy. Either obtain a blood result to allow the whole supply to be made or arrange with pharmacy to dispense a shorter duration if the current blood sample permits.

Reasonable adjustments will be made for disabled clients when reviewing response to non-attendance at clinic. This might include taking blood samples at a different location or in the clients own home.

4.8 RED and AMBER alerts:
Prompt and clear response is required to a RED or AMBER alert due to the risk of neutropenic sepsis which has a high mortality rate. Required actions are outlined in the RED and AMBER Guideline (Appendix 8).
The haematological monitoring company will notify the Clozapine team and registered consultant psychiatrist of a RED Alert as soon as the sample is analysed. This re-enforces the need to ensure that contact details and the correct consultant is recorded with the haematology monitoring company.
If the blood is being analysed in the local laboratories or on a non-psychiatric ward then it is important that the result of the blood is checked medically and uploaded to the haematology monitoring company for validation and classification as GREEN, AMBER or RED.

4.8.1 AMBER alerts. (See Table 1 for ranges) Continue clozapine but increase monitoring of the Full blood count. The majority of AMBER alerts are "one offs" and will usually resolve with no intervention. Other possible causes for a low white cell count should be considered including the effects of other medication. Follow the actions in the RED and AMBER Alert Guide (Appendix 8).

4.8.2 RED Alert
An agreement is in place with the Clinical Assessment Unit (CAU) or Emergency Department (ED) in the Royal Victoria Hospital to fast track patients with suspected clozapine induced neutropenic sepsis. If a patient with a RED alert has a temperature, signs of infection or a neutrophil count

less than 1.0 x 10^9/l, contact CAU/ED urgently to arrange for the patient to be transferred. See "ICP for management of clozapine induced Neutropenic Sepsis on presentation to the Clinical Assessment Unit" (Appendix 9).

A RED ALERT (see Table 1) indicates that the Neutrophil count or total white cell count is low and the patient is at risk of developing sepsis if appropriate action is not taken. Clozapine must be stopped and removed from the patient or ward trolley to prevent further administration of clozapine. Check the patient's temperature and assess for signs of infection. For outpatients, if the patient is not present they must be contacted by phone and told to stop clozapine. Follow the recommendations in the RED AMBER Alert Guide (Appendix 8).

4.9 Myocarditis/Cardiomyopathy:
Myocarditis is more likely to occur in the first four months of treatment and cardiomyopathy after a number of years. These conditions may have atypical presentations and are potentially serious. If there is any clinical concern about the patient the Clinical Assessment Unit (CAU) or if it is urgent, the Emergency Department (ED) should be contacted and the patient transferred. The protocol for the assessment and intervention is outlined in the "ICP for Management of Patients on Clozapine with Suspected Myocarditis and Cardiomyopathy" Appendix 10. This policy includes

- Immediate assessment and response.
- Good communication between ED/CAU staff and the mental health team.

4.10 Smoking and Clozapine
The tar in cigarettes induces liver enzymes which breakdown clozapine. This means that a patient taking clozapine who is a smoker and stops smoking e.g. on admission to hospital is at risk of developing toxicity symptoms. Also if a patient who is taking clozapine starts to smoke this could lead to a reduction in the blood level of clozapine and the risk of relapse.

The clinical management issues with regards patients on clozapine who smoke cigarettes and are admitted to or discharged from a hospital smoke free zone are addressed in the Trust Policy : "The management of patients treated with clozapine who smoke and are admitted to inpatient units following the implementation of the hospital smoke-free policy" (Appendix 13).

The key aspects are:

- The risk of toxicity when a smoker stops smoking. Smoking cessation should be planned with appropriate education and preparation to monitor clozapine levels, toxicity symptoms with the GASS-Clozapine scale and adjustments to the clozapine medication dose.
- The risk of relapse when someone stabilised on clozapine starts to smoke because the liver enzymes are induced resulting in a possible increase in clozapine metabolism and a fall in clozapine levels. The clozapine dose may need to be increased and the decision guided by clozapine plasma levels.
- Nicotine Replacement Therapy (NRT) and e-cigarettes help nicotine withdrawal but has no effect on the liver enzymes and will not prevent clozapine levels increasing when smoking is stopped.

4.11 Treatment Breaks and Re-titration

A treatment break can occur for many reasons, planned or unplanned. Every effort should be made to avoid treatment breaks. Withholding clozapine for medical reasons should be kept under daily review and clozapine restarted as soon as clinically possible. Consider if a reduction in dose rather than stopping might be appropriate. This approach can significantly shorten the time to return to previous dose.

A number of factors need to be considered when recommencing clozapine.

- If the clozapine was stopped because of a Confirmed RED alert, other haematological condition or a serious non-haematological condition such as myocarditis or neuroleptic malignant syndrome then restarting will be unlicensed and should only be considered in exceptional circumstances. See Section 4.12
- If the treatment break was due to accidental omission of clozapine, non-adherence or a non-serious intervening medical condition, consider the points below if restarting clozapine.

    1. Initial starting Dose
    2. Speed of re-titration to previous dose.
    3. The frequency of the ongoing haematological monitoring.
    4. Is the patient an inpatient or an outpatient?
    5. Outpatient re-titration should follow the Clozapine ICP for outpatients and use the standard outpatient dose titration schedule. The need for the level of monitoring required in the initial titration may not be needed depending on the individual case. This should be discussed and agreed between the referring Consultant, the Clozapine Team and the Home Treatment.

- **Breaks of Less the 48 hours.** The patient can usually recommence the previous dose and continue the same frequency of haematological monitoring.

- **Breaks of more than 48 hours.** The consultant psychiatrist should liaise with a mental health clinical pharmacist and the Trust pharmacy that dispenses clozapine and agree a re-titration plan. When re-titration is needed, it always commences with clozapine 12.5mg. Outpatients must be restarted using the appropriate clozapine ICP. If the treatment break only exceeds 48hrs by a short time, it might be possible to use a faster re-titration schedule for inpatients depending on tolerability.

- **Breaks of more than 72 hours.** In addition to the points above for 48hrs, the haematology monitoring company must be notified of the length of the treatment break, as this will have an effect on the patients monitoring frequency.

- **Breaks of more than 28 days** Patients will be de-registered by haematological monitoring company after a break of more than 28 days. They will have to be re-registered with the monitoring company before treatment can commence. Weekly monitoring will be required initially and the monitoring company will advise when this changes.

4.12 Re-challenge with clozapine after serious adverse events

Consider if the patient meets the criteria for Benign Ethnic Neutropenia (BEN) as this may permit the result to be reclassified and treatment to continue under the

BEN criteria. Restarting clozapine after a serious adverse event e.g. a RED Alert (neutropenia) or myocarditis/cardiomyopathy will almost certainly be “Off-Licence” and the monitoring company will usually insist on an “Off-licence agreement” being signed by the Consultant. The consultant should be aware of the increased medico legal responsibility involved when signing this agreement and that it is unlikely they will be able to pass responsibility for harm to the clozapine manufacturer. If appropriate, consider discussing the case with a colleague with expertise in this area however, clinical responsibility remains with the prescribing consultant. Make a clear and comprehensive record of the clinical decision making process in the patients notes.

4.12.1 Re-challenge after neutropenia or agranulocytosis.
When a patient has stopped clozapine due to a confirmed RED Alert their details will be entered into the Central Non-Re-challenge Database (CNRD). All UK clozapine companies check patients’ details against this database at initial registration or re-registration in order to prevent a person who has experienced a RED Alert anywhere in the UK from accidental re-exposure to clozapine. Re-challenge with clozapine after a RED Alert is unlicensed and should only be considered in exceptional circumstances on a case-by-case basis.

Before considering restarting clozapine conduct, a full case review and examine all other treatment options. Consider if a referral to the National Psychosis Unit might be appropriate.

Where there is a clear episode of agranulocytosis attributable to clozapine, restarting clozapine is not considered appropriate.

Before restarting clozapine in a patient who experienced neutropenia/agranulocytosis, review the details of the previous neutropenia/agranulocytosis in order to the likelihood that the first neutropenia/agranulocytosis was a true and typical clozapine-induced dyscrasia. Involve a Consultant Haematologist in this process. The characteristics below point strongly to a clozapine induced dyscrasia and a re-challenge would be considered very high risk and should not normally be attempted.

- The drop in neutrophils was inconsistent with previous counts and was not merely a slight drop in a patient with a pattern of repeated low white cell counts
- The neutropenia/agranulocytosis occurred in the first 18 weeks of treatment
- The drop in neutrophils was severe and fell below 0.5 x 10^9/L
- The blood dyscrasia was prolonged (>10 days)
- There are no alternative explanations apart from clozapine for the first neutropenia/agranulocytosis, such as other medication or an infection

If after careful consideration of all treatment options re-challenge with clozapine is considered appropriate, an Individual Care Plan must be developed for the patient and will form part of the Unlicensed Agreement with the monitoring company. This must include details of required haematology monitoring (twice weekly monitoring for the first 12 weeks is strongly recommended).

Note on use of Lithium:

Lithium increases neutrophil count both acutely and chronically. It does not protect against true clozapine-induced agranulocytosis and there is concern that it may mask impending agranulocytosis. Lithium's use in patients restarting clozapine after a Red Alert should be considered high risk and used with extreme caution.

4.12.2 Re-challenge after Cardiology Issues

Clozapine may have been stopped due to cardiology concerns e.g. myocarditis, cardiomyopathy or prolonged QTc interval. There is no central database that records these events. Record the adverse effect clearly in the patients Drug Allergy Record. The Clozapine SPC includes severe cardiac disorders as a contraindication to clozapine so continuation or re-challenge in the presence of severe cardiac disorders is likely to be "Off-licence". If after careful consideration of all treatment options re-challenge with clozapine is considered, an Individual Care Plan must be developed for the patient. Things that should be considered as a minimum are

- Undertake a full treatment review to ensure all other options have been considered.
- Seek advice from a Cardiologist on the appropriateness of restarting clozapine and work with them to develop an Individualised Care Plan for the patient if appropriate.
- Involve the clozapine Haematology Monitoring company early in the decision making process. An "off-licence" agreement will most likely be required.
- If there is a history of myocarditis, agree on the monitoring schedule (e.g. NTPro-BNP, Echocardiogram, ECG, Troponins and CRP) and ensure a doctor is identified to review these results.
- Re-Challenge should occur in the Inpatient unit.

4.13 Consent;

If a patient has capacity, informed consent must be obtained before the patient can be commenced on clozapine. In addition, they must consent for the Trust to share patient details with the Haematological monitoring company (Appendix 4).

If there are other circumstances e.g. lack of capacity, detained under the Mental Health Order (NI) 1986, the decision and reasoning should be carefully documented, with evidence of consultation with the patient's carer/relative and the outcome of the discussion. It is also important that the patient agrees to take the medication regularly, agrees to the clinical and blood monitoring requirements, and to follow advice regarding being accompanied at all time during the first weeks of a community titration.

It is good practice to consult with the patient's carer/relative irrespective of whether the patient has capacity or not. If the patient is detained under the Mental Health Order (NI) 1986, the relevant procedures and documentation must be completed.

4.13 Admission/Discharge from hospital in the Belfast Trust;

When patients on clozapine are admitted to hospital, it is important that staff are aware of the important clozapine safety issues. Staff on general wards may be less familiar with the clinical issues surrounding clozapine and should seek advice as outlined below.

4.13.1 Admission to any BHSCT Ward or inpatient facility

- Confirm the patient's dose of clozapine with at least two sources e.g. the patient's own medication, the supplying pharmacy or the clozapine team records. As a Hospital Supplied medicine, clozapine may not appear on the patient's ECR record.
- Assess the patients compliance with clozapine in case there has been a "Treatment Break" (refer to section 4.11)
- Check the patient's current blood sample status - in hours contact a Trust Pharmacy department. Out of hours, contact the haematology monitoring company. If necessary, arrange an urgent sample to avoid treatment breaks.
- Ensure that any local haematological blood results are uploaded/communicated to the Haematology Monitoring company - ZTAS Helpline on (0207) 365 58 42
- Ensure that the monitoring of physical observations, side effects and bloods levels continue to be done.
- Check if the patient normally smokes cigarettes and refer to the policy on the hub: "The management of patients treated with clozapine who smoke and are admitted to inpatient units following the implementation of the hospital smoke-free policy" (Appendix 14)

4.13.2 Specific to Psychiatric In patient unit:

- Prior to discharge, arrange a follow-up appointment with the clozapine clinic.
- Clarify if the patient intends to smoke cigarettes on discharge and inform Clozapine clinic.
- In addition to including clozapine on the discharge prescription, complete a Community Clozapine Prescription (Appendix 12) for a duration of 4 weeks and send this to the Trust pharmacy that supplies clozapine for this outpatient. This is to ensure continuity of supply until the patient can be seen by their community team.

4.13.3. Specific to Non-psychiatric Inpatient/general wards

- A Clozapine Acute Clinical Issues chart highlighting important safety issues with clozapine is available on the Trust HUB (Appendix 11).
- The morning after admission of a patient on clozapine, contact the psychiatry liaison team. If it is at the weekend or during bank/public holidays, contact the second-on-call psychiatrist, the following morning. A patient review will be arranged to ensure there are no clozapine related issues.
- Be aware of the side effects and toxic effects of clozapine as these may be the reason for presentation.
- Inform the clozapine clinic/community mental health team
- Prior to discharge, arrange a follow-up appointment with the clozapine clinic.
- Clarify if the patient intends to smoke cigarettes on discharge and inform Clozapine clinic.
- Liaise with pharmacy regarding supply of clozapine on discharge to ensure sufficient clozapine is available until review by community team

- If the patient is attending Mental Health services outside the Belfast Trust Area, contact the relevant team and Trust Pharmacy prior to discharge and agree a discharge plan.

4.14 Specific Issues: These are a number of specific clinical issues for which there are ZTAS information sheets on the Hub at Medicine management/prescribing:

- ZTAS Fact Sheet – Myocarditis and Cardiomyopathy
- ZTAS Fact Sheet – Tachycardia
- ZTAS Fact Sheet – Constipation
- ZTAS Fact Sheet - Fever
- ZTAS Fact Sheet – GCSF (Use of)
- ZTAS Fact Sheet – RED Alert Guideline
- ZTAS Fact Sheet - Neuroleptic Malignant Syndrome
- ZTAS Fact Sheet - Neutropenia and Agranulocytosis
- Clozapine Acute Clinical Issues.

Further information can be obtained form the ZTAS Helpline on (0207) 365 58 42

4.14.1 Clozapine and Chemotherapy or other myelosupressive drugs
Clozapine is contraindicated with other medication that causes immunosuppression including chemotherapy. If a patient treated with clozapine requires chemotherapy or treatment with an immunosuppressive drug (e.g. transplant patients or cancer treatment) and the consultant believes they need to remain on clozapine, they must seek advice from a haematologist and the haematology monitoring company. An Individual Care Plan needs to be developed. A copy of the plan should be shared with the supplying pharmacy as the normal limits for AMBER and RED alerts will be altered. An “off-licence” agreement with the monitoring company must be in place during the chemotherapy.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination:

- All consultant Psychiatrists in Belfast Trust
- In Patient Mental Health, Learning Disability and CAMHS managers
- All Community Mental Health, Learning Disability and CAMHS Team Managers.
- Home Treatment Team
- Acute Day Treatment Team (Mental Health).
- All consultant medical staff and Junior Doctors in the Trust (Policy on Admission /Discharge in non-psychiatric wards).
- Head of Pharmacy and Medicines Management
- All clinical pharmacists and dispensary managers.
- Aspects of clozapine prescribing and management will be covered in psychiatry rotation junior doctor induction

Clozapine Acute Clinical Issues Chart (Appendix 11) will be circulated widely and be available on the HUB. This will highlight the presentation and immediate

management of the potentially serious physical health conditions associated with clozapine.

There will be regular updates on clozapine at the Trust Psychiatry academic meetings

5.2 Resources:

There are no new resource implications as a result of this policy

5.3 Exceptions: There are no exceptions

6.0 MONITORING

- **There will be regular audits and reviews of adverse events**
- There will be regular updates and case presentations at the academic meeting about adverse events or issues that have arisen.

7.0 EVIDENCE BASE / REFERENCES

- Ronaldson KJ; Fitzgerald PB; McNeil JJ. Acta Psychiatrica Scandinavica. 132(4):231-40, 2015 Oct.
- Leyden Delta, (2015, April) ZTAS Online Manual, from www.ztas.com/Manuals/ZTASonlinemanual.pdf
- Medicines.org.uk. (2016). Zaponex 25mg and 100mg tablets (SPC) – (EMC) www.medicine.org.uk/emc/product/7715
- Bleakley, S, & Taylor, D. (2013). Clozapine Handbook (1st Ed.). Norwich: Lloyd-Reinhold

8.0 CONSULTATION PROCESS

The Integrated Care Pathways reference in this policy have been developed, tested and refined in mental health services over a number of years. The policy was sent to all Consultant Psychiatrists for comments, which were reviewed and incorporated where appropriate.

9.0 APPENDICES / ATTACHMENTS

List of Appendices

Appendix 1	ICP for Clozapine Assessment
Appendix 2	ICP for Hospital Titration of Clozapine
Appendix 3	ICP for Community Titration of Clozapine
Appendix 4	Patient Consent Form for Data Sharing.
Appendix 5	Hospital Inpatient Clozapine Titration Schedule
Appendix 6	Community Clozapine Titration Schedule
Appendix 7	ECG Referral Protocol and Request letter
Appendix 8	RED and AMBER Alert guide

Appendix 9	ICP for suspected neutropenic sepsis
Appendix 10	ICP for suspected myocarditis or cardiomyopathy
Appendix 11	Clozapine Acute Clinical Issues
Appendix 12	Clozapine Community Repeat Prescription
Appendix 13	The management of patients treated with clozapine who smoke and are admitted to inpatient units following the implementation of the hospital smoke-free BHSCT policy
Appendix 14	GP Information Letter
Appendix 15	Pharmacist assessment of medication check list
Appendix 16	Patient Red Alert Information Sheet

10.0 EQUALITY STATEMENT

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 this policy/proposal has potential impact and if it should be subject to a full impact assessment. This process is the responsibility of the policy or service lead - the template and guidance are available on the Belfast Trust Intranet. Colleagues in Equality and Planning can provide assistance or support.
The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact ☒

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 **link**.
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).

Stephen Guy

_____ **Date:** 12/06/2019

Authors

Caroline A. Leonard

_____ **Date:** 12/06/2019

Director

Appendix 1

Integrated Care Pathway for Clozapine Assessment

Please click this **link** to view the Integrated Care Pathway for Clozapine Assessment
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Appendix 2

Integrated Care Pathway for Hospital Titration of Clozapine

Please click this **link** to view the Integrated Care Pathway for Hospital Titration of Clozapine

Appendix 3

Integrated Care Pathway for Community Titration of Clozapine

Please click this **link** to view the Integrated Care Pathway for Community Titration of Clozapine

Appendix 4

Patient Consent Form for Data Sharing

Keep this form with the medical records of the patient

>>> CONSENT FORM FOR REGISTRATION WITH ZTAS

Zaponex Treatment Access System®

ZTAS®

Dear Sir or Madam,

Your physician has informed you of the potential risks and benefits of the use of Zaponex® (clozapine). In addition, you have been informed of the procedures that must be followed associated with the use of Zaponex for the monitoring of your health.

The Zaponex Treatment Access System (ZTAS®) is the patient monitoring service associated with your Zaponex treatment. This service is operated by Leyden Delta BV, the license holder of Zaponex.
As per requirement from the UK Health Authorities, all patients treated with Zaponex and their healthcare providers have to participate in and register with the ZTAS. The ZTAS is in place to ensure the safe use of Zaponex, to monitor your blood counts and to assist your healthcare provider in making medical decisions regarding your Zaponex treatment. In the interest of providing your health care, complying with legal obligations, and protecting your vital interests the following personal information and your blood samples are required to be collected and processed by the ZTAS monitoring database and service, your:
Name, NHS number, date of birth, sex, ethnicity, indication for Zaponex use and blood test results.
Your personal data is processed in accordance with the terms outlined in the ZTAS privacy notice that you have been provided with by your physician and/or which is available at www.ztas.co.uk.

If you do not wish to provide your personal data and register with the ZTAS, your physician shall be unable to initiate treatment of your medical condition with Zaponex (clozapine).
The personal information collected from you will be made available to registered users of the ZTAS who need access to the information in support of your Zaponex treatment. Should you experience abnormal low blood results during the course of your Zaponex treatment which could signify a serious threat to your health, Leyden Delta BV will transfer your data to the Central Non Rechallenge Database (CNRD) in order to prevent a future re-exposure to clozapine treatment, as this may jeopardize your health.
Leyden Delta makes use of service providers for support and maintenance of ZTAS database systems. This means that your personal data is shared with other companies that support the ZTAS service.
The ZTAS database is maintained by a service provider in the United States that is required to protect your personal information to recognised standards.

Your data and blood samples may be used by Leyden Delta to perform research on Zaponex and for services connected with Zaponex. Data may be published, but you will in no way be identified in such publications. No identifiable data will be used for research purposes.

We keep your data for as long as you receive Zaponex treatment and as long as required by law.

You have a number of data protection rights (as detailed in the ZTAS privacy notice), including the right to lodge a complaint to any data protection supervisory authority if you have a concern about the processing of your information.

If you experience any health problems or side effects during the course of your Zaponex treatment, other than low blood counts, it is important that you tell your doctor, pharmacist or another member of your care team about it. You can also report side effects directly to the UK health authorities via the Yellow Card Scheme, a national reporting scheme for side effects from medicines. Reports can be at www.mhra.gov.uk/yellowcard or via the MHRA Yellow Card app. By reporting side effects, you can help provide more information on the safety of this medicine.

I hereby signify my freely given consent to undergo treatment with Zaponex® (clozapine). I have read the above text and fully understand the nature and purpose of the processing of my personal information and blood samples. My healthcare provider has given me the opportunity to ask questions about Zaponex, the ZTAS monitoring service and the processing of my personal information and blood samples.

