Name of Policy: Safer Management of Controlled Drugs Policy

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This policy supersedes all previous issues
## Version Control

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Safe Management of Controlled Drugs Policy

1. Introduction

The Government’s response to the Shipman Inquiry’s Fourth Report accepted the need for strengthening the current systems for Safer Management of controlled drugs to minimise risks to patient safety of the inappropriate use 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. 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.

Much of the legislation concerning Controlled drugs has been written to avoid diversion and abuse. It needs to be implemented in a practical and sensible way in a healthcare setting, taking account of both the legal framework and accepted good practice, in order to ensure that patients receive the treatment they need.

2. Policy scope

This document applies to all staff employed by the organisation, either directly or indirectly, who are authorised to prescribe, supply, administer or handle controlled drugs.

3. Aim of policy

This policy is intended to provide guidance on good practice for the management of controlled drugs throughout the Trust. It aims to:-

• ensure the organisation and employees comply with current legal requirements for CDs
• set out robust systems for ordering, storing, supplying, transporting, prescribing, administering, recording and disposing safely of CDs in accordance with the Misuse of Drugs Act 1971 and subsequent Regulations (See references listed at section 14.15)
• clearly identify the responsibility of the employer and employees
• ensure the patient receives the correct, appropriately prescribed medication and that legal requirements surrounding controlled drugs are adhered to.
• There is a clear audit trail for the movement and use of all CDs
• The use of CDs is audited and action is taken if necessary

This policy is not designed to provide advice on the clinical choice or use of CDs.

4. Duties - roles and responsibilities

Trust Board

All designated bodies, including NHS Foundation Trusts, are accountable for the monitoring of all aspects of the use and management of controlled drugs by healthcare professionals whom they employ, with whom they contract or to whom they grant practice privileges.
Every healthcare organisation prescribed as a designated body must appoint an Accountable Officer, who takes organisational responsibility for controlled drugs. The Accountable Officer must be a “fit, proper and suitably experienced person” who does not routinely supply, administer, or dispose of controlled drugs as part of his or her duties. They should have credibility with all healthcare and social care professionals and be of sufficient seniority to be able to take action when concerns are raised. The Accountable Officer must be an Executive Director or report directly to an Executive Director in this role. Individuals such as the Chief Pharmacist, Medical Director and Director of Nursing may be appointed as Accountable Officers

**Accountable Officer**

The Accountable Officer has a statutory duty to ensure that:

- Safe systems are in place for the management and use of CDs
- That staff are trained to carry out their responsibilities
- Robust systems are in place to enable concerns about CDs to be raised, to log these concerns, and initiate investigative actions.

A legal duty of collaboration has been included in the Health Act 2006. This places a statutory responsibility on the Accountable Officer and the NHS Foundation Trust to share information and intelligence relating to controlled drug use across the local health and social care sector. Local organisations are required to co-operate with other healthcare organisations, police, and relevant inspectorates (Care Quality Commission, Royal Pharmaceutical Society). Accountable Officers within PCTs have been deemed responsible for establishing and co-ordinating the intelligence networks.

The Pharmacy Service Manager is currently the named Accountable Officer for this organisation.

Should anyone have concerns about the practice of the Accountable Officer this should be raised with the Medical Director.

**Executive Director**

The Medical Director is the executive lead for the safety of medicines across the Trust. A specific responsibility for Controlled Drugs is to review the quarterly “Occurrence Report – Controlled Drugs Concerns” produced by the accountable Officer, approve actions taken, agree any further actions required, incidents to be reported to the LIN and to keep Trust Board appraised as appropriate. He / she must also ensure the Care Quality Commission is notified of any changes to the Accountable Officer, so that the central register can be kept updated.

**Business Unit Associate Directors and Clinical Directors**

The Business Unit Associate Directors and Clinical Directors are responsible for ensuring that their staff, particularly new starters and locums, follow the procedures within this document, which may differ significantly from elsewhere they may have worked.

**Heads of Department/Business unit/Service Line Managers.**

Heads of Department are responsible for ensuring that their staff, particularly new starters and locums, follow the procedures within this document, which may differ significantly from elsewhere they may have worked.
All staff
All staff in the Trust who manage or handle medicines must familiarise themselves with this document and attend training updates so that they maintain their skills and are familiar with procedures. All staff should ensure any documentation pertaining to medicines should be accurate, comprehensive and legible and stored securely in line with local guidance. It is the responsibility of all staff to ensure they are competent to carry out specific medicines handling tasks relevant to their role.

Responsibilities of the Nurse/ Midwife
The sister/charge nurse is accountable for the safe custody and administration of medicines kept on the ward/department and for ensuring that stocks of controlled drugs, if held, are safe and secure and correspond with the details shown in the register.

The nurse caring for the individual patient is responsible for liaising with pharmacy to ensure the timely supply, safe storage and administration of all medicines required.

In addition the nurse in charge of each ward/department is jointly responsible with pharmacy staff to agree which medicines are held as permanent ward stock.