Patient Name: S U R N A M E

Date: d d - m m - y y y y Signature:

Guardian or legal representative* (if applicable)

Name: S U R N A M E

Date: d d - m m - y y y y Signature:

* Guardian or legal representative with authority to sign the consent on the patient's behalf.

Statement of the physician or other healthcare provider involved with Zaponex® (clozapine) treatment
I confirm that I have fully explained to the patient the purpose, potential benefits and risks of Zaponex treatment and the need for processing his/her personal information and blood samples for the ZTAS monitoring service.

Name: S U R N A M E

Date: d d - m m - y y y y Signature:

NOTE: this consent form should be printed, completed and held with the patient's medical records. It should not be sent to the ZTAS.

Page 1 of 1

Appendix 5

Hospital Inpatient Titration Schedule

Belfast Health and Social Care Trust
caring supporting improving together

Clozapine Inpatient Initiation Prescription Chart (Custom Titration)

Write In CAPITAL LETTERS or use addressograph
Surname:
First Names:
Health & Care No:
DOB:
Consultant: Ward:

NOTES:
- Clozapine must be prescribed on the Main Inpatient Kardex and endorsed "See Clozapine Initiation Chart"
- Select Standard or Custom titration and cross out the one not required. Sign relevant week and add the dates
- Add the dose to each entry in the custom chart. Sign relevant week and add the dates
- There is no Evening Dose on day one of Standard Titration. Give the dose at any time and record the time
- Ensure Clozapine Titration Care Pathway is completed after each administration
- Ensure that Full Blood Count, CRP and Troponins are taken weekly as outlined in the Clozapine titration pathway, and the results reviewed and recorded in the Care Pathway

WEEK 1

Prescriber Signature: Date:
Printed Name: Registration No:

Day	Date	Morning Dose	Given by	Evening Dose	Given by
1		Clozapine		Clozapine	
2		Clozapine		Clozapine	
3		Clozapine		Clozapine	
4		Clozapine		Clozapine	
5		Clozapine		Clozapine	
6		Clozapine		Clozapine	
7		Clozapine		Clozapine	

WEEK 2

Prescriber Signature: Date:
Printed Name: Registration No:

Day	Date	Morning Dose	Given by	Evening Dose	Given by
8		Clozapine		Clozapine	
9		Clozapine		Clozapine	
10		Clozapine		Clozapine	
11		Clozapine		Clozapine	
12		Clozapine		Clozapine	
13		Clozapine		Clozapine	
14		Clozapine		Clozapine	

WEEK 3

Prescriber Signature: Date:
Printed Name: Registration No:

Day	Date	Morning Dose	Given by	Evening Dose	Given by
15		Clozapine		Clozapine	
16		Clozapine		Clozapine	
17		Clozapine		Clozapine	
18		Clozapine		Clozapine	
19		Clozapine		Clozapine	
20		Clozapine		Clozapine	
21		Clozapine		Clozapine	

WEEK 4

Prescriber Signature: Date:
Printed Name: Registration No:

Day	Date	Morning Dose	Given by	Evening Dose	Given by
22		Clozapine		Clozapine	
23		Clozapine		Clozapine	
24		Clozapine		Clozapine	
25		Clozapine		Clozapine	
26		Clozapine		Clozapine	
27		Clozapine		Clozapine	
28		Clozapine		Clozapine	

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Clozapine Inpatient Initiation Prescription Chart (Standard Titration)

Write In CAPITAL LETTERS or use addressograph
Surname:
First Names:
Health & Care No:
DOB:
Consultant: Ward:

NOTES:
- Clozapine must be prescribed on the Main Inpatient Kardex and endorsed "See Clozapine Initiation Chart"
- Select Standard or Custom titration and cross out the one not required. Sign relevant week and add the dates
- Add the dose to each entry in the custom chart. Sign relevant week and add the dates
- There is no Evening Dose on day one of Standard Titration. Give the dose at any time and record the time
- Ensure Clozapine Titration Care Pathway is completed after each administration
- Ensure that Full Blood Count, CRP and Troponins are taken weekly as outlined in the Clozapine titration pathway, and the results reviewed and recorded in the Care Pathway

WEEK 1

Prescriber Signature: Date:
Printed Name: Registration No:

Day	Date	Morning Dose	Given by	Evening Dose	Given by
1		Clozapine 12.5mg, give at any time and record time			
2		Clozapine 12.5mg		Clozapine 12.5mg	
3		Clozapine 12.5mg		Clozapine 25mg	
4		Clozapine 25mg		Clozapine 25mg	
5		Clozapine 25mg		Clozapine 50mg	
6		Clozapine 25mg		Clozapine 75mg	
7		Clozapine 25mg		Clozapine 75mg	

WEEK 2

Prescriber Signature: Date:
Printed Name: Registration No:

Day	Date	Morning Dose	Given by	Evening Dose	Given by
8		Clozapine 50mg		Clozapine 75mg	
9		Clozapine 50mg		Clozapine 100mg	
10		Clozapine 50mg		Clozapine 100mg	
11		Clozapine 50mg		Clozapine 125mg	
12		Clozapine 75mg		Clozapine 125mg	
13		Clozapine 100mg		Clozapine 125mg	
14		Clozapine 100mg		Clozapine 150mg	

WEEK 3

Prescriber Signature: Date:
Printed Name: Registration No:

Day	Date	Morning Dose	Given by	Evening Dose	Given by
15		Clozapine 100mg		Clozapine 175mg	
16		Clozapine 100mg		Clozapine 200mg	
17		Clozapine 100mg		Clozapine 200mg	
18		Clozapine 100mg		Clozapine 200mg	
19		Clozapine 100mg		Clozapine 200mg	
20		Clozapine 100mg		Clozapine 200mg	
21		Clozapine 100mg		Clozapine 250mg	

WEEK 4

Prescriber Signature: Date:
Printed Name: Registration No:

Day	Date	Morning Dose	Given by	Evening Dose	Given by
22		Clozapine 100mg		Clozapine 250mg	
23		Clozapine 100mg		Clozapine 250mg	
24		Clozapine 100mg		Clozapine 300mg	
25		Clozapine 100mg		Clozapine 300mg	
26		Clozapine 100mg		Clozapine 300mg	
27		Clozapine 100mg		Clozapine 300mg	
28		Clozapine 100mg		Clozapine 300mg	

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Appendix 6

Community Clozapine Titration Schedule

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Clozapine Community Initiation Prescription Chart

Write in CAPITAL LETTERS or use Addressograph	Patient Address:
Surname:	
First names:	Key Worker:
Health and Care Number	Registered Clozapine Consultant:
ZTAS Number:	Regular Consultant (if different):
DOB:	Name of GP:

Notes:

- Pharmacy will Supply Day1 to the morning dose of Day 11 against a valid pre-treatment registration blood sample. A blood sample is taken on Day 1 and Day 8 to cover this supply.for
- If side effects become intolerable, it may be necessary to reduce the dose, reduce the rate of increase or hold at the current dose. See notes below. *Note : The patients pre-labelled medication will need changed to reflect the changes – Liaise with Belfast City Hospital Pharmacy*
- A Community Clozapine Prescription must be sent to Belfast City Hospital Pharmacy hospital by Wednesday Day 10

Note; two signed and dated copies are required. One will be retained by pharmacy and one will be used as the prescription/recording sheet during the initiation

Clozapine Titration Prescription and Recording Chart

To reduce titration speed, start a new Prescription/Recording Chart. Clearly cross out ALL the doses in the morning and/or evening Standard Titration column(s) and write the new doses in the relevant Slower Titration column remembering to maintain the correct day of titration. **This should never be used to accelerate the Standard Titration**

			Morning Dose Time:			Evening Dose Time:		
Day	**Date**	**Drug**	**Standard Titration**	**Slower Titration**	**Administered by**	**Standard Titration**	**Slower Titration**	**Administered by**
1 Mon		Clozapine	12.5mg			None		
2		Clozapine	25mg			None		
3		Clozapine	37.5mg			None		
4		Clozapine	50mg			None		
5		Clozapine	75mg			None		
6		Clozapine	75mg			None		
7		Clozapine	75mg			None		
8 Mon		Clozapine	75mg			25mg		
9		Clozapine	75mg			50mg		
10		Clozapine	75mg			75mg		
11		Clozapine	75mg			100mg		
12		Clozapine	100mg			100mg		
13		Clozapine	100mg			100mg		
14		Clozapine	100mg			100mg		
15 Mon		Clozapine	100mg			100mg		
16		Clozapine	100mg			100mg		
17		Clozapine	100mg			100mg		
18		Clozapine	100mg			100mg		

Please Enter Dates Above **Date:**

Prescribers Printed Name:_____ **Signature:**_____ **Registration No.**_____

Week 2: A completed Clozapine Community Prescription must be sent to Belfast City Hospital by Wednesday, Day 10, to ensure ongoing supplies are sent to sampling centre on Friday for collection with the next blood test at the clozapine clinic.

Pharmacy Use Only			
Day 1 – 11		**Day 12 -18**	
Dispensed by:	Checked by:	Dispensed by:	Checked by:

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Appendix 7

ECG Referral and Review Process

ECG - Mental Health Services (18/12/2018) **V 1.0**

Principles: There should be a clear reason for requesting and ECG. The responsibility for interpretation of the results and initial action rests with the person who requests the ECG. It is important that any abnormality identified is communicated to the GP or specialist and appropriate action taken.

Psychiatrists:
1) Should register with MUSE through the IT department to allow access to electronic copies of the ECG (These can be printed if require)
2) **Record who has been sent for an ECG including H&C number, in order to check if results have returned** – e.g. secretaries will organise ECG books
3) Be aware of the Results Process (below)– and follow-up if routine report for outpatients are not back in 2 weeks.
4) Update basic knowledge about ECG (e.g. RCPsych, eLearning module, or other training)

Out Patients – Open Access ECG Clinics

Open access ECG clinics: are based in the R.V.H. and Mater Hospitals.

RVH: Location: Level 9, Critical Care Building (enter through main entrance and ask at reception)
Times: Thursday and Friday between 2pm and 3pm
Tel. No.: 02890633523

Mater: Location: Level 2, ECG Room (enter through ED dept.)
Times: Mon, Wed and Fri, between 2pm and 3pm
Tel.No.: 02895047040

Referral Process: Use the standard Mental Health referral form for ECGs
Give the patient the referral and advised of the location and times of the ECG clinic.
The Referral should include the following information.

- The signature, contact details and address of the person making the referral (**including contact email**)
- Specific reason for the ECG e.g. QT interval and any relevant current and past medical history
- Prescribed and over-the-counter medication

If the referral is urgent please ring the relevant clinic

Results Process:
If an acute abnormality e.g. dysrhythmias or signs of infarction is detected at either clinic it will be immediately referred to a cardiologist on site.

- The results of ECGs conducted at either clinic will be available on MUSE (need H&C number) with an automated report. Automated reports should be reviewed with caution, check for reviewer comments (see below)
- Each ECG is reviewed after the clinic (senior physiologist in RVH and cardiologist trainee in the Mater). Additional comments are written on a paper copy, which is always sent to the referrer.
- A copy of the report will be emailed to the referrer.
- If the report is not received within 2 weeks, check on MUSE that the patient has attended then contact the secretary at the clinic who will have a copy of the report and any updated comments

ECGs for In Patients

Staff who perform Inpatient ECGs should have been trained in the placement of the ECG Leads as this is very important. Training is available from the Cardiac Investigations department and there is an update e-learning module on the HUB. Exercise caution when interpreting automated reports. Advice on an ECG can be obtained by sending ECG to (Fax. no. 02890263888)

Cardiology Advice

If clinical advice is needed, contact the cardiology secretaries and have the details of the patient including H&C number so that the cardiologist can access the E.C.G

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Psychiatry ECG Open Access Referral Form

Name	
H+C Number	
DOB	

Dear _____

I would be grateful if you would attend the Open Access ECG Clinic to have an ECG carried out (a heart tracing). The ECG Department operates an open access service and overleaf is a list of the days and times when this service is available. I would suggest you try to attend around ten minutes before the start time as these sessions can be busy.

Please bring this letter with you when you attend.

Indications:

(Tick all that apply)	
Pre-assessment prior to commencing medication (specifically assessing QTc and rhythm)	
Routine monitoring due to current medications (specifically assessing QTc and rhythm)	
Repeat to assess QTc as previously prolonged	
Repeat to assess rhythm as previous abnormality	
Other (please provide details) -	

Current Medications:

Medication	**Dose**	**Frequency**	**Medication**	**Dose**	**Frequency**

Known CVD Risk Factors:

(Tick all that apply)							
Hypertension		Diabetes		High Cholesterol		Angina	
Previous MI		Smoker		Family History CVD		High BMI	

Please E Mail result to:

Yours sincerely,

Signature	
Name	
Date of Referral	
Address	
Contact Phone No	

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Direct Access ECG Clinics

Mater Hospital

- Monday 2-3pm
- Wednesday 2-3pm
- Friday 2- 3pm

The ECG Clinic is based in Level 2, Outpatients Department. Patients should go to Reception 3 and ask for directions to the ECG room.

Telephone Number: 02895047040

Royal Victoria Hospital

- Thursday 2-3pm
- Friday 2-3pm

The ECG Clinic is based at Cardiac Investigations, Level 9 Critical Care Building. Ask for directions at the main reception area of RVH

Telephone Number: 02890633523

Appendix 8

RED and AMBER alert Guide for Clozapine

Background:

This procedure outlines the actions required when a RED or AMBER alert is received for a clozapine patient. This procedure should be used in conjunction with the **ZTAS Red Alert Guidelines** *(Clozapine folder on the Trust HUB in, Medicines Management, prescribing section)* or by contacting the ZTAS helpline. (02073655842 24hrs).

Neutropenia occurs in 3% of patients taking clozapine and may be severe in around 1% of patients with a significant risk of neutropenic sepsis. The majority of cases present before 18 weeks after starting treatment with clozapine but can occur at any time. **A patient with neutropenic sepsis can deteriorate very rapidly and within two to three hours be in multi-organ failure. Neutropenic sepsis is a medical emergency and requires immediate action.** Key decisions about a patient's care should be made in conjunction with a haematologist and the ZTAS adviser.

Receiving a RED or AMBER alert

- In clinics with Point of Care Testing, a RED or AMBER alert will be flagged immediately by the PocHi machine and confirmed by ZTAS.
- With local testing, the person entering the blood result to ZTAS will be notified of a RED or AMBER alert at the point of sample entry to ZTAS.
- The staff member receiving the alert is responsible for ensure the actions in the relevant flow chart are initiated. These actions will normally be conducted by the Clozapine Team for Community Patients and by ward staff for hospital inpatients.
- Out of hours, contact the Second On Call Psychiatrist using the Golden Number 90454999.

Traffic Light Reporting of Blood Results

	Neutrophil ($x10^9$ /L)	**White cell** ($x10^9$ /L)
Green	>2.0	> 3.5
Amber	1.5 to 2.0	3.0 to 3.5
Red	**< 1.5** If < **1.0** send directly to ED as "suspected neutropenic sepsis" **even with a normal temperature**	**<3.0**

Critical Warning Signs

1) Raised temperature, sore throat, any symptoms of infection or feeling generally unwell.
2) Neutrophil count less than 1.0 $x10^9$ /L (temperature may not be raised)

Action if Critical Warning Signs are Present

- Send the patient directly to Emergency Department (ED)
- Ring ED in advance and speak to senior member of staff e.g. Consultant or Registrar and inform them that the patient has a "Suspected Neutropenic Sepsis"
- Inform the patient's consultant psychiatrist.
- Maintain contact with ED to ensure that patient has arrived and "Suspected neutropenic sepsis policy" has been implemented"
- The "Suspected neutropenic sepsis policy" reflects the seriousness of the condition and has a timescale of one hour from point of arrival in ED to administering IV antibiotics or if the patient appears unwell, IV antibiotics are given immediately.

AMBER Alert Guide

	First Result	
First Result	AMBER	• Inform patient and carer as appropriate • Arrange Repeat blood count within 3 days, normally on a Thursday. • Notify Patient's Consultant Psychiatrist • **Continue Clozapine** • Look for possible causes including other medication
	Second Result	
Second Sample Result	GREEN	• Liaise with ZTAS advisor regarding required frequency of ongoing monitoring • **Continue Clozapine**
	AMBER	• **If neutrophil or WCC is equal to or greater than that of the first sample** ○ Arrange repeat blood in 4 days, normally a Monday ○ Continue FBC twice each week until two consecutive GREEN results obtained • **If neutrophil or WCC is lower than that of the first sample** ○ For community patient, alert Home Treatment Team (HTT) to a potential referral ○ Arrange a repeat sample the next day ○ If repeat sample is GREEN repeat following Monday. Liaise with ZTAS advisor regarding frequency of ongoing monitoring. **Continue Clozapine** ○ If third sample is AMBER refer community patient to HTT ○ HTT to do daily FBC and daily observations (NEWS) out of hours. ○ Results reviewed by Second on Call over weekend (community patient) or Senior House Officer for ward cover. **Continue clozapine** ○ If AMBER results continue review actions with ZTAS ○ If a RED alert occurs -follow RED Alert Procedure
	RED	• **STOP Clozapine and remove medication from patient or ward trolley.** • **Follow RED Alert guide**

RED Alert Guide

	First Result	
First sample Result	RED Neutrophil are <1.5 x 10^9/l Or White Cell Count <3.0 x 10^9/l	•**Clozapine/Ward nurse to contact patient (and carer if appropriate) immediately, if necessary, by phone.** Explain a RED Alert has occurred and give the patient (and carer if appropriate) the Red Alert Information Sheet. •**STOP Clozapine**. For inpatient, discontinue on Kardex. For an outpatient, remove clozapine from home •**Notify the patient's Consultant and the ward doctor for an inpatient** •**Send patient Directly to ED if:** •There are signs of infection e.g. fever, sore throat, raised temperature •A Neutrophil count <1.0 x 10^9/l even if temperature is normal •Contact ED staff and advise a patient is attending with "Suspected Neutropenic Sepsis" •Ensure patient attend ED •Update patient's Consultant Psychiatrist. •**If patient does not need to go to ED** •Arrange daily FBC, confirm who will check result •Check temperature, pulse and BP (NEWs Chart) •Ask about signs of infection •Liaise with ZTAS as required
	Second Result	
Second Sample Result	GREEN	•Only restart clozapine with ZTAS approval •Normally, two consecutive daily GREEN blood results are required to restart but this may vary. •If restart is permitted, re-titration from 12.5mg will be required if treatment break has exceeded 48hrs
	AMBER	•**Do not restart Clozapine** •**Refer community patient to Home Treatment** •Continue daily FBC and observations as for Red alert below •Maintain daily contact with ZTAS
	RED	•**A second RED is a "Confirmed RED"** •**Clozapine must be permanently stopped** •**Refer community patient to Home Treatment for ongoing daily monitoring.** •**Provide Home Treatment phone number** •Continue FBC daily. Maintain daily contact with ZTAS •Liaise with Trust haematology if required •Conduct NEWs chart observations at least once daily •Check for signs of infection •Second on call doctor to check blood results at weekend •Send immediately to ED if there are signs of infection or if neutrophils <1.0 x 10^9/l

Appendix 9

Integrated Care Pathway for Suspected Neutropenic Sepsis

Please click this **link** to view the Integrated Care Pathway for Suspected Neutropenic Sepsis

Appendix 10

Integrated Care Pathway for Suspected Myocarditis or Cardiomyopathy

Please click this **link** to view the Integrated Care Pathway for Suspected Neutropenic Sepsis

Appendix 11

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CLOZAPINE ACUTE CLINICAL ISSUES

PRESENTATION

Signs of infection including fever or sore throat.

CONSIDER CLOZAPINE INDUCED NEUTROPENIC SEPSIS

WBC 10^9/l	NEUTROPHIL 10^9/l	ACTION
≥3.5	≥2.0	Continue clozapine
≥3.0 & <3.5 and/or	≥1.5 & <2.0	Continue clozapine FBC within 24 hrs Notify ZTAS*
<3.0 and/or	<1.5	Stop clozapine Urgent FBC Notify ZTAS*

MANAGEMENT

- For results in green or amber ranges continue clozapine. Manage any infection according to clinical guidelines. Repeat FBC within 24hrs
- For a result in the RED range, STOP clozapine and manage according to ZTAS Red Alert Guidelines and Trust Clozapine Policy on Trust Hub (Medicines Management, Prescribing).
- If Red Alert with Pyrexia manage according to Neutropenic Sepsis Guideline (NICAN).

PRESENTATION

Persistent tachycardia at rest, palpitations, arrhythmias, chest discomfort, heart failure, fatigue, dyspnoea, tachypnoea or symptoms that mimic myocardial infarction.

CONSIDER MYOCARDITIS OR CARDIOMYOPATHY

DIAGNOSTIC AIDS FOR MYOCARDITIS

- Remember myocarditis may be asymptomatic
- Tachycardia and elevated temperature can be benign transient side effects of clozapine
- Eosinophilia is a poor prognostic marker
- Elevated troponin, CRP or NTProBNP may be reported with myocarditis
- ECG changes and abnormal ECHO may occur.

MANAGEMENT

- **STOP CLOZAPINE**
- Consult urgently with cardiology
- See ZTAS Myocarditis and Tachycardia Fact Sheet on Trust Hub (Medicines Management, Prescribing).

PRESENTATION

Constipation, diarrhoea (overflow), abdominal pain, fever, nausea, or distended abdomen.

CONSIDER CLOZAPINE INDUCED CONSTIPATION

RISKS

- Onset of severe symptoms may be sudden
- Risk increased with high clozapine dose and other drugs/conditions linked to constipation
- Intestinal obstruction and paralytic ileus can occur
- Deaths have occurred.

MANAGEMENT

- Manage according to severity of symptoms
- In very severe cases consider withholding clozapine until symptoms have resolved
- See ZTAS Constipation Fact Sheet on Trust Hub (Medicines Management, Prescribing).

Other Clinical Issues

- Seizures can occur with clozapine, these are dose related
- Neuroleptic malignant syndrome can occur rarely. The presentation can be atypical with absence of raised temperature and muscle rigidity. Creatinine Kinase levels may be raised
- Stopping smoking may lead to rise in clozapine plasma levels with resultant toxicity.

Caution: Avoid unnecessary breaks in clozapine treatment. Consider a lower dose instead of stopping clozapine. If clozapine has been not been taken for over 48hrs, DO NOT RESTART without consultation with patient's consultant.

For further information contact ZTAS Helpline: 020 7365 5842

*ZTAS is the monitoring company for Clozapine. All local blood results should be reported to ZTAS on 020 7365 5842.

Version 1 04/05/2016

Appendix 12

Community Clozapine Prescription

Belfast Health and Social Care Trust

Clozapine Prescription

Name:	**ZTAS No.**
Address:	**H&C Number**
	Blood Sampling Frequency **Weekly ☐ Fortnightly ☐ 4 weekly ☐**
DOB: **Hosp No.** **Consultant:** **CPN Name & Phone No.**	**Dispensing Frequency** **Weekly ☐ Fortnightly ☐ 4 weekly ☐**

Clozapine Clinic Location: _____

For prescriptions with a dose change, Contact BCH Pharmacy team (42003) to agree a changeover date.

Enter drug name and dose due at each time

	Enter Dose Due at each time in relevant box			
Drug Name	**Breakfast time**	**Lunch Time**	**Tea Time**	**Bed Time**

Supply Valid for: _____ (Max duration 12 months)

After the 1st dispensing, the prescription may be repeated according to the dispensing frequency shown for a period not exceeding the period of supply above.
A new prescription must be supplied if dose, frequency or times of administration change.

Signature of Prescriber: _____ **Date:** _____

Name in Print: _____ **Registration No.** _____ **Phone No.** _____
Designation: _____

For Pharmacy Use Only

Date Dispensed	No of 25mg tablets	No of 100mg Tablets	Dispensed by	Checked by	Date Dispensed	No of 25mg tablets	No of 100mg Tablets	Dispensed by	Checked by

Photocopy and attach additional copies as needed for recording dispensing.

Version 4.0 Updated 10th December 2018

Appendix 13

The management of patients treated with clozapine who smoke and are admitted to inpatient units following the implementation of the hospital smoke- free policy

Please click this link to view the above BHSCT policy

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Appendix 14
Clozapine Information sheet for General Practitioners

Surname:
First Names:
Health & Care No.
DOB:

Consultant.

Your patient has been prescribed clozapine, which is a Red List medicine so the Consultant Psychiatrist will prescribe clozapine, monitor full blood counts for neutropenia and clozapine will be dispensed by the Trust pharmacy. Please ensure this patient's records reflect clozapine is prescribed so it will be considered in your patient assessments and prescribing decisions. The Belfast Trust Acute Clinical Issues sheet (attached) highlights the Traffic Light coding of blood results and potentially life threatening complications of clozapine treatment.

Patient presenting with Fever
It is critical to rule out neutropenia/agranulocytosis by arranging for an urgent full blood count, which may need to be done in an Emergency Department. Particular attention should be paid to flu-like complaints such as fever or sore throat and to other evidence of infection.
Also, consider the possibility of neuroleptic malignant syndrome (NMS) or myocarditis/pericarditis. See the Acute Clinical Issues sheet for actions.
If the FBC results are within the Green or Amber range, treat the patient's infection according to normal guidelines. Advise the psychiatrist of Amber results as further testing is required. If the results are in the Red range, tell the patient not to take any more clozapine, contact the Emergency Department and send the patient there. Also, inform the mental health team.

Constipation
Constipation is a common side effect (>1/10) of clozapine and is linked to anticholinergic blockade. This is dose related and aggravated by other drugs that cause constipation. Some patients can develop significant gastrointestinal hypo motility leading to paralytic ileus, faecal impaction and intestinal obstruction and fatalities have occurred. Constipation must be proactively managed and the mental health team may request that you prescribe appropriate laxatives. Refer to the ZTAS Fact Sheet on constipation on the GP Web for management advice.

Smoking
Patients who smoke may require a higher clozapine dose due to enzyme induction by tar in cigarettes. Patients who stop smoking may need their clozapine dose reduced or they may develop clozapine toxicity in one or two days. Signs of toxicity include increased hypersalivation, drowsiness, coma, seizures and rarely death. Please note that using NRT or electronic cigarettes do not prevent these problems. Patients who commence smoking may experience a relapse of psychiatric symptoms and may need a dose adjustment.
If there is any change in smoking behaviour or a plan to change smoking status, please inform the clozapine nurse.

Cardiac problems
Clozapine is associated with cardiac complications including myocarditis and cardiomyopathy. Presentation can be atypical (see Acute Clinical Issues sheet) If you have concerns about a patient, please refer to an Emergency Department.

Weight Gain and Metabolic problems
Clozapine is associated with significant weight gain, dyslipidaemia and diabetes. These should be managed according to the relevant NICE guideline
List of Potential Interactions with clozapine
The Table overleaf list the most common interactions associated with clozapine *(Zaponex Summary of Product Characteristics, Electronic medicines Compendium, assessed 17th October 2016)*

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Appendix 14
Clozapine Information sheet for General Practitioners

Drug	Interactions	Comments
Bone marrow suppressants (e.g. carbamazepine, chloramphenicol), sulphonamides (e.g. co- trimoxazole), pyrazolone analgesics (e.g. phenylbutazone), penicillamine, cytotoxic agents and long-acting depot injections of antipsychotics	Interact to increase the risk and/or severity of bone marrow suppression	Clozapine **must not be used** concomitantly with other agents having a well-known potential to suppress bone marrow function (see section 4.3)
Benzodiazepines	Concomitant use may increase risk of circulatory collapse, which may lead to cardiac and/or respiratory arrest	Whilst the occurrence is rare, caution is advised when using these agents together. Reports suggest that respiratory depression and collapse are more likely to occur at the start of this combination or when clozapine is added to an established benzodiazepine regimen
Anticholinergics	Clozapine potentiates the action of these agents through additive anticholinergic activity	Observe patients for anticholinergic side-effects, e.g. constipation, especially when using to help control hypersalivation
Antihypertensives	Clozapine can potentiate the hypotensive effects of these agents due to its sympathomimetic antagonistic effects	Caution is advised if clozapine is used concomitantly with antihypertensive agents. Patients should be advised of the risk of hypotension, especially during the period of initial dose titration
Alcohol, MAOIs, CNS depressants, including narcotics and benzodiazepines	Enhanced central effects. Additive CNS depression and cognitive and motor performance interference when used in combination with these substances	Caution is advised if clozapine is used concomitantly with other CNS active agents. Advise patients of the possible additive sedative effects and caution them not to drive or operate machinery
Highly protein bound substances (e.g. warfarin and digoxin)	Clozapine may cause an increase in plasma concentration of these substances due to displacement from plasma proteins	Patients should be monitored for the occurrence of side effects associated with these substances, and doses of the protein bound substance adjusted, if necessary
Phenytoin	Addition of phenytoin to clozapine regimen may cause a decrease in the clozapine plasma concentrations	If phenytoin must be used, the patient should be monitored closely for a worsening or recurrence of psychotic symptoms
Lithium	Concomitant use can increase the risk of development of neuroleptic malignant syndrome (NMS)	Observe for signs and symptoms of NMS
CYP1A2 inducing substances (e.g. omeprazole)	Concomitant use may decrease clozapine levels	Potential for reduced efficacy of clozapine should be considered
CYP1A2 inhibiting substances (e.g. fluvoxamine, caffeine, ciprofloxacin)	Concomitant use may increase clozapine levels	Potential for increase in adverse effects. Care is also required upon cessation of concomitant CYP1A2 inhibiting medications as there will be a decrease in clozapine levels

Version 1.0 September 2018

Appendix 15

Pharmacist assessment of medication check list

Clozapine initiation medication checklist	Patient Name: ..... ZTAS no: ..... H&C Number: ..... (*or affix label)*

Indication for Clozapine (please tick)

Treatment Resistant Schizophrenia ☐

Untreatable neurological effects from other antipsychotic including atypical ☐

Other indication: Please state:…….....
(Contact pharmacy and Inform ZTAS as use will be "off label")

Physical Health Status: Identify any significant issues:

……
……
……
……

Previous Antipsychotic Medication: List previous antipsychotics and doses taken for at least six weeks (Must include at least one atypical antipsychotic)

Name of medicine (Print)	Dose	Approximate duration

Record significant adverse reactions to any medicines

……
……
……
……

Signature: ..... Date: .....

Please provide a complete list of currently Prescribed medication.
NOTE: This must include all medication not just psychiatric medication.

Outpatients-Provide a current ECR Medication Printout ☐

Inpatients – Provide a copy of the Prescription Kardex and if inpatient for more than one month a copy of GP Medication List on ECR ☐

Signature: …….. Date: ……

Scanned/Faxed form to be sent to Mental Health Clinical Pharmacist – check with Belfast City Hospital Pharmacy for details

For Pharmacy use	Patient Name: .....……..……..... ZTAS no: ..... H&C Number: ..... (*or affix label)*

For inpatients, confirm all medicines have been reconciled with ECR
(Note any unreconciled medicines and action take to resolve) Yes ☐ No ☐

Record Below any current medicine related issues

Name of medicine	**Route, Dose and Frequency**	**Issue with Clozapine identified**	**Is combination contraindicated?** (yes/no)

Comments and Actions:
Pharmacist should record actions taken to address issues identified. Attach copies of correspondence with Consultant

……
…..……
……..……
……..……
……..……
……..……
……..……
……..……
……..……

Initiation of Clozapine has been: Agreed / Not agreed

Signature (Pharmacist) …… Date: ……..

(Signed copy retained in Pharmacy and copy canned or faxed to nurse)

Nurse must staple copy to Care Pathway.

Appendix 16

Clozapine Red Alert Information Sheet

Clozapine Red Alert Information sheet V1.0 February 2019

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Clozapine *Red* Alert Information

You have been given this leaflet because your blood test today was classed as a Red Alert. This means that your white blood cell count is much lower than normal. White blood cells are important because they help your body to fight infections.

Service Users Name: _____

D.O.B: _____

Health & Care Number: _____

Full Blood Count Date: _____

White Cell count: _____ $x10^{9/l}$

Neutrophil count: _____ $x10^{9/l}$

Clozapine Red Alert Information Sheet

What do I need to know?

- You must stop taking clozapine straight away and not start taking it again until your doctor or the clozapine nurse tells you it is safe for you to take clozapine again.
- You should bring any clozapine tablets you have left back to the clozapine team.
- You will have to have a blood test taken every day until your white cell count returns to normal. The clozapine team will tell you when and where to go for the test.
- You will have your temperature, pulse and blood pressure checked at least once a day.
- You should go to the nearest hospital Accident and Emergency Department if you start to have any of the symptoms in the list below;
  - **Sore throat**
  - **Fever**
  - **Flu-like symptoms**
- Bring this leaflet with you and show it to the doctor or nurse in A&E. Tell them you were taking clozapine and have had a Red Alert.

Clozapine Red Alert Information sheet V1.0 February 2019

Information for Medical and Nursing Staff.

This person has been taking clozapine and has experienced a significant fall in their white cell or neutrophil count and clozapine has been stopped. Red Alert patients are at risk of developing severe infections and must be managed accordingly. The following resources are available

- Clinical Assessment Unit Integrated Care Pathway for Management of Patients on Clozapine with Suspected Neutropenic Sepsis
- A clozapine Red Alert Guide is available on the Trust HUB (search for ZTAS).
- Trust clozapine policy on Trust HUB provides additional support information on managing a Red Alert (Appendix 8)
- Clozapine Acute Clinical Issues Sheet on the Trust Hub (search for Clozapine)

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Reference No: SG 30/20

Title:	**Clozapine and COVID-19**			
Author(s)	Stephen Guy, Lead Mental Health Pharmacist, Tel: [redacted] Dr Ruth Barr, Consultant Psychiatrist, Tel: [redacted]			
Ownership:	Caroline Leonard, Surgery and Specialist Services Director			
Approval by:	Drugs and Therapeutics Committee Standards and Guidelines Committee Executive Team Meeting		**Approval date:**	20/04/2020 09/06/2020 05/08/2020
Operational Date:	April 2020		**Next Review:**	July 2020
Version No.	1	**Supercedes**	New Policy	
Key words:	Clozapine, COVID-19			
Links to other policies	BHSCT Clozapine Policy (2019) SG 10/19			

Date	Version	Author	Comments
12/03/2020	0.1	Stephen Guy	Initial draft
13/03/2020 - 01/04/2020	0.2 – 0.14	Stephen Guy	Multiple revisions by R Barr, Clair Erki, P Sloan. Incorporation of new guidance from South London and Maudsley Hospital, recognition that pneumonia is a risk with clozapine and patient may be at greater risk of complication of COVID-19. Agreement with ED to triage clozapine patients referred by Unscheduled care. Addtion of advice on blood dyscrasias
16/04/2020	1	Stephen Guy	Approval by the Drugs and Therapeutics Committee for the period 3 April 2020 to 30 June 2020 in the first instance. To be Uploaded to the HUB immediately. To be noted at the next available Standards and Guidelines Committee and Executive Team Meeting and then final reloaded to the Hub.

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

To provide advice on essential monitoring and maintain safety for patients taking clozapine during the COVID-19 Pandemic. Fever is a common symptom of COVID-19 infection and is also a possible indicator of clozapine induced neutropenia.

1.2 Purpose

This advice is needed to provide a framework for staff to follow regarding clozapine blood monitoring during the COVID-19 pandemic. It also offers advice on management of essential blood monitoring during periods of self-isolation due to actual or suspected COVID-19 and management advice for patients who develop complications as a result of COVID-19

1.3 Objectives

- Provide guidance on routine blood monitoring that must continue during COVID-19 pandemic
- To provide guidance on actions required to continue clozapine when a patient is self-isolating but has no symptoms
- To provide guidance on actions required if a patient who is self isolating develops fever or sore throat
- To provide guidance on supply of clozapine beyond the normal monitoring frequency using the extended sample validity and to use a risk based approach to extending clozapine supply when absolute sample validity has been exceeded.
- To provide guidance on ongoing treatment with clozapine if admission to a medical ward is required

2.0 SCOPE OF THE POLICY

This policy applies to any Belfast Trust patient prescribed clozapine and to any other patient prescribed clozapine who is admitted to a Belfast Trust Hospital

3.0 ROLES/RESPONSIBILITIES

It is the role of the Chair of Division and Divisional Nurse for Mental Health Services to ensure that all staff involved in the prescribing and monitoring of clozapine are aware of this policy.

It is the role of the Service Manager for the Clozapine & Lithium Service to ensure that monitoring of lithium follows the recommendations in this policy

4.0 KEY POLICY PRINCIPLES

4.1 Definitions

- Extended Sample Validity –
    - The additional time permitted by the clozapine monitoring company that can be used in exceptional circumstances to continue clozapine until a blood sample can be obtained.
- Maximum Sample Validity
    - The maximum time that treatment with clozapine can continue without a valid blood sample.
- Unlicensed use -
    - In this policy unlicensed use refers to continuing clozapine treatment beyond the maximum sample validity allowed by the clozapine monitoring company for that patient. An unlicensed agreement with the monitoring company must be completed by the Consultant or their deputy.

4.2 Key Policy Statement(s)

4.3 Policy Principles

- Staff must follow all Infection Control recommendations active during COVID-19 including recommendations for use of PPE
- All patients should continue to have routine blood monitoring for clozapine at their normal frequency when this is possible.
- The normal ZTAS and Trust Red and Amber alert guidance must be followed.
- The Guidance makes recommendation for blood monitoring and supply of clozapine for patients who are self-isolating with and without fever or other symptoms of COVID-19.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

- Consultant Psychiatrists
- Mental Health Nurses
- Clinical Pharmacists.

5.2 Resources

There are no new resource implications

5.3 Exceptions

There are no exceptions.

6.0 MONITORING

There are no specific monitoring requirements for this policy.
Any incidents associated with this Covid-19 related policy must be recorded on datix and reviewed by the appropriate team

7.0 EVIDENCE BASE / REFERENCES

- Leyden Delta ZTAS Manual, September 2018, accesed at ztas.co.uk 7/4/2020
- Leyden Delta,COVID-19 Infetion and blood monitoring via ZTAS, 12th March 2020
- Leyden Delta HCP's Guide to clozapine use during the corona crisis, 29th March 2020
- Gee at al, COVID-19 and psychotropic medication, South London and Maudsley NHS Foundation Trust, 13/3/2020
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- Gee et al, Clozapine and blood dyscrasias in patients with coronavirus (COVID19). South London and Maudsley NHS Trust 25/3/20
- Mistura Enterprises Ltd Choice and Medication Handy Chart, Clozapine and COVID-19, March 2020
- Pandarakalam, BMJ Response: Potential risk of Covid19 in Clozapine treated patients. Published on-line: 23/3/20
- Abdelmawla, N., & Ahmed, M. (2009). Clozapine and risk of pneumonia. British Journal of Psychiatry, 194(5), 468-469. doi:10.1192/bjp.194.5.468

8.0 CONSULTATION PROCESS

- Clinical Lead for Recovery Services
- Lead Pharmacist for Community Mental Health

9.0 APPENDICES / ATTACHMENTS

Appendix 1 Clozapine and COVID-19

10.0 EQUALITY STATEMENT

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 this policy/proposal has potential impact and if it should be subject to a full impact assessment. This process is the responsibility of the policy or service lead - the template and

guidance are available on the Belfast Trust Intranet. Colleagues in Equality and Planning can provide assistance or support.
The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact ☒

11.0 DATA PROTECTION IMPACT ASSESSMENT

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

Alternative arrangements will be made for people who have difficulties attending the clozapine clinc for testing.

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

21/04/2020

_____ **Date:** _____

Authors

21/04/2020

_____ **Date:** _____

Director

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Appendix 1

Clozapine and COVID-19

General Advice to provide to Outpatients taking clozapine

Give all patients the Choice and Medication Clozapine and COVID-19 handy chart.

Regularly remind the patient of the importance of reporting flu-like symptoms, such as fever or sore throat immediately. Ensure they have contact details to do this and they will be given guidance on next steps

Mon-Fri 9am-5pm: Contact 028 95041327

Out of hours and at week-ends: Contact 028 95045830

Remind patients to tell any healthcare professional that they take clozapine, especially if they are admitted to hospital.
Tell patients to contact the clozapine team if they have to self-isolate and to remain at home and contact their GP. They should contact the numbers above immediately if they develop fever.

Pre-screening telephone call for COVID -19

Remember that all patients must be contacted by phone in advance of face-to-face clinical contact to complete pre-screening for COVID-19.

Clozapine Blood Testing

Always follow the normal recommendations of the RED, AMBER, GREEN blood-reporting protocol.
At present, there is no waiver for blood testing which must continue in line with normal ZTAS recommendations. This may become difficult if patients are isolated or there are staff shortages. The extended test validity can be used to keep supply and administration of clozapine within its product license. Continuing to supply or take clozapine beyond the maximum sample validity is outside the clozapine product license and would be a clinical decision based on a risk-benefit assessment. The patient should consent to treatment outside the product license and ZTAS must be informed.

Table 1: Routine and Extended sample Validities

Normal Blood Sample Frequency	Routine Sample Validity	Extended Sample Validity
Weekly	7 days	14 days (two weeks)
Fortnightly	14 days	21 days (three weeks)
4-Weekly	28 days	42 days (six weeks)

NOTE: avoid leaving testing to the last day

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Blood Testing for patients NOT required to self-isolate

Repeat COVID Pre-screening including temperature check before admission to clinical area.

Weekly and Fortnightly Patients

Test at their normal frequency using the 7-day extension if tests are delayed. Contact BCH pharmacy to arrange additional supply of clozapine as an advance on the current prescription if required.

4-Weekly Patients

Continue to test at 4-weekly intervals using the 14-day extension if tests are delayed and supply clozapine according to the patients agreed dispensing frequency. Contact BCH pharmacy to arrange additional supply of clozapine as an advance on the current prescription if required.

Blood Testing for Self-Isolating Patients with NO signs of infection

Remind the patient they must seek urgent medical advice if they develop flu-like symptoms such as fever or sore throat (see numbers above and guidance in next section)**.**

If an outpatient has less than the required supply of clozapine to last for the self-isolation period, arrange an additional supply of clozapine from BCH pharmacy up to the maximum allowed sample validity.
If the period of self-isolation exceeds the maximum sample validity by less than one week, in order to avoid a treatment break, consider if it is appropriate to continue clozapine for up to 7 days over the maximum validity.
NOTE: This is unlicensed and must be approved by a Consultant or Senior doctor and a ZTAS Unlicensed Agreement completed and sent to ZTAS before contacting BCH pharmacy to arrange supply.
In all cases, obtain a full blood count as soon as self-isolation ends. If blood tests are required during the self-isolation period they should be taken at the community mental health designated area for COVID19, using personal protective equipment (PPE) and techniques as recommended by the trust. In some circumstances, it may be necessary for the blood test to be taken at the patient's home (in PPE).The risk benefit of a home visit should always be discussed with the relevant consultant and team leader.

Patients with Fever or other symptoms of COVID-19

If a patient develops fever, they should make contact immediately on the number given above. **It is important that an urgent FBP is taken to exclude neutropenia associated with clozapine**. Please note, that clozapine treatment is also associated with increased risk of pneumonia and vulnerability to the complications of influenza. Clozapine treated patients who develop COVID19 are therefore likely to experience increased complications (Abdelmawla et al, 2009, Pandarakalam, 2020). In addition, many patients have significant physical co-morbidity and are smokers. Full physical assessment is necessary if the patient reports symptoms of infection.

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Mon- Fri 9am-5pm: Patient makes contact on number above and is connected to the clozapine team. Clozapine team inform relevant consultant. If there is concern regarding severity of symptoms or deterioration, then staff should advise the patient to go to RVH ED directly for assessment, or NIAS contacted. If the patient is very stable and asymptomatic (other than pyrexia), after discussion with the consultant, it may be appropriate for the clozapine team to arrange an urgent FBP and COVID19 test swab at the designated area for COVID19 at Old See House. In all circumstances, consideration should be given as to whether further medical assessment (e.g. Chest X-ray) is required in ED. *Consider immediate transfer to hospital (dial 999) if warranted by severity of symptoms at any stage*. Clozapine team staff should always link with ED staff and ensure they are aware of the risk of neutropenia and COVID19 complications in clozapine treated patients. If the patient requires admission, the Clozapine Team should also contact Liaison Psychiatry Team who can ensure the relevant ward is aware of particular issues with clozapine.

Out of hours, including weekends: Patient calls contact number above. Patient speaks with a member of Unscheduled Care Team at RVH who advise them to attend ED for medical assessment. USC staff then link with ED Triage staff to ensure they are made aware of the risk of neutropenia and increased complications from COVID19 (see also clozapine plasma levels below). If patient is admitted, USC staff will ensure Liaison Team are informed.

Act on RED or AMBER results in the usual manner. If neutropenia is identified, this is a **medical emergency.**

For patients presenting with **flu-like symptoms, chest pain and shortness of breath**: **WITHHOLD** clozapine (suspect myocarditis) and arrange for immediate transfer to ED.

Full blood counts should be repeated as clinically indicated (daily after a RED alert) and results uploaded to ZTAS

Clozapine Plasma Levels

Fever and rises in CRP, indicative of systemic inflammation, can cause a reduction in the metabolism of clozapine via CYP1A2 liver enzymes. This results in a rise in clozapine plasma levels. It is possible that infection with COVID-19 will have this effect. Patients MUST be monitored closely for signs of clozapine toxicity e.g. drowsiness, sedation, lethargy, confusion, agitation, tachycardia, hypotension, respiratory depression and seizures. Careful consideration should be given to a reduction in clozapine dose if there are any concerns regarding possible toxicity. A reduction of up to 50% may be appropriate and kept under review as the clinical picture (including results of serum levels) develops (please see ZTAS HCP Guide to Clozapine Use during the Corona Virus). I*n addition, if the patient is a smoker who reduces their smoking due to either a respiratory infection or admission to hospital, clozapine levels may rise further.* Refer to the BHSCT Clozapine and Smoking Policy. If necessary, clozapine plasma level tests may be ordered from Magna Laboratories, sample and postal kits are available from RVH, BCH and Mater Pharmacy Departments. Results

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will not be available for at least 4 days. Contact Magna labs on 01989 763333

A clear plan should always be in place to increase the clozapine dose in steps to the previous maintenance dose to reduce the risk of relapse after the infection has resolved.

Patients **with severe respiratory infection:** Liaise with medical team and WITHHOLD clozapine until symptoms resolve. (See note on Treatment Breaks)

Patients with **mild respiratory infection:** seek medical advice: clozapine treatment can usually continue. See Clozapine Plasma Level Section above.

Clozapine and blood dyscrasias in patients with COVID-19

The haematological concerns with clozapine focus on a reduction in neutrophils, which increases the risk of agranulocytosis. Current data suggest that COVID-19 infection may cause a lowered total white cell count (WCC), primarily due to a reduction in lymphocytes. Clozapine monitoring requirements include the total WCC in the criteria for a Red Alert. Therefore, it is possible that patients with COVID-19 may be declared as a Red Alert with a normal or even raised neutrophil count. Normal practice is to withdraw clozapine after a Red Alert but the monitoring company will consider possible alternative explanations for a Red Alert. It is important that this unique effect of COVID-19 is considered so that inappropriate discontinuation of clozapine and associated relapse of psychotic symptoms can be avoided.

Treatment Break exceeding 48 hours

If dose re-titration is required. Contact psychiatry liaison, the patient's community consultant, the clozapine team or BCH Pharmacy for advice before proceeding.

References:

Abdelmawla, N., & Ahmed, M. (2009). Clozapine and risk of pneumonia. British Journal of Psychiatry, 194(5), 468-469. doi:10.1192/bjp.194.5.468

Gaughran et al, Clozapine and COVID19: Initiation, continuation and special precautions. South London and Maudsley NHS Trust. 31/3/20

Gee et al, Clozapine and blood dyscrasias in patients with coronavirus (COVID19). South London and Maudsley NHS Trust 25/3/20

Pandarakalam, BMJ Response: Potential risk of Covid19 in Clozapine treated patients. Published on-line: 23/3/20

Siskind et al, Consensus statement on use of clozapine during the COVID19 pandemic: Journal of Psychiatry and Neuroscience, published online: 3/4/20

ZTAS: Official Statement regarding COVID 19.Leyden Delta 12/3/20

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Reference No: SG 30/20

Title:	**Clozapine and COVID-19**			
Policy Author(s)	Stephen Guy, Lead Mental Health Pharmacist Tel: [redacted] Dr Ruth Barr, Consultant Psychiatrist, Clinical Lead for Recovery Services in Adult Social and Primary Care Tel: [redacted]			
Responsible Director:	Gillian Traub, Director of Adult Social and Primary Care			
Policy Type: (tick as appropriate)	*Directorate Specific ☐	Clinical Trust Wide ☒	Non Clinical Trust Wide ☐	
If policy type is confirmed as ***Directorate Specific** please list the name and date of the local Committee/Group that policy was **approved**				
Name:		**Date:**		
Approval process:	Drugs and Therapeutics Committee Standards and Guidelines Committee Executive Team Meeting		**Approval date:**	07/08/2020 13/10/2020 11/11/2020
Operational Date:	November 2020		**Review Date:**	~~May 2021~~ ~~August 2021~~ February 2022
Version No.	2	**Supercedes**	V1 – April 2020 – July 2020	
Key Words:	Clozapine, COVID-19			
Links to other policies	BHSCT Clozapine Policy (2019) SG 10/19			

1.0 INTRODUCTION / SUMMARY OF POLICY

1.1 Background

To provide advice on essential monitoring and maintain safety for patients taking clozapine during the COVID-19 Pandemic. Fever is a common symptom of COVID-19 infection and is also a possible indicator of clozapine induced neutropenia.

1.2 Purpose

This advice is needed to provide a framework for staff to follow regarding clozapine blood monitoring during the COVID-19 pandemic. It also offers advice on management of essential blood monitoring during periods of self-isolation due to actual or suspected COVID-19 and management advice for patients who develop complications as a result of COVID-19

1.3 Objectives

- Provide guidance on routine blood monitoring that must continue during COVID-19 pandemic
- To provide guidance on actions required to continue clozapine when a patient is self-isolating but has no symptoms
- To provide guidance on actions required if a patient who is self-isolating develops fever or sore throat
- To provide guidance on supply of clozapine beyond the normal monitoring frequency using the extended sample validity and to use a risk based approach to extending clozapine supply when absolute sample validity has been exceeded.
- To provide guidance on ongoing treatment with clozapine if admission to a medical ward is required

2.0 SCOPE OF THE POLICY

This policy applies to any Belfast Trust patient prescribed clozapine and to any other patient prescribed clozapine who is admitted to a Belfast Trust Hospital.

3.0 ROLES AND RESPONSIBILITIES

It is the role of the Chair of Division and Divisional Nurse for Mental Health Services to ensure that all staff involved in the prescribing and monitoring of clozapine are aware of this policy.

It is the role of the Service Manager for the Clozapine & Lithium Service to ensure that monitoring of lithium follows the recommendations in this policy

4.0 CONSULTATION

- Clinical Lead for Recovery Services
- Lead Pharmacist for Community Mental Health

5.0 POLICY STATEMENT/IMPLEMENTATION

5.1 Dissemination

- Consultant Psychiatrists
- Mental Health Nurses
- Clinical Pharmacists.

5.2 Resources

There are no new resource implications

5.3 Exceptions

There are no exceptions.

5.4 Definitions

- Extended Sample Validity –
  - The additional time permitted by the clozapine monitoring company that can be used in exceptional circumstances to continue clozapine until a blood sample can be obtained.
- Maximum Sample Validity
  - The maximum time that treatment with clozapine can continue without a valid blood sample.
- Unlicensed use -
  - In this policy unlicensed use refers to continuing clozapine treatment beyond the maximum sample validity allowed by the clozapine monitoring company for that patient. An unlicensed agreement with the monitoring company must be completed by the Consultant or their deputy.

5.5 Policy Principles

- Staff must follow all Infection Control recommendations active during COVID-19 including recommendations for use of PPE
- All patients should continue to have routine blood monitoring for clozapine at their normal frequency when this is possible.
- The normal ZTAS and Trust Red and Amber alert guidance must be followed.
- The Guidance makes recommendation for blood monitoring and supply of clozapine for patients who are self-isolating with and without fever or other symptoms of COVID-19.

6.0 MONITORING AND REVIEW

There are no specific monitoring requirements for this policy.
Any incidents associated with this Covid-19 related policy must be recorded on datix and reviewed by the appropriate team

7.0 EVIDENCE BASE/REFERENCES

- Leyden Delta ZTAS Manual, September 2018, accesed at ztas.co.uk 7/4/2020
- Leyden Delta,COVID-19 Infetion and blood monitoring via ZTAS, 12th March 2020
- Leyden Delta HCP's Guide to clozapine use during the corona crisis, 29th March 2020
- Gee at al, COVID-19 and psychotropic medication, South London and Maudsley NHS Foundation Trust, 13/3/2020
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- Mistura Enterprises Ltd Choice and Medication Handy Chart, Clozapine and COVID-19, March 2020
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- Abdelmawla, N., & Ahmed, M. (2009). Clozapine and risk of pneumonia. British Journal of Psychiatry, 194(5), 468-469. doi:10.1192/bjp.194.5.468

8.0 APPENDICES

Appendix 1 Clozapine and COVID-19

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 **link**.

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 equalityscreenings@belfasttrust.hscni.net

The outcome of the equality screening for the policy is:

Major impact ☐
Minor impact ☐
No impact ☒

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 ☐

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).

13/10/2020

_____ **Date:** _____

Authors

11/11/2020

_____ **Date:** _____

Director

Appendix 1

Clozapine and COVID-19

General Advice to provide to Outpatients taking clozapine

Give all patients the Choice and Medication Clozapine and COVID-19 handy chart.

Regularly remind the patient of the importance of reporting flu-like symptoms, such as fever or sore throat immediately. Ensure they have contact details to do this and they will be given guidance on next steps

Mon-Fri 9am-5pm: Contact 028 95041327

Out of hours and at week-ends: Contact 028 95045830

Remind patients to tell any healthcare professional that they take clozapine, especially if they are admitted to hospital.
Tell patients to contact the clozapine team if they have to self-isolate and to remain at home and contact their GP. They should contact the numbers above immediately if they develop fever.

Pre-screening telephone call for COVID -19

Remember that all patients must be contacted by phone in advance of face-to-face clinical contact to complete pre-screening for COVID-19.

Clozapine Blood Testing

Always follow the normal recommendations of the RED, AMBER, GREEN blood-reporting protocol.
At present, there is no waiver for blood testing which must continue in line with normal ZTAS recommendations. This may become difficult if patients are isolated or there are staff shortages. The extended test validity can be used to keep supply and administration of clozapine within its product license. Continuing to supply or take clozapine beyond the maximum sample validity is outside the clozapine product license and would be a clinical decision based on a risk-benefit assessment. The patient should consent to treatment outside the product license and ZTAS must be informed.

Table 1: Routine and Extended sample Validities

Normal Blood Sample Frequency	Routine Sample Validity	Extended Sample Validity
Weekly	7 days	14 days (two weeks)
Fortnightly	14 days	21 days (three weeks)
4-Weekly	28 days	42 days (six weeks)

NOTE: avoid leaving testing to the last day

Blood Testing for patients NOT required to self-isolate

Repeat COVID Pre-screening including temperature check before admission to clinical area.

Weekly and Fortnightly Patients

Test at their normal frequency using the 7-day extension if tests are delayed. Contact BCH pharmacy to arrange additional supply of clozapine as an advance on the current prescription if required.

4-Weekly Patients

Continue to test at 4-weekly intervals using the 14-day extension if tests are delayed and supply clozapine according to the patients agreed dispensing frequency. Contact BCH pharmacy to arrange additional supply of clozapine as an advance on the current prescription if required.

Blood Testing for Self-Isolating Patients with NO signs of infection

Remind the patient they must seek urgent medical advice if they develop flu-like symptoms such as fever or sore throat (see numbers above and guidance in next section)**.**

If an outpatient has less than the required supply of clozapine to last for the self-isolation period, arrange an additional supply of clozapine from BCH pharmacy up to the maximum allowed sample validity.
If the period of self-isolation exceeds the maximum sample validity by less than one week, in order to avoid a treatment break, consider if it is appropriate to continue clozapine for up to 7 days over the maximum validity.
NOTE: This is unlicensed and must be approved by a Consultant or Senior doctor and a ZTAS Unlicensed Agreement completed and sent to ZTAS before contacting BCH pharmacy to arrange supply.
In all cases, obtain a full blood count as soon as self-isolation ends. If blood tests are required during the self-isolation period they should be taken at the community mental health designated area for COVID19, using personal protective equipment (PPE) and techniques as recommended by the trust. In some circumstances, it may be necessary for the blood test to be taken at the patient's home (in PPE).The risk benefit of a home visit should always be discussed with the relevant consultant and team leader.

Patients with Fever or other symptoms of COVID-19

If a patient develops fever, they should make contact immediately on the number given above. **It is important that an urgent FBP is taken to exclude neutropenia associated with clozapine**. Please note, that clozapine treatment is also associated with increased risk of pneumonia and vulnerability to the complications of influenza. Clozapine treated patients who develop COVID19 are therefore likely to experience increased complications (Abdelmawla et al, 2009, Pandarakalam, 2020). In addition, many patients have significant physical co-morbidity and are smokers. Full physical assessment is necessary if the patient reports symptoms of infection.

Mon- Fri 9am-5pm: Patient makes contact on number above and is connected to the clozapine team. Clozapine team inform relevant consultant. If there is concern regarding severity of symptoms or deterioration, then staff should advise the patient to go to RVH ED directly for assessment, or NIAS contacted. If the patient is very stable and asymptomatic (other than pyrexia), after discussion with the consultant, it may be appropriate for the clozapine team to arrange an urgent FBP and COVID19 test swab at the designated area for COVID19 at Old See House. In all circumstances, consideration should be given as to whether further medical assessment (e.g. Chest X-ray) is required in ED. *Consider immediate transfer to hospital (dial 999) if warranted by severity of symptoms at any stage*. Clozapine team staff should always link with ED staff and ensure they are aware of the risk of neutropenia and COVID19 complications in clozapine treated patients. If the patient requires admission, the Clozapine Team should also contact Liaison Psychiatry Team who can ensure the relevant ward is aware of particular issues with clozapine.

Out of hours, including weekends: Patient calls contact number above. Patient speaks with a member of Unscheduled Care Team at RVH who advise them to attend ED for medical assessment. USC staff then link with ED Triage staff to ensure they are made aware of the risk of neutropenia and increased complications from COVID19 (see also clozapine plasma levels below). If patient is admitted, USC staff will ensure Liaison Team are informed.

Act on RED or AMBER results in the usual manner. If neutropenia is identified, this is a **medical emergency.**

For patients presenting with **flu-like symptoms, chest pain and shortness of breath**: **WITHHOLD** clozapine (suspect myocarditis) and arrange for immediate transfer to ED.

Full blood counts should be repeated as clinically indicated (daily after a RED alert) and results uploaded to ZTAS

Clozapine Plasma Levels

Fever and rises in CRP, indicative of systemic inflammation, can cause a reduction in the metabolism of clozapine via CYP1A2 liver enzymes. This results in a rise in clozapine plasma levels. It is possible that infection with COVID-19 will have this effect. Patients MUST be monitored closely for signs of clozapine toxicity e.g. drowsiness, sedation, lethargy, confusion, agitation, tachycardia, hypotension, respiratory depression and seizures. Careful consideration should be given to a reduction in clozapine dose if there are any concerns regarding possible toxicity. A reduction of up to 50% may be appropriate and kept under review as the clinical picture (including results of serum levels) develops (please see ZTAS HCP Guide to Clozapine Use during the Corona Virus). I*n addition, if the patient is a smoker who reduces their smoking due to either a respiratory infection or admission to hospital, clozapine levels may rise further.* Refer to the BHSCT Clozapine and Smoking Policy. If necessary, clozapine plasma level tests may be ordered from Magna Laboratories, sample and postal kits are available from RVH, BCH and Mater Pharmacy Departments. Results will not be available for at least 4 days. Contact Magna labs on 01989 763333

A clear plan should always be in place to increase the clozapine dose in steps to the previous maintenance dose to reduce the risk of relapse after the infection has resolved.

Patients **with severe respiratory infection:** Liaise with medical team and WITHHOLD clozapine until symptoms resolve. (See note on Treatment Breaks)

Patients with **mild respiratory infection:** seek medical advice: clozapine treatment can usually continue. See Clozapine Plasma Level Section above.

Clozapine and blood dyscrasias in patients with COVID-19

The haematological concerns with clozapine focus on a reduction in neutrophils, which increases the risk of agranulocytosis. Current data suggest that COVID-19 infection may cause a lowered total white cell count (WCC), primarily due to a reduction in lymphocytes. Clozapine monitoring requirements include the total WCC in the criteria for a Red Alert. Therefore, it is possible that patients with COVID-19 may be declared as a Red Alert with a normal or even raised neutrophil count. Normal practice is to withdraw clozapine after a Red Alert but the monitoring company will consider possible alternative explanations for a Red Alert. It is important that this unique effect of COVID-19 is considered so that inappropriate discontinuation of clozapine and associated relapse of psychotic symptoms can be avoided.

Treatment Break exceeding 48 hours

If dose re-titration is required. Contact psychiatry liaison, the patient's community consultant, the clozapine team or BCH Pharmacy for advice before proceeding.

References:

Abdelmawla, N., & Ahmed, M. (2009). Clozapine and risk of pneumonia. British Journal of Psychiatry, 194(5), 468-469. doi:10.1192/bjp.194.5.468

Gaughran et al, Clozapine and COVID19: Initiation, continuation and special precautions. South London and Maudsley NHS Trust. 31/3/20

Gee et al, Clozapine and blood dyscrasias in patients with coronavirus (COVID19). South London and Maudsley NHS Trust 25/3/20

Pandarakalam, BMJ Response: Potential risk of Covid19 in Clozapine treated patients. Published on-line: 23/3/20

Siskind et al, Consensus statement on use of clozapine during the COVID19 pandemic: Journal of Psychiatry and Neuroscience, published online: 3/4/20

ZTAS: Official Statement regarding COVID 19.Leyden Delta 12/3/20

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Reference No: SG 30/16

Title:	**Guidance for Prescribing and Monitoring of High Dose Antipsychotics in Mental Health Services**		
Author(s)	Stephen Guy: Lead Mental Health Pharmacist Email: [redacted] Phone: [redacted]		
Ownership:	Catherine McNicholl, Adult and Social Primary Care		
Approval by:	Drugs and Therapeutics Standards and Guidelines Committee Policy Committee Executive team Meeting	**Approval date:**	13/04/2016 13/04/2016 01/06/2016 08/06/2016
Operational Date:	June 2016	**Next Review:**	June 2019
Version No.	V1	**Supercedes**	New Guideline
Key words:	Antipsychotics, High Dose, monitoring		
Links to other policies			

Date	Version	Author	Comments
18/6/2013	0.1	Stephen Guy	First Draft
20/3/2014	0.2	Stephen Guy	Comments from Psychiatry D&T committee
9/10/2014	0.3	Stephen Guy	Comments after consultation with consultant team
22/12/2014	0.4	Stephen Guy	Correction of Typos, update of High Dose Antipsychotic Monitoring Sheet. Inclusion of reference to Lester UK Adaptation Positive Cardiometabolic Health Resource

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

High Dose antipsychotic prescribing is defined as either

- A total daily dose of a single antipsychotic which exceeds the upper daily limit in the British National Formulary (BNF)
- A total daily dose of two or more antipsychotics which exceeds the BNF maximum using the percentage method (Add together the percentage of maximum dose of each drug, if this exceeds 100% this is High Dose Prescribing)

Current evidence does not justify the routine use of high dose antipsychotics medication in general adult mental health services. If a high dose is to be prescribed for an individual case, this should only be after evidence based strategies have failed and as a carefully monitored therapeutic trial.

1.2 Purpose

This Guidance is to ensure that the BNF advice based on the Royal College of Psychiatrists on the prescribing and monitoring of doses above the BNF upper limit is followed when high doses of antipsychotics are prescribed

- Consensus statement on high-dose antipsychotic medication. CR190, Royal College of Psychiatrists, November 2014

2.0 SCOPE OF THE POLICY

This Guidance applies to the prescribing and monitoring or recommendation for prescribing and monitoring of high dose antipsychotics in all mental health and learning disability services, including Child and Adolescent Mental Health Services (CAHMS).

It applies to both inpatient and outpatient services.

This Guidance does not apply.

- When antipsychotics are prescribed or administered for short term management of violent or disturbed behaviour. In these cases, follow the Trust Guidance, *Rapid Tranquillisation Guideline for the immediate pharmacological management of violent and aggressive behaviour in adults and adolescent patients in the Belfast Health and Social Care Trust.*
- During a short term cross over between two antipsychotics

3.0 ROLES/RESPONSIBILITIES

The Associate Medical Director for Mental Health and Learning disability services is responsible for ensuring all medical staff are aware of this policy and follow the recommendations
All medical staff should be made aware of this Guidance during induction and should follow the Policy when prescribing High Dose Antipsychotics

All Clinical Pharmacists working in mental health should be made aware of this Guidance at induction and should consider the Policy when reviewing prescriptions for antipsychotics

4.0 KEY POLICY PRINCIPLES

4.1 Prescribing High Dose Antipsychotics

4.1.1 The regular use of high dose antipsychotics should not be routine clinical practice

4.1.2 The decision to prescribe high dose antipsychotics (of either an individual agent or by combination of antipsychotics) should be taken explicitly and should involve an individual risk assessment led by a Consultant Psychiatrist but including the wider clinical team, the patient and, if the patient wishes, their carer. The ultimate responsibility lies with the Consultant Psychiatrist.

4.1.3 The following risk factors should be considered

- Old age
- Female sex
- Cardiac History, in particular MI, arrhythmias, abnormal ECG – Conduct a baseline ECG – see section 4.1.4 for more information
- Hepatic Impairment (dosage reductions may apply and the normal maximum dose may no longer apply)
- Renal Impairment (dosage reductions may apply and the normal maximum dose may no longer apply)
- Diabetes
- Obesity/anorexia nervosa – record BMI
- Illicit substance use including use of “legal highs”
- Alcohol use
- Smoking status – if smoking status changes consider if there should be an alteration to the dose of prescribed antipsychotic
- Extreme physical exertion/stress or shock
- Metabolic disturbances (hypokalaemia, hypomagnesaemia, hypocalcaemia)

4.1.4 Cardiovascular Safety

Antipsychotics as a group are probably associated with an increased risk of QTc prolongation. Normal limits of QTc are less than 440ms in men and less than 470ms in women. Limited evidence suggests the risk of arrhythmia increases exponentially beyond normal limits, with strong evidence that QTc greater than 500ms is clearly linked to an increased risk of arrhythmia. The risk is dose related and the risks for individual drugs are probably additive when they are used in combination.

Table 1 summarises the risk for common antipsychotics

Table 1

Low Effect **No or average increase <10msec at clinical doses or severe effect only reported following overdose**	**Moderate Effect** **Average increase >10msec at clinical doses or ECG officially recommended**	**High Effect** **Average increase >20msec**
Aripiprazole Asenapine Clozapine Flupentixol Fluphenazine Lurasidone Olanzapine Paliperidone Risperidone Sulpiride	Amisulpride* Chlorpromazine Haloperidol Levomepromazine Quetiapine	Any intravenous antipsychotic Pimozide Sertindole *Any antipsychotic or combination of antipsychotics used in doses exceeding BNF maximum dose*

*Torsades de pointes common in overdose with Amisulpride
Table adapted from the Maudsley Guideline 12th edition, 2015

The NICE Guideline CG 178 Psychosis and schizophrenia in adults: prevention and management recommends that before starting an antipsychotic, an ECG should be offered if the person is admitted as an inpatient. In particular, the Summary of Product Characteristics for haloperidol recommends a baseline ECG for all patients.

A number of non-psychotropic medications are associated with prolonged QTc. These are shown in Table 2

Table 2

Antibiotics	**Antimalarials**	**Antiarrhytmics**	**Others**
Erythromycin Clarthromycin Ampicillin Co-trimoxazole Ciprofloxacin Levofloxacin Moxifloxacin	Chloroquine Mefloquine Quinine	Quinidine Disopyramide Procanamide Sotalol Amiodarone Bretylium	Amantadine Ciclosporin Dipehnydramine Hydroxyzine Methadone Nicardipine Tamoxifen

Table adapted from the Maudsley Guidelines 12th edition, 2015

4.1.5 Consider any potential drug interactions.
In particular, use with caution when prescribing

- Drugs which alter electrolyte balance (e.g. diuretics)
- Drugs which prolong QT interval, see Table 2 above

Drugs which can increase antipsychotic levels, **Check the BNF for interactions with the patients current medication**
Drugs which have pharmacodynamics interactions with antipsychotics e.g. increased sedation, hypotensive effect. **Check the BNF for interactions with the patients current medication interactions**

4.1.6 The rationale for prescribing high dose antipsychotics should be recorded in the patient's notes and High Dose Monitoring Form (Appendix 1)

4.1.7 The patients consent should be obtained and recorded in the notes. Note: This may not be possible for patients who are receiving treatment under the relevant section of the Mental Health Order

4.1.8 Dose escalation should be in relatively small increments, allowing adequate time for clinical response

4.1.9 The use of "as required" (PRN) antipsychotic medication should be kept under review. Staff prescribing and administering PRN antipsychotics should be aware of the potential for PRN administration to raise the total daily dose of an antipsychotic over the threshold for high dose prescribing

4.1.10 Responsibility for monitoring patients on high dose antipsychotics, including outpatients, remains with patient's Consultant Psychiatrist. The results of all tests must be communicated to the patient's GP.

4.1.11 When discharging a patient from hospital on high dose antipsychotics, it should be agreed which Consultant team is responsible for ongoing monitoring and review and include this information in the care plan and discharge summary

4.1.12 When recommending high dose antipsychotics for an outpatient, the GP should be advised of the rationale supporting this recommendation

4.2 High Dose Monitoring and review – High Dose Monitoring Record

4.2.1 A High Dose Antipsychotic Monitoring Record (Appendix 1) should be initiated at the start of treatment. Document the following on this form

- Patient Risk factors or relative contraindications
- The calculation of High dose status (use the percentage method)
- Baseline and ongoing monitoring in the relevant sections
- A short note on the rationale for high dose antipsychotic use and a management plan to manage any potential risks or relative contraindications

4.2.2 A baseline ECG should be obtained before exceeding BNF dose. Pay particular attention to QT interval and consider a different approach from High Dose Antipsychotics, including changing the current antipsychotic, if the baseline QT interval is cause for concern. Document all relevant information in the patient's notes

4.2.3 Repeat ECG after a few days and then every 1-3 months in the early stages of high dose treatment. Thereafter an ECG should be repeated as clinically indicated or at least every six months. If QT interval increases to a level that is cause for concern review treatment and

considering reducing the total antipsychotic dose or switching to antipsychotics with a lower risk of QT prolongation (see section 4.1.4)

4.2.4 Repeat all baseline tests at the same frequency of ECG checks in 4.2.3

4.2.5 Check and record the following on the High Dose Antipsychotic Monitoring Record

- Weight and Variance from Baseline
- ECG
- Blood pressure
- Lipid profile
- Blood glucose
- HbA1c
- Liver Function Test (LFT)
- Urea and Electrolytes (U&E)
- Full Blood Count (FBC)

4.2.6 Record any variances observed during monitoring on the High Dose Antipsychotic Monitoring Record and actions taken. Use the Lester Positive Cardiometabolic Health Resource to determine when intervention is necessary (available at www.rcpsych.ac.uk?quality/NAS/resources)

4.2.7 The High Dose Antipsychotic Monitoring Record should be kept with the Prescription Kardex for inpatients and in the medication section of Out Patient notes.

4.2.8 There should be regular, documented, review of high dose therapy to determine if sufficient clinical improvement has been obtained to justify continued prescribing at high dose. Abandon and return to standard doses if there is insufficient improvement after 3 months

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This policy has relevance for

- All doctors delivering mental health and learning disability services to patient over 18 years of age
- All doctors delivering mental health and learning disability in CAMHS
- All Clinical Pharmacists working in mental health or learning disability services

The recommendations of this policy should be implemented within six months of Policy approval

The Chair of the Psychiatry D&T Subcommittee should be notified of any delays or barriers to implementation.

5.2 Resources

The majority of tests will be covered in the routine physical health monitoring guidelines for patients prescribed antipsychotics. There may be an increase in frequency of blood tests and ECGs

5.3 Exceptions

There are no exceptions

6.0 MONITORING

A regular audit of completion of High Dose Antipsychotic Monitoring Record Sheets will be conducted

7.0 EVIDENCE BASE / REFERENCES

- Consensus statement on high-dose antipsychotic medication. CR190, Royal College of Psychiatrists, November 2014
- Lester UK Adaptation – Positive Cardiometabolic Health Resource, Shiers DE, Rafi I, Cooper SJ, Holt RIG. 2014 update

8.0 CONSULTATION PROCESS

- Circulation to all Consultant Psychiatrists for comment
- Comments by mental health pharmacy team

9.0 APPENDICES / ATTACHMENTS

Appendix 1 - High Dose Antipsychotic Monitoring Record Sheet

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. ☐

SIGNATORIES

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

Stephen Guy

_____ **Date: ____ June 2016_____**

Author

_____ **Date: _____June 2016_____**

Direoctor

Appendix 1

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High Dose Antipsychotic Monitoring Record Sheet

Patient Details	Potential Risk Factors/Relative Contraindications		
Patient Name:	**Risk Factors**	**Y/N**	**Comments - information**
Ward or Address: Fix address label here if available	Cardiac History		
	Hepatic Impairment		
	Renal Impairment		
Date of Birth:	Diabetes		
Health & Care No.	BMI - Overweight?		
GP Name:	Substance Misuse		
GP Address:	Alcohol Use		
	Smoker		
	If smoker, has smoking cessation been discussed		

Potential Interactions	
Potential Issue	**Drug Name(s)**
Drugs affecting electrolyte levels	
Drugs with QTc prolongation risk	
Drugs increasing antipsychotic levels	
Other interactions	

Antipsychotic Details			
Drug Name	**Dose/frequency**	**% BNF Maximum**	**Comment**
	Cumulative Total Max Dose (%) = →		

Rational for Prescribing High Dose Antipsychotics	
State the rationale for High Dose antipsychotic therapy. If there are relative contraindications identified above, outline risk management plan.	

Record of Tests								
Record actions in table overleaf if weight >5kg from baseline								
	Baseline	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Date →								
Weight (kg)								
Variance from baseline (kg)								
Tick box to record test has been done, record any variance/actions in the table overleaf								
ECG								
Blood pressure								
Lipids								
Glucose								
HbA1c								
LFTs								
U&Es								
FBC								
Enter initials →								

Appendix 1

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High Dose Antipsychotic Monitoring Record Sheet

Use the Lester UK Positive Cardiometabolic Health Resource[1] as a guide on when to intervene on abnormal results. Don't just SCREEN-INTERVENE

Date & Test No.	Abnormal result/Comments	Action	Dr's signature

[1] www.rcpsych.ac.uk/quality/NAS/resources

Belfast Health and Social Care Trust
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Reference No: SG 30/16

Title:	**Guidance for Prescribing and Monitoring of High Dose Antipsychotics in Mental Health Services**		
Policy Author(s)	Stephen Guy: Lead Mental Health Pharmacist Tel: [redacted]		
Responsible Director:	Aidan Dawson, Adult Social and Primary Care interim Director		
Policy Type: (tick as appropriate)	*Directorate Specific ☒	Clinical Trust Wide ☐	Non Clinical Trust Wide ☐
If policy type is confirmed as ***Directorate Specific** please list the name and date of the local Committee/Group that policy was **approved**			
Date:			

Approval process:	Drugs and Therapeutics Committee Standards and Guidelines Committee Executive Team Meeting	**Approval date:**	08/01/2021 02/02/2021 17/02/2021
Operational Date:	February 2021	**Review Date:**	February 2026

Version No.	2	**Supercedes**	V1 – June 2016 – June 2019
Key Words:	Antipsychotics, High Dose, monitoring		
Links to other policies			

Date	Version	Policy Author	Comments
18/06/2013	0.1	Stephen Guy	First draft
20/03/2014	0.2	Stephen Guy	Comments from Psychiatry D&T committee
09/10/2014	0.3	Stephen Guy	Comments after consultation with consultant team
22/12/2014	1	Stephen Guy	Correction of Typos, update of High Dose Antipsychotic Monitoring Sheet. Inclusion of reference to Lester UK Adaptation Positive Cardiometabolic Health Resource
06/03/2020	1.1	Stephen Guy Dr Michael Doherty Martina Elliot Dr Claire McLoughlin	Review and update of previous version
06/08/2020	1.2	Stephen Guy	Addition of Dr Barr's comments on frequency of monitoring
15/10/2020	1.3	Stephen Guy Dr Michael Doherty	Inclusion of Consultation comments
19/03/2021	2	Stephen Guy Dr Ruth Barr Dr Michael Doherty	Full review of policy, incorporation of new GMC prescribing guidelines. Minimum review frequency changed from 12 to 6 months

1.0 INTRODUCTION / SUMMARY OF POLICY

1.1 Background

High Dose antipsychotic prescribing is defined as either

- A total daily dose of a single antipsychotic medication which exceeds the upper daily limit in the British National Formulary (BNF)
- A total daily dose of two or more antipsychotic medications which exceeds the BNF maximum using the percentage method (Add together the percentage of maximum dose of each drug, if this exceeds 100% this is High Dose Prescribing)

Current evidence does not justify the routine use of high dose antipsychotic medications in general adult mental health services. If a high dose is to be prescribed for an individual patient, this should only be after evidence based strategies have failed. These should include several adequate trials of antipsychotic monotherapy and optimised treatment with clozapine. If High Dose therapy is instituted it should be **as a carefully monitored therapeutic trial, monitoring closely for side effects and therapeutic response.** If there is no good therapeutic response during the trial of high Dose antipsychotic medication, it should be discontinued.

1.2 Purpose

This Guidance is to ensure that the BNF advice based on the Royal College of Psychiatrists on the prescribing and monitoring of doses above the BNF upper limit is followed when high doses of antipsychotic medications are prescribed

- Consensus statement on high-dose antipsychotic medication. CR190, Royal College of Psychiatrists, November 2014

2.0 SCOPE OF THE POLICY

This Guidance applies to the prescribing and monitoring or recommendation for prescribing and monitoring of high dose antipsychotics in all mental health and intellectual disability services, including child and adolescent mental health services (CAHMS).

It applies to both inpatient and outpatient services.

This Guidance does not apply to the following scenarios:

- When antipsychotics are prescribed or administered for short-term management of violent or disturbed behaviour. For these patients, follow the Trust Guidance, *Rapid Tranquillisation Guideline for the immediate pharmacological management of violent and aggressive behaviour in adults and adolescent patients in the Belfast Health and Social Care Trust.*
- During a short term cross over between two antipsychotics

3.0 ROLES AND RESPONSIBILITIES

The Associate Medical Directors for Mental Health, Child and Adolescent Mental Health and Intellectual Disability Services are responsible for ensuring all medical staff are aware of this policy and follow the recommendations
All medical staff should be made aware of this Guidance during induction and should follow the Policy when prescribing High Dose Antipsychotics

All clinical pharmacists working in mental health should be made aware of this Guidance at induction and should consider the Policy when reviewing prescriptions for antipsychotic medication

4.0 CONSULTATION

Circulation to all Consultant Psychiatrists for comment
Comments by mental health pharmacy team

5.0 POLICY STATEMENT/IMPLEMENTATION

5.1 Prescribing High Dose Antipsychotic medication

The regular use of high dose antipsychotics should not be routine clinical practice**.** All consultants should make themselves familiar with RCPsych Consensus statement on high-dose antipsychotic medication CR190 (2014)

5.1.1 Clinical Decision:

The decision to prescribe high dose antipsychotics (by one antipsychotic or by combination of antipsychotics) should be taken explicitly and involve an individual risk assessment led by a Consultant Psychiatrist and include:

- Follow the GMC Good practice in prescribing and managing medicines and devices (April 2021) in respect to prescribing medicines outside their product license.
- Clear documentation of the treatments that have failed
  - to include several adequate trials of antipsychotic monotherapy
  - optimised treatment trial with clozapine or documented refusal of consent for clozapine
  - target symptoms should be stated prospectively and success of the trial measured against these
  - High dose therapy should be for a time limited period and reviewed regularly: abandon if no improvement against target symptoms after 3 months (return to stand doses)
  - Systematic assessment of side effects using a recognised assessment tool e.g. Glasgow Antipsychotic Side effect Scale GASS)
- the multi-disciplinary team
- the patient or carer if appropriate
  - Provide a copy of the Choice and Medication information sheet on High Dose Antipsychotics (explains the risks and benefits)
  - Explain the rationale for High Dose Prescribing

- Obtain and record consent. If consent is not obtained, record why starting High Dose antipsychotic without consent. Documentation of the patient's capacity to give consent, using relevant documentation and second opinions if they are detained under the NI Mental health Order (1986) and documentation through the introduction of the new Mental Capacity Act, when implemented. Doctors should adhere to the GMC Guidance on decision Making and Consent (2020)
- Informing the General practitioner of the rationale and the observations which will be carried out

The ultimate responsibility lies with the Consultant Psychiatrist.

5.1.2 Risk Factors:

The following risk factors should be considered in the assessment for starting a patient on High Dose antipsychotic medication:

- Old age especially >70 years
- Female gender
- Cardiac History (personal), in particular MI, arrhythmias, abnormal ECG and hypertension
- Family cardiac history: including sudden death
- Hepatic or renal Impairment (dosage reductions may apply and the normal maximum dose may no longer apply)
- Diabetes
- Extremes of BMI
- Illicit substances use including use of psychoactive substances.
- Alcohol use
- Smoking status – if smoking status changes consider if there should be an alteration to the dose of prescribed antipsychotic especially if prescribed clozapine
- Extreme physical exertion/stress or shock
- Electrolyte disturbances (e.g. hypokalaemia, hypomagnesaemia, hypocalcaemia)
- Metabolic disorders: Diabetes, thyroid disorder,
- Other individual risk factors

5.1.3 Cardiovascular Safety:

a) Baseline ECG:

- Antipsychotics as a group are probably associated with an increased risk of QTc prolongation. The risk is dose related and the risks for individual drugs are probably additive when they are used in combination.
- Obtain an ECG before commencing High Dose therapy. Particular attention should be paid to QTc interval. If this gives cause for concern, consider an alternative approach and if necessary liaise with a cardiologist.
- Normal limits of QTc are less than 440ms in men and less than 470ms in women. Limited evidence suggests the risk of arrhythmia increases exponentially beyond normal limits, with strong evidence that QTc greater than 500ms is clearly linked to an increased risk of arrhythmia.

b) Review current and any new proposed medication:

- Obtain a list of current medication using NIECR and confirm using a second source.
- The potential impact of antipsychotic medication on QTc is summarised in Table 1 and for non-psychotropic medication in Table 2.

Table 1
Relative Risk of QTc Prolongation with Antipsychotic Medication

Low Effect No or average increase <10msec at clinical doses or severe effect only reported following overdose	**Moderate Effect Average increase >10msec at clinical doses or ECG officially recommended**	**High Effect Average increase >20msec**
Aripiprazole Asenapine Cariprazine Clozapine Flupentixol Loxapine Lurasidone Olanzapine Paliperidone Risperidone Sulpiride	Amisulpride* Chlorpromazine Haloperidol Levomepromazine Quetiapine	Any intravenous antipsychotic Pimozide Sertindole *Any antipsychotic or combination of antipsychotics used in doses exceeding BNF maximum dose*

*Torsades de pointes common in overdose with Amisulpride
Table adapted from the Maudsley Guideline 13th edition, 2018

Table 2
Non-Antipsychotic Medication with Potential Risk of Prolonging QTc

Antibiotics	**Antimalarials**	**Antiarrhytmics**	**Others**
Erythromycin Clarithromycin Ampicillin Co-trimoxazole Ciprofloxacin Levofloxacin Moxifloxacin Ofloxacin Pentamidine	Chloroquine Mefloquine Quinine	Quinidine Disopyramide Procanamide Sotalol Amiodarone Bretylium	Amantadine Ciclosporin Dipehnydramine Hydroxyzine Methadone Nicardipine Tamoxifen

Table adapted from the Maudsley Guidelines 13th edition, 2018
This Table is not an exhaustive list.
There is a website https;//crediblemeds.org which can give more detailed information on the relative risk of QTc prolongation

5.1.4 Consider potential drug interactions.

Review current and any new proposed medication for interactions. In particular, use caution when prescribing with:

- Drugs which alter electrolyte balance (e.g. diuretics)
- Drugs which prolong QTc interval, see Table 2 above
- Drugs which can increase antipsychotic levels, **Check the BNF for interactions with the patients current medication**
- Drugs that have pharmacodynamics interactions with antipsychotics e.g. increased sedation, hypotensive effect. **Check the BNF for interactions with the patients current medication interactions**

5.1.5 Rationale for High Dose Prescribing

The rationale for prescribing high dose antipsychotic medication should be explicitly recorded in the patient's notes and High Dose Monitoring Form (Appendix 1) by the consultant psychiatrist. This should include the points highlighted in 5.1.1 with regard to the previous failures of trials of medication and other evidenced based therapies. The need for continuing this medication should be regularly reviewed and documented at least every six months.

5.2 Monitoring required during treatment with High Dose Antipsychotics

A range of observations and tests are required before initiation High Dose Antipsychotic treatment and these should be repeated at regular intervals. The frequency of monitoring should be indicated by the Consultant and some tests e.g. ECG should be conducted more frequently during the early stages of High Dose Treatment. The list below outlines the required monitoring and who is responsible for this.

a) Medical/Consultant responsibilities:

- ECG
- Assess for side effects, in particular extrapyramidal side effects (EPSE) and for symptoms of hyperprolactinaemia
- Reviewing Results of observations and blood tests
- Review antipsychotic and non-antipsychotic medication
- Completion of Initiation and Monitoring Record for Patients on High Dose Antipsychotics

b) Trust Nursing Responsibilities:

- Completion of Glasgow Antipsychotic Side Effect Scale (GASS)
- Weight, height **and BMI**. Record variance from Baseline
- Abdominal Girth (Circumference from and to the umbilicus to include the superior aspect of both iliac crests.)
- Blood pressure, sitting and standing
- Pulse
- Full Blood Count (FBC)
- Cholesterol and Lipid profile
- Fasting Blood glucose
- HbA1c
- Liver Function Test (LFT)

- Urea and Electrolytes (U&E)
- Serum Prolactin
- Thyroid Function test if on Quetiapine

5.2.1 Monitoring for patient on High Dose Antipsychotic medication

The High Dose Antipsychotic Record sheet (Appendix 1) should be initiated at the start of treatment with High Dose Antipsychotics. Document the following on this form:

- Patient Risk factors or relative contraindications (Section 5.1.2)
- Review and record medication that may prolong QTc (section 5.1.3)
- Review and record any drug interactions (section 5.1.4)
- Record the prescribed antipsychotics, calculate and record the Total Dose as percentage
- Record the rationale for high dose antipsychotic use and a management plan for any potential risks or relative contraindications
- Baseline and ongoing monitoring in the relevant sections (Section 5.2) NOTE the prescriber should indicate the frequency of monitoring. Consider a higher frequency if physical state warrants this during the early stage of High Dose treatment.

Completed Initiation and Monitoring Sheets should be copied into the patients PARIS record in a Medication Monitoring Case note. A copy should be sent to the community nurse who is doing the monitoring with a recommendation of frequency of ongoing monitoring.

5.2.2 Dose increases during High Dose Treatment

Dose increases should be in small increments no more frequently than once a week, allowing adequate time for clinical response with relevant monitoring of pulse blood pressure and ECGs (See section 5.2.1).

5.2.3 As Required (PRN) Antipsychotic

The use of “as required” (PRN) antipsychotic medication should be kept under review. Staff prescribing and administering PRN antipsychotics should be aware of the potential for PRN administration to raise the total daily dose of an antipsychotic over the threshold for high dose prescribing

5.3 High Dose Monitoring and Review

The frequency of review of patients on High Dose Antipsychotics should be determined by the Consultant taking account of individual patient’s risk factors. A higher frequency of monitoring should be considered during the early stages of High Dose Treatment.
The need for high dose therapy and rationale should be reviewed and documented at least every six months.

The information in section 5.3.1 below should be used as a guide for monitoring frequency

5.3.1 Frequency of monitoring:

a) Repeat ECG after a few days (within one week) after commencing High Dose therapy. Also a few days (within one week) after each increase in medication. On reaching the Steady dose, repeat at three months and then at least every 6 months, unless clinically indicated to do more frequently.

b) Physical Observations should be done at the same frequency as ECG at least. If the patient is in hospital, the NEWS chart should be completed.

c) Blood test should be taken 1 month after commencing High Dose Therapy, then 3 monthly initially and then move to 6 monthly when clinically appropriate.

d) Where there are significant risk factors or medication interactions more frequent monitoring of ECG, physical observations and blood results should be stipulated by the prescriber.

e) If QTc interval increases to a level that is cause for concern, review treatment

a) If urgent consult a cardiologist,

b) Consider reducing the total antipsychotic dose or switching to antipsychotics with a lower risk of QT prolongation (see section 5.1.3).

f) Record actions on high Dose antipsychotic monitoring form and patient's medical notes.

g) Record any changes in medication doses and re-calculate high dose percentage at each review.

5.3.2 Record variances observed during monitoring on the High Dose Antipsychotic Monitoring Record and actions taken. Use clinical judgement and the Lester Positive Cardiometabolic Health Resource to determine when intervention is necessary. (Available at www.rcpsych.ac.uk?quality/NAS/resources)

5.3.3 There should be regular, documented, review of high dose therapy to determine if sufficient clinical improvement has been obtained to justify continued prescribing at high dose. Abandon and return to standard doses if there is insufficient improvement after 3 months**.** Consultants should document in the patients notes (electronically or paper) that they have reviewed the results and what actions if any were required. The patient's GP should be updated as required

5.3.4 Specific points for inpatients:

- Identifying inpatients who are on High Dose antipsychotic medication will be by either the pharmacist or medical staff
- These patients should be identified on the PiPA VDU board and marked red and when assessments are carried out marked green.
- The initiation and monitoring sheet should be kept with the notes and scanned/copied into PARIS.
- Frequency of the monitoring will be determined by the consultant psychiatrist.
- Discharge: When discharging a patient from hospital on high dose antipsychotic medication:
  - ❖ It should be agreed which Consultant team, including Home Treatment Team (HTT) is responsible for on-going monitoring and review and include this information in the care plan and discharge letter.

- ❖ Refer the patient to the High Dose Antipsychotic monitoring clinic and indicate where the most recent Monitoring Form is saved
- ❖ Consultant needs to advise the community nurse or nurse at the physical health clinic on the frequency of the blood tests.

5.3.5 Specific points for outpatients: If a patient is identified as already on or going to be commenced on High dose antipsychotic medication;

The consultant should:

- Ensure that they carry out their responsibilities as per 5.2
- Refer the patient using the High dose Initiation and Monitoring form to the appropriate nurse.
- Recommend the frequency with which the patient should be seen.
- Organise the ECGs
- Liaise with the GP or hospital specialist if there are any abnormalities which require intervention.
-

The nurse should:

- Carry out the physical health assessments and blood tests
- Screen the results
- Scan a copy of the results (or if consultant prefers notify them results are available on line) and the physical health monitoring sheet to the consultant

5.3.6 Failure to attend for monitoring (DNA)

Reasonable adjustments will be made for disabled clients when reviewing response to non-attendance at clinic. This might include, if possible, taking blood samples at a different location or in the clients own home.

- **1st DNA Inform key worker and consultant. Liaise with carer**
  If first apt Send for Again in 1 month, unless specified otherwise
- **2nd DNA** Same as above. Consider joint visit to home or Key worker bringing patient to clinic, if resources permit
- **3rd DNA**: inform consultant and ask them to re-refer the patient when they next see them
- If patient refuses to participate this has to be respected. Inform consultant who can make decisions about ongoing treatment.

Always make a clear statement, in notes, as to why the patient has not attended and steps taken to improve attendance

5.4 Dissemination

This policy has relevance for

- All doctors delivering mental health and intellectual disability services to patient over 18 years of age
- All doctors delivering mental health and intellectual disability in CAMHS
- All Clinical Pharmacists working in mental health or intellectual disability services

The recommendations of this policy should be implemented within six months of Policy approval

The Chair of the Psychiatry D&T Subcommittee should be notified of any delays or barriers to implementation.

5.5 Resources

The majority of tests will be covered in the routine physical health monitoring guidelines for patients prescribed antipsychotics. There may be an increase in frequency of blood tests and ECGs

5.6 Exceptions

There are no exceptions

6.0 MONITORING AND REVIEW

A regular audit of completion of High Dose Antipsychotic Monitoring Record Sheets will be conducted. The Trust will participate in Prescribing Observatory for Mental Health (POMH) High Dose Audit when these are arranged.

7.0 EVIDENCE BASE/REFERENCES

- Consensus statement on high-dose antipsychotic medication. CR190, Royal College of Psychiatrists, November 2014
- Lester UK Adaptation – Positive Cardiometabolic Health Resource, Shiers DE, Rafi I, Cooper SJ, Holt RIG. 2014 update
- Maudsley Guidelines 13th Edition Taylor et al,, Willey Blackwell
- Psychosis and schizophrenia in adults: prevention and management (CG178) 2014, www.nice org.uk
- Guidance on decision Making and Consent: GMC (2020)
- Good Practice in prescribing and managing medicines and devices: GMC (2021)

8.0 APPENDICES

Appendix 1 High Dose Antipsychotic Monitoring Record Sheet

9.0 NURSING AND MIDWIFERY STUDENTS

Nursing and/or Midwifery students on pre-registration education programmes, approved under relevant 2018/2019 NMC education standards, must be given the opportunity to have experience of and become proficient in **Guidance for Prescribing and Monitoring of High Dose Antipsychotics in Mental Health Services,** where required by the student's programme. This experience must

be under the appropriate supervision of a registered nurse, registered midwife or registered health and social care professional who is adequately experienced in this skill and who will be accountable for determining the required level of direct or indirect supervision and responsible for signing/countersigning documentation.

Direct and indirect supervision

- Direct supervision means that the supervising registered nurse, registered midwife or registered health and social care professional is actually present and works alongside the student when they are undertaking a delegated role or activity.
- Indirect supervision occurs when the registered nurse, registered midwife or registered health and social care professional does not directly observe the student undertaking a delegated role or activity. (NIPEC, 2020)

This policy has been developed in accordance with the above statement.

Wording within this section must not be removed.

10.0 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 **link**.

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 equalityscreenings@belfasttrust.hscni.net

The outcome of the equality screening for the policy is:

Major impact ☐
Minor impact ☐
No impact ☐

Wording within this section must not be removed

11.0 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 ☐

Wording within this section must not be removed.

12.0 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.

13.0 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).

02/02/2021

_____ **Date:** _____

Policy Author

02/02/2021

_____ **Date:** _____

Director

Appendix 1: Initiation and Monitoring Sheet for Patients on High Dose Antipsychotics

Patient Details	Potential Risk Factors/Relative Contraindications
Patient Name:	**Risks**: Specify any Individual Risks. **See Section 5.1.2, 5.1.3 and 5.1.4 of High Dose Policy**
Ward or Address:	
Date of Birth:	
Health & Care No.	
Paris No.	**Is there a history of Violence/Aggression: YES / NO** (please circle)
GP Name:	
GP Address:	
Key Worker:	

Antipsychotic Details			
Drug Name	**Dose/frequency**	**% BNF Maximum**	**Comment**
	Cumulative Total Max Dose (%) = →		

Non-antipsychotic Medication which may prolong QTc		
Drug Name	**Dose Frequency**	**Comment**

Rationale for Prescribing High Dose Antipsychotics	
• State the rationale for High Dose antipsychotic therapy • Plan for Review. • If there are relative risks/contraindications identified above, outline risk management plan.	

Additional Information: Include frequency of monitoring
I will review the rationale for High Dose Antipsychotics every six months and have explained the required monitoring to the patient Signed: Grade: Date:

Appendix 1: Initiation and Monitoring Sheet for Patients on High Dose Antipsychotics

Patient Details	Any Major Update about Physical History
Patient Name and H&C no.	

Record of Observations								
Record actions in table overleaf if weight increase >5kg from baseline or BMI >25								
Height;	**Baseline**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Date →								
Weight (kg)								
Variance from baseline (kg)								
BMI								
Abdom. Girth								
B.P. (Sitting)								
B.P. (Standing)								
Pulse								
ECG: (last date as per emuse, if applicable)								
Lipids & Cholesterol								
FBC								
Fasting Blood Sugar								
HbA1c								
LFTs								
U&Es								
Prolactin								
Thyroid Function Test (If on Quetiapine)								
Prolactin Symptoms*								
EPS Symptoms**								
Initials								

Appendix 1: Initiation and Monitoring Sheet for Patients on High Dose Antipsychotics

* Gynecomastia, galactorrhoea, reduced libido, menstrual irregularity
** Stiffness, tremor, excessive saliva, involuntary movements

If raised Prolactin or prolactinaemia symptoms – consider pregnancy

Patient Name and H&C No.

Use the Lester UK Positive Cardiometabolic Health Resource as a guide on when to intervene on abnormal results. Don't just SCREEN-INTERVENE
www.rcpsych.ac.uk/quality/NAS/resources

Date	**Actions/Advice by Nurse**	**Initials**
	Is the patient still on High Dose medication? **Any Changes to Physical health (Personal or Family) or Risk** **Intervention:** **Discussion:** **Action Plan:**	

Date	**Actions/Advice by Nurse**	**Initials**
	Is the patient still on High Dose medication? **Intervention:** **Any Changes to Physical health (Personal or Family) or Risk** **Discussion:** **Action Plan:**	

Appendix 1: Initiation and Monitoring Sheet for Patients on High Dose Antipsychotics

Patient Name and H&C No.

Use the Lester UK Positive Cardiometabolic Health Resource as a guide on when to intervene on abnormal results. Don't just SCREEN-INTERVENE
www.rcpsych.ac.uk/quality/NAS/resources

Date	Actions/Advice by Nurse	Initials
	Is the patient still on High Dose medication? **Any Changes to Physical health(Personal or Family) or Risk** **Intervention:** **Discussion:** **Action Plan:**	

Date	Actions/Advice by Nurse	Initials
	Is the patient still on High Dose medication? **Intervention:** **Any Changes to Physical health(Personal or Family) or Risk** **Discussion:** **Action Plan:**	

NHS England

Stopping Over-Medication of People with a Learning Disability, Autism or Both (STOMP)

Reducing inappropriate psychotropic drugs in people with a learning disability, autism or both in general practice and hospitals

We all need to make it a priority to reduce and stop the use of inappropriate drugs, to reduce adverse side effects and potential drug interactions. This is vital to the person's safety and their quality of care.

The goal is to improve the quality of life of people with a learning disability, autism or both by reducing the potential harm of inappropriate psychotropic drugs this includes being used wholly inappropriately, as a "chemical restraint" to control challenging behaviour, or in place of other more appropriate treatment options. It is time for action, it is time for you to lead a medication review of all people with a learning disability, autism or both, with a view to implementing a planned supervised dose reduction and stopping of inappropriate psychotropic drugs.

Aim of this document

Multiple psychotropic drug use often starts at a specialist level which is then passed onto primary care with or without follow up. Many GPs are overseeing the management and prescribing long term. Following the Banerjee report (2009) and the national drive to reduce inappropriate use of antipsychotic drugs in dementia to save lives, confidence has grown amongst GPs and care teams to review prescribing.[1] This document aims to provide support to begin the process of challenging continued use in people with a learning disability, autism or both.

Why reduce the use of psychotropic drugs in people with a learning disability, autism or both?

Public Health England have estimated that on an average day in England, between 30,000 and 35,000 adults with a learning disability, autism or both are taking a prescribed antipsychotic, an antidepressant or both without appropriate clinical indications (psychosis or affective/anxiety disorder). A substantial proportion of people with a learning disability, autism or both who are prescribed psychotropic drugs for behavioural purposes can safely have their drugs reduced or withdrawn.

This research showed that among adults known to their GP to have a learning disability, (excluding only those in hospital as inpatients) on any average day:

- 17.0% were taking prescribed antipsychotic drugs
- 16.9% antidepressants
- 7.1% drugs used in mania and hypomania
- 4.2% anxiolytics
- 2.7% hypnotics

Now is the right time to stop prescribing inappropriate psychotropic drugs

Challenging behaviour has been described as behaviour which puts an individual or others at risk in any social situation and limits their access to services. Causes tend to be personal factors such as communication difficulties and physical health issues and/or environmental factors such as abusive or restrictive social environments. Assessment usually requires observation and a physical assessment to exclude physical causes with the development of a behavioural support plan and referral to secondary care services.

National Institute for Health and Social Care Excellence (NICE)[3] advises that specialists consider prescribing antipsychotic medication to manage behaviour that challenges only if:

- Psychological or other interventions alone do not produce change within an agreed time or
- Treatment for any coexisting mental or physical health problem has not led to a reduction in the behaviour or
- The risk to the person or others is very severe (for example, because of violence, aggression or self-injury)

Only offer antipsychotic medication in combination with psychological or other interventions.

If there is a positive result the specialist needs to conduct a full multidisciplinary review after three months and then at least every six months covering all prescribed medication (including effectiveness, side effects and plans for stopping).

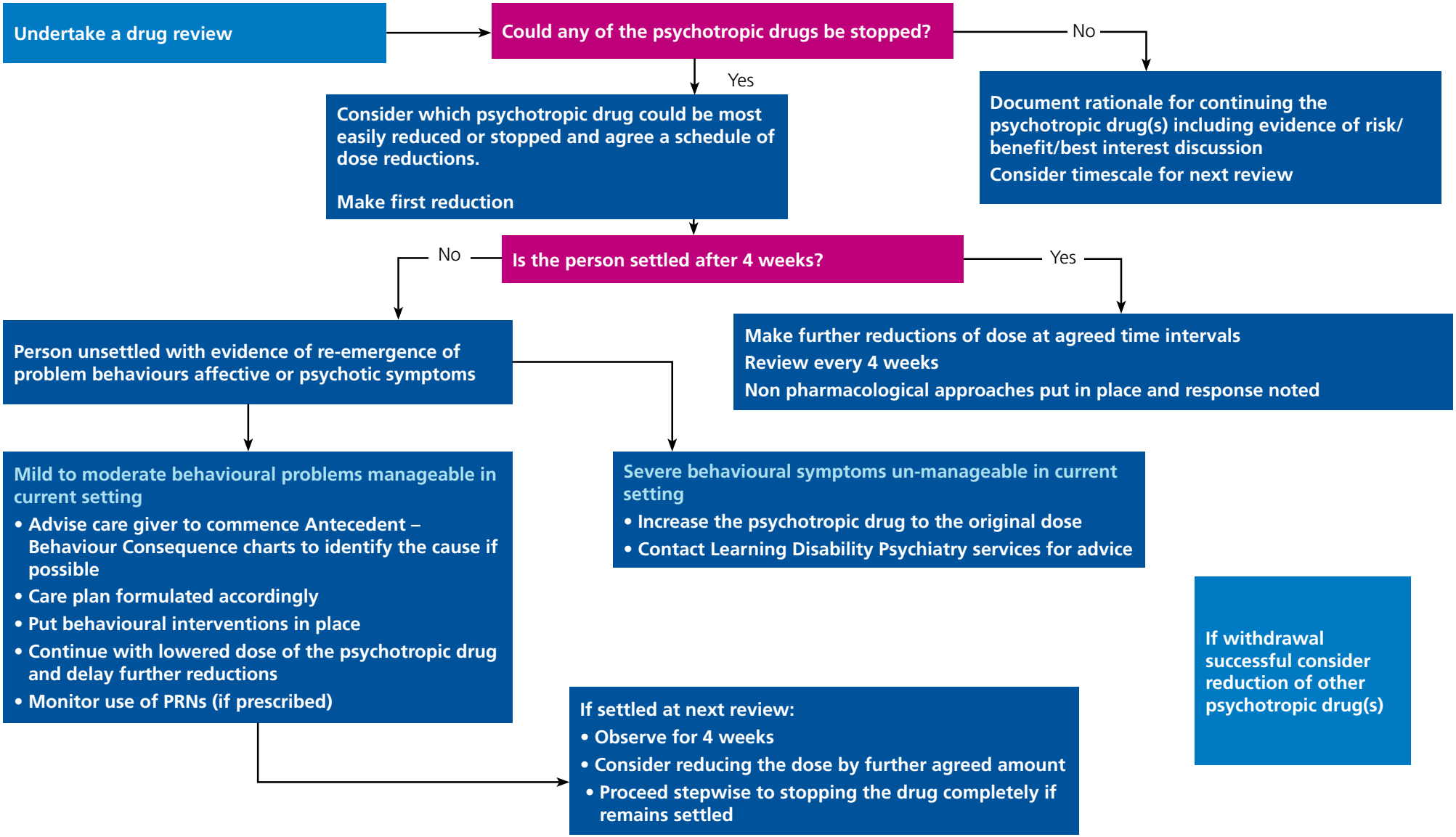
A person-centred approach is necessary when reducing or withdrawing psychotropic drugs. If prescribed for behaviours that challenge there is the expectation that the drugs will stop unless:

- There is evidence that the person with a learning disability, autism or both has gained significant benefit from the use of the psychotropic drug(s) and recent attempts to withdraw the drug(s) has resulted in a deterioration
- The nature of the behaviours experienced prior to prescribing psychotropic drug(s) was so severe that withdrawal is considered clinically inappropriate by the carers and others

If the psychotropic drug is prescribed for a mental illness there is the expectation that the drug treatment will follow the recommendations of the relevant NICE guidance. If the person with a learning disability has been symptom free for some time maintenance may not the best course and they may need referral to the specialist person with a learning disability team.

APPENDIX 1

Algorithm for the review, reduction or stopping of psychotropic drugs in people with a learning disability, autism or both



APPENDIX 2

Suggested steps for your GP practice

Practice-wide steps

1. Have a meeting to discuss the issue and appoint a GP lead.

2. Organise for a practice team member to interrogate the practice prescribing system or work with the CCG Pharmacy team to obtain details of all people with a learning disability, autism or both on psychotropic drugs.

3. Share the results with the practice team, the people with a learning disability specialist and teams and others who can help.

4. Together develop an agreement about a programme of reviews with their named individual GPs and ensure follow up. Make this part of their annual health checks.

Steps for an individual with a learning disability, autism or both

1. Undertake a drug review and find out when and why each drug was started. Try to find out what were the indications and/or behaviours and concerns that prompted the start of each drug:

    a. Undertake medicines reconciliation by checking with your GP records and secondary care letters.

    b. Check with the person, family and their carers. Ensure accessible information and any necessary communication support is available[4].

    c. If behaviour is part of a mental illness or autistic spectrum disorder/ADHD (Neurodevelopmental Disorder) then discuss with a people with a learning disability psychiatrist.

2. Check whether previous attempts at drug reduction and withdrawal have been tried, how it was undertaken and what was the outcome. Remember:

    a. Sudden withdrawal of psychotropic drugs may result in discontinuation effects.

    b. The carers may not give the drugs sometimes. Find out why and what happens.

3. Achieve a consensus amongst carers, family, the person (if possible) and involved professionals that there is scope to reduce or stop psychotropic drug use and it is in the person with a learning disability, autism or both's best interest.

Additional actions for consideration

4. Agree a regular review with consistency about the source and format of information about the impact of the reduction in psychotropic drugs from family or carers that know the person well.

5. Ensure there is a plan for dealing with re-emergent behaviours and liaise with the local community people with a learning disability team.

6. When acting or making decisions on behalf of someone who lacks capacity to make a decision for themselves, you should be able to explain and record how you have had regard to the Mental Capacity Act Code of Practice by acting in their 'Best Interest' and still discussed the medication with them.[5] The Royal College of General Practitioners has a mental capacity toolkit to help you.[6]

Principles of dose reduction and drug discontinuation

1. Make reductions stepwise and realistic, keeping specialists involved. Generally withdraw or reduce one drug at time. Choose the drug with the least evidence of benefit first.

2. The rate of reduction should depend on an agreement between the carers, and if possible the person and the prescriber. This should be informed by the level of concern of the carers, the history of the behaviours associated with the introduction of the drugs, the duration of exposure, dose of drug, half-life of drug, previous response to such reduction / discontinuation and the availability of other strategies and support for the carers to deal with re-emergent behaviours.

3. For drugs with a long half-life (e.g. fluoxetine) or delivered as long acting injections withdrawal will take longer. For drugs with significant drug-drug interactions (carbamazepine) withdrawal may impact on the effects of the other drugs.

Some potential problems

Accept that the reduction may take some time and will be difficult from time to time.

a. Sometimes if behaviours deteriorate it can be difficult to judge whether it is a withdrawal effect (usually occurs within the first week), the person adapting to the absence of the drug (usually in the first month), a return of the behaviours for which the drug(s) was prescribed. Sometimes the person may just be more alert and the carers may have difficulties with the impact of this on their usual working practice. Observe PRN usage in these circumstances.

b. It is better to slow down the rate of reduction rather than sticking to a rigid plan if there are concerns about the person's behaviours.

Be aware of drug discontinuation effects (see table below). These are usually mild and self-limiting but may be difficult to elicit in people with a learning disability, autism or both.

Psychotropic drug class	Discontinuation effects	Management
Antipsychotics	No consensus about whether there are discontinuation problems. Some older antipsychotics worsen tardive dyskinesia	Slow down rate of reduction
Antidepressants	Most SSRI and other antidepressants are associated with discontinuation effects. Flu-like symptoms, dizziness, insomnia and irritability are common	If mild – reassurance If severe – reintroduce antidepressant
Benzodiazepines and Z drugs	At least 1/3 of long term users suffer discontinuation problems – stiffness, weakness and flu-like symptoms	Minimal intervention and reduce slowly Consider switch to diazepam
Mood stabilisers	Rapid withdrawal of anticonvulsants has been associated with seizures	Slow down rate of reduction

APPENDIX 3

Practice Examples

Trafford Clinical Commissioning Group (CCG) has employed a clinical pharmacist from the Greater Manchester West Mental Health NHS Foundation Trust to assist with the identification of potential cases for the 'Call to Action'.

Following a request from the CCG Medicines Management Lead the five biggest (in terms of catchment / number of people with a learning disability on register) practices agreed to participate. There was an average of 50 people per practice with a learning disability diagnosis, obtained through READ codes.

Working with the practice managers and staff the clinical pharmacist set up the search criteria on Egton Medical Information System (EMIS) using the general term of 'Learning Disability'. He then worked through each person with a learning disability case to identify any prescribing of psychotropic drugs. Once that cohort of people was identified, the list was examined to find any instances of prescribing for challenging behaviour. A pro-forma was imported into EMIS to record the review and any recommendations made.

In Salford they are reviewing 150 people who are seen by the people with a learning disability psychiatry team and are prescribed PRN psychotropic drugs. This review will involve either face to face review or telephone review.

They are firstly exploring the frequency of use of PRN psychotropic drugs, and then devising a plan to reduce any that have not been used for a number of months. This reduction will be done in partnership with the individual and a responsive action plan devised if for some reason a deterioration is reported. They are also updating the local policy for staff teams administering PRN drugs as part of the wider Positive Behaviour Support Policy.

NHS Newcastle Gateshead Clinical Commissioning Group (CCG) and NHS North Tyneside CCG are collaborating with Northumberland, Tyne and Wear NHS Foundation Trust on a psychotropic drug review pilot. The overall aim of the pilot is to provide high quality, evidence based services for people with a learning disability and to understand the resources needed to keep people and their carers involved and safe while psychotropic drugs and alternative therapies are considered in the community. A key principle in this work is that people with complex needs must have a review led by specialists.

Through a data sharing agreement, the CCGs identified the number of people with a learning disability on psychotropic drugs and those on the GP register of people with a learning disability but without a serious mental health diagnosis.

A sample of GP practices then carried out a desk-top case review of people in this group using a multi-professional agreed questionnaire. The questionnaire included the duration of psychotropic drugs prescribed, associated diagnosis or indication and whether other non-pharmacological interventions have been implemented. The findings of this case review will guide the priority with which the person with a learning disability will receive a multi-disciplinary review, and the resources that may be needed long term.

APPENDIX 4

Examples of psychotropic drug reduction

A man with a learning disability was treated for 2 years with risperidone 2mg (challenging behaviour) and mirtazapine 30mg (depression). He was monitored by the care home for 3 months post admission. Then risperidone was reduced by 0.5mg every 3-4 weeks until stopped. Final reduction from 0.5mg to zero lasted for 6 weeks at the person with a learning disability's request. Withdrawal totally successful. Mirtazapine was then withdrawn reducing by 50% for two weeks then stopped.

Lessons learnt: The person with a learning disability dictated the pace and was involved in all decision making; good observation from trained staff to monitor for behavioural worsening; slow but steady reduction planned and implemented.

A seventy-two year old man with a mild learning disability who had lived in an institution since childhood. Returned to the community when in his sixties. Staff reported that he was often 'restless', not able to sit still, legs always moving. Difficult for staff to reassure him and to take part in activities. Prescribed sulpiride 800mg daily and trifluoperazine 30mg daily commenced in the hospital, but prescriptions issued by the GP. Psychiatrist reviewed the psychotropic drugs. Evidence of akathisia secondary to antipsychotic. No signs of psychosis. Challenging behaviour in attempting to hit people when he thought staff were not listening to him. Habit of touching the breasts of female workers. Trifluoperazine reduced and withdrawn over six months by Psychiatrist supported by GP. Sulpiride reduced thereafter to 100mg but a resurgence of challenging behaviour. Period of reduction was twelve months. Currently using 200mg daily only. No signs of akathisia. Placement is secure and no longer in jeopardy since the re-instatement of sulpiride 200mg. Good support in the community from support staff.

A lady with a learning disability (aged 42) was prescribed zuclopenthixol decanoate injection 200mg every 4 weeks for approximately 14 years but the clinical reason for this was unclear from the clinical notes. As part of the people with a learning disability health check, the GP felt this could be reviewed. Following a review by the learning disability psychiatry team, there were no signs of current mental illness nor mention in the available notes. Although the lady had not experienced side effects from the injection, there was no clear benefit from using this. A reduction/stop was discussed with the lady. She was reluctant to stop the injection initially, but agreed to try reducing it slowly with support. The dose was reduced to 100mg every 4 weeks for 3 months. No deterioration in behaviour has been observed and the plan is for the GP to stop the drug and monitor the situation.

References

1 Department of Health. The use of antipsychotic medication for people with dementia: Time for action. A report for the Minister of State for Care Services by Professor Sube Banerjee. October 2009 *webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_108302.pdf*

2 Public Health England /CPRD (2015) Prescribing of psychotropic drugs to people with learning disabilities and/or autism by general practitioners in England. *http://www.improvinghealthandlives.org.uk/securefiles/160419_1226//Psychotropic%20medication%20and%20people%20with%20learning%20disabilities%20or%20autism.pdf*

3 NICE. [NG11] 2015 'Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges' *www.nice.org.uk/guidance/ng11*

4 In line with the Accessible Information Standard (SCCI1605 Accessible Information), see www.england.nhs.uk/accessibleinfo

5 Office of the Public Guardian (2005) Mental Capacity Act Code of Practice *https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice*

6 RCGP Mental Capacity toolkit *www.rcgp.org.uk/~/media/Files/CIRC/CIRC-76-80/CIRC-Mental-Capacity-Act-Toolkit-2011.ashx*

Notes:

Notes:

This document has been endorsed by the Royal College of General Practitioners, the Royal Pharmaceutical Society, the Royal College of Nursing, the Royal College of Psychiatrists, and the British Psychological Society and the Challenging Behaviour Foundation.

Further information is available at: www.england.nhs.uk

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	CRANFIELD FEMALE	Date	29 / 9 / 11
Time taken:			Mudiwanzo

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N Y / (N)	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	(Y) / N (Y) / N	
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	Y / (N)	balance transfers not done consistently.
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	(Y) / N	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
4/7/11	68	Methimet 10mg F Rush	30	(Y) / N	(Y) / N
15/7/11	72	Methimet 10mg F Rush	30	(Y) / N	(Y) / N
13/7/11	71	Methimet 5mg F Rush	30	(Y) / N	(Y) / N
11/7/11	67	Temazepam 10mg T Getty	28	(Y) / N	(Y) / N
14/9/11	88	Temazepam 10mg T Getty	28	(Y) / N	(Y) / N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**CD3 or NPA register entry correct?**	**Pharmacy CDR entry correct?**
26/9/11	90	Methimet 10mg	10	(Y) / N	(Y) / N / NA
26/9/11	92	Methimet 5mg	10	(Y) / N	(Y) / N / NA
26/9/11	91	School supply Methylphenidate 10mg	10	(Y) / N	(Y) / N / NA

Ward ~~IS~~ IS NOT (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)

balance transfers not completed consistently

Remedial action required:

ensure balance transfers recorded at top of each page ~~not~~ consistently

Signature (Ward Manager): Ethna Mallon	Signature (Pharmacist): 27/9/11

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other

Bronagh Grills Primary & Social Care Servic.

Belfast Health and Social Care Trust

Report on CD inspection

Ward Name ____Cranfield_____ Date of Inspection _____27/9/2011_____

Pharmacist____Stephen Guy_____ Ward staff seen___Helen Burke_____

Review of Security	Keys security is appropriate CD cupboard is appropriate The cupboard is within a cupboard with other medicines stored in the outer cupboard.
Check Ward SOP	Sop copy on ward
Check List is signatories	Signature list received
Handover Check	Hand over check completed in new Trust Format
Stock Check	All correct
Quality of record keeping	Balance transfers of stock form page to page not conducted as per SOP **Action** Staff to complete balance transfers as per SOP
Patients Own Drugs	None held

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	CRANFIELD ICU	Date	27 / 9 / 11
Time taken:			Mucheneye

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N Y / (N)	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	Y / N Y / N	
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	- suggest change format to trust preferred
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	Y / (N)	See below
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / (N)	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
15/7/11	76	Temazepam 10mg E Shivers	28	Y / N	Y / N
14/9/11	78	Temazepam 10mg E Shivers	28	(Y) / N	Y / N
12/8/11	77	Temazepam 10mg E Shivers	28	(Y) / N	Y / N
				Y / N	Y / N
				Y / N	Y / N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**CD3 or NPA register entry correct?**	**Pharmacy CDR entry correct?**
				Y / N	Y / N / NA
				Y / N	Y / N / NA
				Y / N	Y / N / NA

Ward ~~IS~~ / (IS NOT) (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)
No 76 not recorded correctly as a separate entry in CD Register.
Balance transfer not conducted as per policy & annotation to register not as per policy

Remedial action required:

Signature (Ward Manager): Eimhen O'Kane

Signature (Pharmacist): Stephen Guy 27/9/11

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other

Damien O'Kane Primary & Social Care Govt

Belfast Health and Social Care Trust

Report on CD inspection

Ward Name ____Cranfield ICU_____ Date of Inspection _____27/9/2011_____

Pharmacist____Stephen Guy_____ Ward staff seen___Damien O'Kane _____

Review of Security	Keys security is appropriate CD cupboard is appropriate No additional items stored
Check Ward SOP	Signed copy on ward
Check List is signatories	Signature list received
Handover Check	Hand over check conducted – recording quantities for each drug in stock
Stock Check	No controlled drugs in stock, all returned to pharmacy, register balances all NIL
Quality of record keeping	Noted on page 1 of the register for temazepam , from7/7/2011 to 11/7/2011 the stock balance had been altered by obliteration of the original entry and a new entry made. There was no signature beside the alterations and no explanation. The stock balance was correct. Examination of the records showed that on the 7th July, the person administering the temazepam had added one tablet on to the balance instead of subtracting one tablet. This error was perpetuated until the 11th July when the corrections were made. Examination of the handover checks where balances of tablets were recorded showed the correct figure to be in stock. The handover records did not match the CDRB entries. Staff had not been verifying stock balances in the register against the CDRB **Action** Discussed with ward manager – suggested that the handover check be changed to the Trust Proforma version where stock balances are not recorded in the check. This will focus staff on the quantity in the CDRB. Staff need to be aware that changes must not be made to entries already made and that the correct method would have been to make an adjusting entry, signed and witnessed with an explanation of the error on the date the error was discovered. The original entries should be left untouched Requisition No.76 was not entered correctly as a separate entry in the register – stock balance was simply increased by the amount received from pharmacy **Action** All staff to follow the SOP and record entries from pharmacy on a

	separate line with the date, amount received, where received from, signed and witnessed and balance adjusted accordingly Balance transfers not in accordance with SOP **Action** Staff to complete balance transfers in accordance with SOP
Patients Own Drugs	None held

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	CRANFIELD MALE	Date	27/9/11
Time taken:	Mackenzie		

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N Y / (N)	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	(Y) / N (Y) / N	
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	Y / (N)	Balance transfers not completed correctly
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y (N)	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
4/7/11	97	Durogesic 75. J Hamilton	5	(Y) / N	(Y) / N
26/7/11	100	Durogesic 75 M. Taylor	5	(Y) / N	(Y) / N
4/8/11	1	Concerta XL 36mg L Sands	30	(Y) / N	(Y) / N
6/9/11	3	Concerta XL 36mg M Steele	30	(Y) / N	(Y) / N
				Y / N	Y / N

Date of return	Reqn Number	Item	QTY returned	CD3 or NPA register entry correct?	Pharmacy CDR entry correct?	
26/7/11	~~6~~ 6	Durogesic 75 Nº 002	6	(Y) N	(Y) / N / NA	
22/7/11	95	Temazepan 10mg	1	(Y) / N	(Y) / N / NA	destroyed
				Y / N	Y / N / NA	

Ward ~~IS~~ / (IS NOT) (delete one) compliant with Trust Controlled Drug procedures

Details of ~~deviations~~: (continue on separate page if necessary)

~~bad~~ balance transfers not completed correctly as per SOP

Remedial action required:

balance transfers to be conducted using the shaded section at the top of each page as per SOP

Signature (Ward Manager): J Hamilton SIN

Signature (Pharmacist): Stephens 27/9/11

Copy to:

Ward Manager; Pharmacy Services Manager (If required); Other Bert Lewis Primary + Social Care

Belfast Health and Social Care Trust

Report on CD inspection

Ward Name ____Cranfield Male_____ Date of Inspection _____27/9/2011_____

Pharmacist____Stephen Guy_____ Ward staff seen___J hamilton_____

Review of Security	Keys security is appropriate CD cupboard is appropriate The cupboard is within a cupboard with other medicines stored in the outer cupboard.
Check Ward SOP	Sop copy on ward
Check List is signatories	Signature list received
Handover Check	Hand over check completed in new Trust Format
Stock Check	All correct
Quality of record keeping	Balance transfers of stock form page to page not conducted as per SOP **Action** Staff to complete balance transfers as per SOP
Patients Own Drugs	None held

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	DONEGORE	Date	27/5/11
Time taken:			Mid-morning

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N Y / (N)	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	Y / (N) Y / (N)	asked for but not received
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	Y / (N)	not signed every day due to access restrictions
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	due to remedial works
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / (N)	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
5/7/11	42	Temazepam 10mg Rhonda Belton	28	(Y) / N	Y / N
2/7/11	43	Temazepam 10mg M McBride	28	(Y) / N	Y / N
3/8/11	44	Temazepam 10mg P Lennon	28	(Y) / N	Y / N
9/8/11	45	Temazepam 10MG P Lennon	28	(Y) / N	Y / N
14/9/11	47	Temazepam 10mg P Lennon	28	(Y) / N	Y / N
17/8/11					

Date of return	Reqn Number	Item	QTY returned	CD3 or NPA register entry correct?	Pharmacy CDR entry correct?
				Y / N	Y / N / NA
				Y / N	Y / N / NA
				Y / N	Y / N / NA

Ward IS/ IS NOT (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)

See separate sheet

Remedial action required: Signature sheet required immediately see separate sheet
Change the time handover check completed to ensure done at least once a day

Signature (Ward Manager): Michael McBride.	Signature (Pharmacist):

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other

Michael McBride. Primary & Social Care Service

Belfast Health and Social Care Trust

Report on CD inspection

Ward Name ____Donegore_____ Date of Inspection _____27/9/2011_____

Pharmacist____Stephen Guy_____ Ward staff seen___ _____

Review of Security	Keys security is appropriate CD cupboard is appropriate No additional items stored
Check Ward SOP	yes
Check List is signatories	A list of signatures has not be received by pharmacy – **Action** Signature list to be sent to pharmacy immediately
Handover Check	Hand over check being conducted inconsistently. The ward manager explained that remedial works on the units roof had restricted access to the clinical area at particular times of the day **Action** Access is always available in the morning so recommended that handover check be conducted at this time
Stock Check	All correct
Quality of record keeping	No issues
Patients Own Drugs	None held

Additional notes.

Due to remedial works on Donegore's roof, some patients have been moved to Mallow ward. Both units need to stock temazepam. I inspected the CD arrangements in Mallow. An appropriate CD cupboard is in used with keys managed correctly. Mallow has its own CD register and recording book. The first supply of temazepam to Mallow was made against a requisition from Donergore's order book. A new book for Mallow had been requested from Pharmacy but this was not sent in time and an order was necessary. The incoming stock is correctly recorded in Mallow's register. There isn't a copy of the CD SOP on Mallow but staffing is by Donegore staff and the Ward manager is responsible for both units

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	ERNE	Date	27 / 9 / 11
Time taken:			Mucharcie

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N Y / (N)	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	(Y) / N (Y) / N	
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDR8 and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	Y / N	-- balance transfers not completed as per SOP
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDR8	Y / (N)	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
5/7/11	46	Temazepam 10mg Julie Flanagan	28	(Y) / N	(Y) / N
15/7/11	47	Temazepam 10mg E/L Shaves	28	(Y) / N	(Y) / N
11/8/11	48	Temazepam 10mg H. Burke	28	(Y) / N	(Y) / N
13/9/11	51	Temazepam 10mg D. Mckeown	28	(Y) / N	(Y) / N
				Y / N	Y / N

Date of return	Reqn Number	Item	QTY returned	CD3 or NPA register entry correct?	Pharmacy CDR entry correct?
				Y / N	Y / N / NA
				Y / N	Y / N / NA
				Y / N	Y / N / NA

Ward ~~IS~~ / IS NOT (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)
Balance transfers not completed consistently

Remedial action required:
records are correct but balance transfer not complete - To start doing this as per SOP from today

Signature (Ward Manager): Helen Burke.

Signature (Pharmacist): Stella Cty 27/9/11

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other

Helen Burke Primary & Social Care

Belfast Health and Social Care Trust

Report on CD inspection

Ward Name ____Erne_____ Date of Inspection _____27/9/2011_____

Pharmacist____Stephen Guy_____ Ward staff seen___Helen Burke_____

Review of Security	Keys security is appropriate CD cupboard is appropriate The cupboard is within a cupboard with other medicines stored in the outer cupboard.
Check Ward SOP	Sop copy on ward
Check List is signatories	Signature list received
Handover Check	Hand over check completed in new Trust Format
Stock Check	All correct
Quality of record keeping	Balance transfers of stock form page to page not conducted as per SOP **Action** Staff to complete balance transfers as per SOP
Patients Own Drugs	None held

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	GREENAN	Date	27/9/11
Time taken:			Mucharmore

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N Y / (N)	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	(Y) / N (Y) / N	
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / (N)	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
7/7/11	46	Temazepam 10mg Hazel Crahan	~~28~~ 56	(Y) / N	(Y) / N
26/7/11	50	Temazepam 10mg Colette Carey	56	(Y) / N	(Y) / N
19/7/11	49	Temazepam 10mg Hazel Crahan	28	(Y) / N	(Y) / N
* 9/8/11	52	Temazepam 10mg B Konrad		Y / N	Y / N
13/9/11	59	Temazepam 10mg H. Crahan	28	(Y) / N	(Y) / N

Date of return	Reqn Number	Item	QTY returned	CD3 or NPA register entry correct?	Pharmacy CDR entry correct?
				Y / N	Y / N / NA
				Y / N	Y / N / NA
				Y / N	Y / N / NA

Ward (IS) / ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)

Remedial action required:

None

Signature (Ward Manager): B. Konrad

Signature (Pharmacist): [signature] 27/9/11

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other [signature]

* My error - was for Midazolam - no record necessary

Mary Boyle Primary & Social Care Service

Tweagl

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	IVEAGH BROADWAY	Date	16 / 12 / 2011
Time Taken:	25MINS.		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) / N (Y) / N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Check for exceptional usage or peculiar patterns of usage of CDs	(Y) / N	
Check and update list of authorised signatories	(Y) / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	(Y) / N	none

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
3/10/11	91	Dexamfetamine 5mg P. Bradley	56	(Y) / N	(Y) / N
17/10/11	92	Dexamfetamine 5mg P Bradley	56	Y / N	(Y) / N
15/8/ 24/10/11	81	Methylphenidate XL 27mg S Murray	30	(Y) / N	(Y) / N
31/10/11	93	Dexamfetamine 5mg P Bradley	56	(Y) / N	(Y) / N
1/11/11	94	Dexamfetamine 5mg D. McCabe	56	(Y) / N	(Y) / N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**Register Entry Correct**	**Pharmacy log completed**
21/9/11	88	Methylphenidate 10mg	14	(Y) / N	(Y) / N
21/9/11	89	Concerta XL 27mg	28	(Y) / N	(Y) / N
21/9/11	90	Concerta XL 18mg	14	(Y) / N	(Y) / N

Ward IS/ ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

Signature (Ward/dept sister/nurse or midwife in charge):	Signature (Pharmacist):
Sheila McLaughlin.	Stephen Grey.

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

Tweagl

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	UEAGH	Date	27/9/11
Time taken:			Mackenzie

Checklist	Y/N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N (Y) / N	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	(Y) / N (Y) / N	
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	need to add page number in all balance transfer
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDR8	Y / (N)	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
15/7/11	77	Concerta XL 27mg Colleen Bones	30	(Y) / N	(Y) / N
21/7/11	79	Concerta XL 27mg Deirdre McAbe	30	(Y) / N	(Y) / N
21/7/11	78	Medikinet 10mg Alison Anderson	30	(Y) / N	(Y) / N
18/8/11	65	Concerta XL 18mg Gillespie	30	Y / N	Y / N
20/9/11	87	Dexamfetamine 5mg S McLaughlin	28 x2	(Y) / N	(Y) / N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**CD3 or NPA register entry correct?**	**Pharmacy CDR entry correct?**
21/9/11	88	Methylphenidate 10mg	14	Y / N	Y / N / NA
21/9/11	89	Concerta XL 27	20	Y / N	Y / N / NA
21/9/11	90	Concerta XL 18mg	14	Y / N	Y / N / NA

Ward (IS) ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)
Balance transfers conducted – a small number had no page numbers but otherwise correct

Remedial action required: /

Signature (Ward Manager): Paul Bradley. Signature (Pharmacist):

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other

Paul Bradley Primary & Social Care Service

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	KILLEAD	Date	27/9/11
Time taken:			Mucknore

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N Y / (N)	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	(Y) / N (Y) / N	
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / (N)	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
25/7/11	96	Temazepam 10mg L McCabe	28	(Y) / N	(Y) / N
9/8/11	97	Temazepam 10mg R. McGilk	28	(Y) / N	(Y) / N
23/8/11	99	Temazepam 10mg A Cassidy	28	(Y) / N	(Y) / N
2/9/11	1	Temazepam 10mg S Quinn	28	(Y) / N	(Y) / N
				Y / N	Y / N

Date of return	Reqn Number	Item	QTY returned	CD3 or NPA register entry correct?	Pharmacy CDR entry correct?
				Y / N	Y / N / NA
				Y / N	Y / N / NA
				Y / N	Y / N / NA

Ward IS / ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)

Remedial action required:

No action

Signature (Ward Manager): Assumpta Cullinan

Signature (Pharmacist): [signature] 27/9/11

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other [signature]

Assumpta Cullinan Area Primary & Social Care Servs

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	CRANFIELD FEMALE MULLAMORE	Date	16 / 12 / 11
Time Taken:	25 minutes		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) / N (Y) N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	Y (N)	key needs to be separated
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	Y / N	second signature not done for methylphenidate on 16/12/11 requisition numbers not always recorded
Check for exceptional usage or peculiar patterns of usage of CDs	Y (N)	
Check and update list of authorised signatories	(Y) N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	(Y) N	recorded correctly

Spot check of requisition entries / returns to pharmacy

Date of Issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
7/10/11	95	Temazepam 10mg T. Getty	28	Y/(N)	(Y) N
7/10/11	2	Methimat 10mg E Mallon	30	(Y) N	(Y) N
24/10/11	7	Methimat 10mg E Boyd	30	(Y) N	(Y) N
14/10/11	5	Methimat 5mg C Meenan	30	(Y) N	(Y) N
17/10/11	4	Temazepam 10mg E Mallon	28	(Y) N	(Y) N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**Register Entry Correct**	**Pharmacy log completed**
26/9/11		Equasym 5mg	10	Y/N	Y/N
				Y/N	Y/N
				Y/N	Y/N

Ward IS/ (IS NOT) (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)
Key for CD cupboard on general key ring - must be separated
Requisition numbers not consistently recorded - to be raised with ward managers
Noted that methylphenidate given on the morning of 16/12/11 had no witness - only one nurse on ward S/N Mallon - second nurse arriving at 11am - Explained Trust policy - email to ward manager

Signature (Ward/dept sister/nurse or midwife in charge): Ethna Mallon	Signature (Pharmacist): Stephen Gray

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	CRANFIELD ICU MUCKAMORE	Date	16 / 12 / 11
Time Taken:	10 MINS		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) N (Y) N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y) N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y (N)	
Check and update list of authorised signatories	(Y) N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y (N)	NONE

Spot check of requisition entries / returns to pharmacy

Date of Issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
11/10/11	74	Temazepam 10mg E Shivers	28	(Y) N	(Y) N
28/11/11	83	Temazepam 10mg E Shivers	28	(Y) N	(Y) N
31/10/11	82	Temazepam 10mg G Carey	28	(Y) N	(Y) N
				Y / N	Y / N
				Y / N	Y / N

Date of return	Reqn Number	Item	QTY returned	Register Entry Correct	Pharmacy log completed
		NONE recorded during		Y / N	Y / N
		period of check.		Y / N	Y / N
				Y / N	Y / N

Ward (IS/ ~~IS NOT~~) (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

None

Signature (Ward/dept sister/nurse or midwife in charge):	Signature (Pharmacist):
Charlotte Dynes SIN	Stephen Carey

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	CRANFIELD MEN MULHAMORE	Date	16 / 12 / 11
Time Taken:	15 Mins		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) / N (Y) / N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y / (N)	
Check and update list of authorised signatories	(Y) / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	(Y) / N	none

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
4/10/11	4	Concerta XL 36mg L Taggart	30	(Y) / N	(Y) / N
31/11/11	6	Concerta XL 36mg L Sands	30	(Y) / N	(Y) / N
5/12/11	8	Concerta XL 36mg J Hamilton	30	(Y) / N	(Y) / N
31/10/11	5	Temazepam 10mg J. Hamilton	28	(Y) / N	(Y) / N
				Y / N	Y / N

Date of return	Reqn Number	Item	QTY returned	Register Entry Correct	Pharmacy log completed
		no return - during		Y / N	Y / N
		3 month period.		Y / N	Y / N
				Y / N	Y / N

Ward (IS) / IS NOT (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

Signature (Ward/dept sister/nurse or midwife in charge);	Signature (Pharmacist):

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	DONEGORE MUCKAMORE	Date	14 / 12 / 2011
Time Taken:	15 Min		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) N (Y) N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y) N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y (N)	
Check and update list of authorised signatories	(Y) N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y (N)	None.

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
~~12 Nov~~ In Error *	1	~~Temazepam 10mg P McCaffery~~	28	Y/N	Y/N
13/10/11	49	Temazepam 10mg R Byton	28	(Y) N	(Y) N
27/10/11	50	Temazepam 10mg A Wilson	28	(Y) N	(Y) N
24/11/11	52	Temazepam 10mg P Cupples	28	(Y) N	Y/N
11/11/11	51	Temazepam 10mg R. Brennan	28	(Y) N	(Y) N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**Register Entry Correct**	**Pharmacy log completed**
		No return to pharm during period.		Y/N	Y/N
				~~Y/N~~	~~Y/N~~
				Y/N	Y/N

Ward IS/~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

Signature (Ward/dept sister/nurse or midwife in charge); TZ Duff S/N	Signature (Pharmacist):

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

* entered in error – this item was issued when the ward was split in two temporarily – This register is no longer in use.

MAH Exhibit

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	ERNE (MUCKAMORE)	Date	16/12/11
Time Taken:	10MINS		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y)/N (Y)/N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y)/N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y)/N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y/(N)	
Check and update list of authorised signatories	(Y)/N	updated
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y/(N)	None

Spot check of requisition entries / returns to pharmacy

Date of Issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
10/01/11	53	Temazepam 10mg J. Flannagan	28	(Y)/N	(Y)/N
25/01/11	54	Temazepam 10mg H. Burke	28	(Y)/N	(Y)/N
7/1/11	55	Temazepam 10mg J. Flannagan	28	(Y)/N	(Y)/N
24/1/11	60	Temazepam 10mg H. Burke	28	(Y)/N	(Y)/N
6/12/11	62	Temazepam 10mg H. Burke	28	(Y)/N	(Y)/N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**Register Entry Correct**	**Pharmacy log completed**
		no returns during		Y/N	Y/N
		3 month period		Y/N	Y/N
				Y/N	Y/N

Sheets cancelled

Ward IS/ ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

Signature (Ward/dept sister/nurse or midwife in charge); Aubrey Lewis	Signature (Pharmacist):

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	GREENAN MUCKAMORE	**Date**	16 / 12 / 2011
Time Taken:	10MINS		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) / N (Y) / N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y / (N)	
Check and update list of authorised signatories	Y / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / N	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
4/10/11	63	Temazepam 10mg C. Carey	28	(Y) N	(Y) N
11/10/11	64	Temazepam 10mg H. Graham	28	(Y) N	(Y) N
17/10/11	65	Temazepam 10mg H. Graham	28	(Y) N	(Y) N
15/11/11	70	Temazepam 10mg C. Carey	56	(Y) N	(Y) N
29/11/11	73	Temazepam 10mg H. Graham	28	(Y) N	(Y) N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**Register Entry Correct**	**Pharmacy log completed**
		No returns		Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N

Ward (IS)/NS NOT (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

Signature (Ward/dept sister/nurse or midwife in charge);	Signature (Pharmacist):

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	KILLEAD MACRAMORE	Date	16 / 12 / 11
Time Taken:	60 MINS		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) / N (Y) / N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y / (N)	
Check and update list of authorised signatories	(Y) / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / (N)	NONE

Spot check of requisition entries / returns to pharmacy

Date of Issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
10/10/11	2	Temazepam 10mg A Cassidy	28	(Y) / N	(Y) / N
9/11/11	3	Temazepam 10mg S Quinn	28	(Y) / N	(Y) / N
7/12/11	5	Temazepam 10mg S Quinn	28	(Y) / N	(Y) / N
				Y / N	Y / N
				Y / N	Y / N

Date of return	Reqn Number	Item	QTY returned	Register Entry Correct	Pharmacy log completed
		No returns during 3		Y / N	Y / N
		Month period		Y / N	Y / N
				Y / N	Y / N

Ward (IS) / IS NOT (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

Signature (Ward/dept sister/nurse or midwife in charge):	Signature (Pharmacist):

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	OLDSTONE Muchamore	Date	16 / 12 / 2011
Time Taken:	20minutes		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) N Y / N	no Stock
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y) N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) N	
Check for exceptional usage or peculiar patterns of usage of CDs	(Y) N	
Check and update list of authorised signatories	(Y) N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	(Y) N	None in stock.

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
~~14/9/11~~		no Stock on ward.		Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N

Date of return	Reqn Number	Item	QTY returned	Register Entry Correct	Pharmacy log completed
14/11/11	40	MST 30mg	68	(Y) N	(Y) N
14/11/11	40	Seredol 10mg	21	(Y) N	(Y) N
14/9/11	40	Diamorphine 10mg.	1	(Y) N	(Y) N

Ward (IS) ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

Signature (Ward/dept sister/nurse or midwife in charge);	Signature (Pharmacist):
E Taylor.	Stephen Gus.

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	RATHMULLAN MUCKAMORE	Date	16 / 12 / 2011
Time Taken:	15mins		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) / N (Y) / N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y / (N)	
Check and update list of authorised signatories	(Y) / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / (N)	No patient own drugs

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
6/10/11	18	Temazepam 10mg D Johnston	28	(Y) / N	(Y) N
20/10/11	19	Temazepam 10mg J. Burch	28	(Y) / N	(Y) N
31/10/11	20	Temazepam 10mg D Johnston	28	(Y) / N	(Y) N
17/11/11	21	Temazepam 10mg S Barratt	28	(Y) / N	(Y) / N
2/12/11	23	Temazepam 10mg D. Johnston	28	(Y) N	(Y) / N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**Register Entry Correct**	**Pharmacy log completed**
		No returns		Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N

Ward (IS)/ ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

None

Signature (Ward/dept sister/nurse or midwife in charge);	Signature (Pharmacist): Stephen Gray

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	SIXMILE ASSESSMENT MULCHAMORE	Date	16 / 12 / 11
Time Taken:	10MINS		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	Y / N Y / N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	Y / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	Y / N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y / N	
Check and update list of authorised signatories	Y / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / N	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
		No Stock		Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N

Date of return	Reqn Number	Item	QTY returned	Register Entry Correct	Pharmacy log completed
4/1/12	11	Concerta XL 36mg	25	Y / N	Y / N
4/1/12	12	Concerta XL 36mg	7	Y / N	Y / N
				Y / N	Y / N

Ward IS / ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

Signature (Ward/dept sister/nurse or midwife in charge);	Signature (Pharmacist):

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check

Ward/Dept:	SIXMILE TREATMENT MACKAMORE	Date	11 / 12 / 2011
Time Taken:	10 MINS		

Checklist	Y/N Delete as appropriate	Comment
Stock Check Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist.	(Y) / N (Y) / N	
Review of security Keys held by appropriate person, regulation cabinet in use, all CDs and stationary appropriately in locked cabinet, any additional items stored in CD cabinet	(Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Check for exceptional usage or peculiar patterns of usage of CDs	Y / (N)	
Check and update list of authorised signatories	(Y) / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	(Y) / N	recorded correctly

Spot check of requisition entries / returns to pharmacy

Date of Issue	Reqn Number	Item	QTY Issued	Register Entry Correct	Authorised Signatory
4/10/11	1	Methylphenidate YL 36mg R McLaughlin	30	(Y) / N	(Y) / N
8/10/11	2	Methylphenidate XL 36mg F Shaw	30	(Y) / N	(Y) / N
9/10/11	Rx 10945	Methylphenidate YL 36mg K Donnan	4 x 30 tabs	(Y) / N	(Y) / N
5/12/11	Rx 1501	Methylphenidate YL 36mg K Donnan	16 tabs	(Y) / N	(Y) / N
				Y / N	Y / N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**Register Entry Correct**	**Pharmacy log completed**
		no returns		Y / N	Y / N
				Y / N	Y / N
				Y / N	Y / N

Ward IS / ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations AND remedial action required: (continue on separate page if necessary)

Signature (Ward/dept sister/nurse or midwife in charge);	Signature (Pharmacist):
T. Law.	

Copy to: Ward/dept sister/nurse or midwife in charge; Pharmacy Services Manager (If required); Other

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	OLDSTONE	Date	27/9/11
Time taken:			Mucknamore

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N (Y) / N	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	Y / (N)	Was left & signed in June but could not be found
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	Y / (N) Y / N	Asked for but not completed
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	Some signatures missed each day signed at least once
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	NO STOCK
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	Y / (N)	Balance transfers not conducted as per SOP
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / (N)	NONE

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
21/7/11	24	Diamorphine 30mg inj R. McConnell	5	(Y) / N	Y / N
21.7.11	23	Diamorphine 5mg inj R. McConnell	5	(Y) / N	Y / N
19/7/11	22	MST 10mg MR Dorthy Irwin	60	(Y) / N	Y / N
4/7/11	21	MST 30mg MR Dorothy Irwin	60	(Y) / N	Y / N
17/8/11	26	MST 10mg MR E Taylor	60	(Y) / N	Y / N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**CD3 or NPA register entry correct?**	**Pharmacy CDR entry correct?**
14/9/11	040	MST ~~10mg~~ 5mg	30	Y / N	(Y) / N / NA
14/9/11	040	MST 10mg	74	(Y) / N	(Y) / N / NA
14/9/11	040	Diamorphine 30mg	7	(Y) / N	~~(Y)~~ / N / ~~NA~~ destroyed

Ward ~~IS~~ / (IS NOT) (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)

See separate page

Remedial action required:

see separate page

Signature (Ward Manager); P Heaney

Signature (Pharmacist):

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other _____

Pat Heaney Primary & Social Care

Belfast Health and Social Care Trust

Report on CD inspection

Ward Name ____Oldstone_____ Date of Inspection _____27/9/2011_____

Pharmacist____Stephen Guy_____ Ward staff seen___Pat HEaney _____

Review of Security	Keys security is appropriate CD cupboard is appropriate No additional items stored
Check Ward SOP	A copy of the Trust SOP could not be found despite one being signed by the ward manager and left on the ward in June 2011 **Action** Search for signed copy of SOP, notify pharmacy if this can't be found
Check List is signatories	A list of signatures has not be received by pharmacy – **Action** Signature list to be sent to pharmacy immediately
Handover Check	Hand over check being conducted – on a few occasions only one signature was given and not a second. There was at least one check a day **Action** Move to the proforma template in the new CD policy Ward manager to remind all staff of correct procedure for handover check
Stock Check	No controlled drugs in stock, all returned to pharmacy, register balances all NIL
Quality of record keeping	Balance transfers not conducted as per SOP **Action** Need to implement balance transfers in accordance with new Trust CD policy.
Patients Own Drugs	None held

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	RATHMULLAN	Date	27 / 9 / 11
Time taken:			Madeleine

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N Y / (N)	
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	(Y) / N (Y) / N	
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	(Y) / N	
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / (N)	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
11/7/11	10	Temazepam 10mg C Robinson	28	(Y) / N	(Y) / N
15/7/11	11	Temazepam 10mg Deirdre Johnston	28	(Y) / N	(Y) / N
11/8/11	14	Temazepam 10mg Jenifer Burch	28	(Y) / N	(Y) / N
8/9/11	16	Temazepam 10mg D Johnston	28	(Y) / N	(Y) / N
21/9/11	17	Temazepam 10mg M. Murphy	28	(Y) / N	(Y) / N
Date of return	**Reqn Number**	**Item**	**QTY returned**	**CD3 or NPA register entry correct?**	**Pharmacy CDR entry correct?**
				Y / N	Y / N / NA
				Y / N	Y / N / NA
				Y / N	Y / N / NA

Ward (IS) / ~~IS NOT~~ (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)

Remedial action required:

No action required

Signature (Ward Manager): Gm'Quilla

Signature (Pharmacist): Stanley

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other

Sean Murray Primary & Social Care Service

BHSCT Ward Quarterly Controlled Drugs Check (Form CD2A)

Ward/Dept:	SH MILE ASSESSMENT	Date	27 / 9 / 11
Time taken:	Midmorning		

Checklist	Y / N Circle or delete as appropriate	Comment
Review of security Keys held by appropriate person, regulation cupboard in use, all CDs and stationery appropriately in locked cupboard. Are any additional items stored in CD cupboard	(Y) / N Y / (N)	NONE
Check ward CD SOPs Ensure ward has up-to-date SOPs covering all CD activities	(Y) / N	NONE
Check list of authorised signatories Obtain copy of list to bring to Pharmacy	(Y) / N (Y) / N	NONE
Check ward shift change CD stock check records Ensure these records are held on file in ward/dept for 2 years	(Y) / N	NONE
Stock Check Prior to ward stock check; review all issues of CDs in last 3 months which may highlight exceptional or peculiar usage Quantity in stock tallies with balance in register A record of the stock check should be made in the CDRB and signed and dated by pharmacist. Inspect expiry date of CD stock	Y / (N) (Y) / N (Y) / N (Y) / N	
Review quality of record keeping Accurate indexing, separate page used for each drug and strength, correct balance transfers, quantity recorded is number of units not number of boxes, receipts recorded correctly accurate recording of administration and witnessed destruction	Y / (N)	See below.
Patients' own drugs Check patients' own controlled drugs currently being held on the ward have been correctly entered into CDRB	Y / N	

Spot check of requisition entries / returns to pharmacy

Date of issue	Reqn Number	Item	QTY Issued	CDRB entry correct?	Authorised signatory?
4/8/11	6	Concerta XL 36mg Rossin Loughlin	30	(Y) / N	(Y) / N
8/8/11	7	Concerta XL 36mg Richard Magee	30	(Y) / N	(Y) / N
15/9/11	9	Concerta XL 36mg R Loughlin	30	(Y) / N	(Y) / N
				Y / N	Y / N
				Y / N	Y / N

Date of return	Reqn Number	Item	QTY returned	CD3 or NPA register entry correct?	Pharmacy CDR entry correct?
		no returns noted		Y / N	Y / N / NA
				Y / N	Y / N / NA
				Y / N	Y / N / NA

Ward ~~IS~~ / (IS NOT) (delete one) compliant with Trust Controlled Drug procedures

Details of deviations: (continue on separate page if necessary)
- Balance ~~record~~ transfers not consistently recorded. Note entries being made for home leave. Two pages held no date (6 & 7) - methylphenidate + separate sheet.

Remedial action required:

Signature (Ward Manager): Maria Kelly

Signature (Pharmacist): S Coyle-Gray

Copy to:
Ward Manager; Pharmacy Services Manager (If required); Other Dr

Dr McAuley Primary + Social care Servic

Belfast Health and Social Care Trust

Report on CD inspection

Ward Name ____Six Mile Assessment____ Date of Inspection _____27/9/2011_____

Pharmacist____Stephen Guy_____ Ward staff seen___Maria Kelly_____

Review of Security	Keys security is appropriate CD cupboard is appropriate
Check Ward SOP	Copy on ward
Check List is signatories	Signature sheet has been received
Handover Check	Hand over check being completed
Stock Check	All stock correct
Quality of record keeping	1. Balance transfers form page to page had been completed on several occasions but not for every page 2. Two pages for methylphenidate XL 36mg were noted not to have a page title 3. There is no need to enter anything in the register when a patient is not on the ward – an entry should only be made when an administration has taken place. There are several instances in the register where "home Leave" leave has been recorded on a line in the book **Action** Improve the quality of recording by ensuring balance transfers are always conducted
Patients Own Drugs	1. Recording of home leave for KD. This was done well on page 100 of the register but in page 99 has deteriorated. There are unnecessary gaps being left in the recording and there seems to be an error in the recording on 16/9/2011 – A total of 3 x 36mg are recorded as received from pharmacy on Rx No. 11324. I have checked our register and we supplied 12 tablets on this date against this prescription number 2. A receipt is recorded on 19th Sep of 12 tablets from pharmacy but has not been witnessed or signed in the register – we did not supply any tablets on the 19/9/2011 3. It would appear from the register that on 19/9/2011 you should have 15 in stock when in fact there are only 12 which would tally with supplies from pharmacy

	Action Investigation requested to explain the recording error An IR1 form 66359 has been completed