Registered Nurse or Midwife in Charge of Ward or Department:-
Responsible for the safe and appropriate management of CDs in that area. The registered nurse or midwife in charge can delegate control of access (ie key holding) to the CD cupboard to another, such as another registered nurse or operating department practitioner. However, legal responsibility remains with the registered nurse or midwife in charge. Whilst the task can be delegated, the responsibility cannot.

Registered Nurse or Midwife or Operating Department Practitioner in charge of an Operating Theatre:-
The registered nurse or midwife or Operating Department Practitioner in charge of an operating theatre or theatre suite is responsible for the safe and appropriate management of CDs.
The registered nurse or midwife in charge or Operating Department Practitioner can delegate control of access (ie key holding) to the CD cupboard to another, such as another registered nurse or operating department practitioner. However, legal responsibility remains with the registered nurse or midwife or Operating Department Practitioner in charge. Whilst the task can be delegated, the responsibility cannot.

The registered nurse or midwife or Operating Department Practitioner in charge can delegate control of access (ie key holding) to the CD cupboard to another, such as a registered nurse or an ODP. A nurse or an ODP may then only remove CDs from the cupboard and/or return them to the cupboard on the specific authority of either the registered nurse or midwife or Operating Department Practitioner or doctor. However, legal responsibility remains with the registered nurse or midwife or Operating Department Practitioner 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.
Responsibilities of the Pharmacy Service
Pharmacy staff are responsible for the safe & effective procurement of all medicines to be used in the Trust.

Pharmacy staff are responsible for the stock of medicines held in the pharmacy and that there is a supply and distribution process in place which ensures medicines are provided in a safe, accurate and timely manner.

Dispensing processes are managed through a range of standard operating procedures held within the pharmacy department. The Chief Technician and the Pharmacy Operational Services manager are jointly responsible for ensuring these reflect best practice and are kept up to date.

It is the responsibility of Pharmacy staff to provide evaluated, independent information and advice to patients and health care professionals, and to monitor and evaluate prescriptions for appropriateness of prescribing.

Pharmacy staff oversee the safe, effective and economic use of medicines across the trust. This process includes regular monitor of prescriptions to ensure appropriateness, accuracy, safety and clarity of prescribing. This is further described in MM04, Pharmacy Standards for chart annotation.

To undertake checks of all CDs held on wards and departments every three months and raise any stock discrepancies, concerns about security, quality of record keeping or adherence to this policy with the registered nurse or midwife in charge.

Responsibilities of Prescribers: Medical and Non-medical Prescribers
Medical staff are responsible for the majority of prescribing of medicines for patients. They and other authorised prescribers must adhere to the standards described in MM04.

Prescribers must sign all prescriptions for medicines and it is essential that the identity of the prescriber is known. Prescribers should print their name and/or professional registration pin number on all prescriptions for this purpose.

Non-compliance with the prescribing policy will be reported to the clinical lead and discussed at the multi-disciplinary team meeting. Medical doctors who have not achieved full registration with GMC are permitted to prescribe CDs on in patient prescriptions but are not permitted to prescribe CDs for discharge prescriptions or for outpatients.

Responsibilities of Other Registered Healthcare Staff.
Some other healthcare staff may be involved in the medicine supply and administration processes. The healthcare professional will be authorised to undertake a specific role and will do so in accordance with the directions of a prescriber, prescription or patient group direction and follow appropriate training and assessment, e.g. radiographers, operating department assistants. Access to medicines and responsibilities for medicine stocks must be clearly defined in all clinical areas and be in line with the requirements of medicines legislation.
Portering Staff
Portering staff are responsible for the safe and timely delivery of medicines from the pharmacy to the wards, departments and clinics.

The roles and responsibilities of more explicit duties are described in each policy MM02-MM07.

5 Definitions

<table>
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<tr>
<th>Accountable Officer</th>
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<td>Controlled Drugs (CDs)</td>
<td>The drugs listed in schedules 1-5 of the Misuse of Drugs Regulations 2001 (as amended)</td>
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<td>Bound book in which records are made of CDs received and administered in wards, theatres and departments.</td>
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<td>CD order book (CDOB)</td>
<td>Bound book used by wards, theatres and departments to order CDs</td>
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<td>Discrepancy</td>
<td>Difference between the amount shown in the register or record book and the amount that is physically present</td>
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<td>Diversion</td>
<td>Removal of CDs for unauthorised use; theft</td>
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<td>Local Intelligence Network (LIN)</td>
<td>A network established by the Accountable Officer of a Clinical Commissioning Group for sharing information regarding the management and use of CDs</td>
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6. Management of Controlled Drugs in wards and departments

6.1 Ward/Department Controlled Drug Stocks

6.1.1 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 or midwife in charge.

6.1.2 The list should be modified if practices change and should be subject to regular review at agreed intervals. This list must define drug form, strength and quantity required.

6.1.3 New order and record books will be issued as detailed in MM01 Controlled Stationery Paragraph 6.7

6.2 Ward/Department Requisitioning of Controlled Drugs

The registered nurse or midwife in charge of a ward or department is responsible for the requisitioning of controlled drugs for that area. Whilst undertaking the task can be delegated to another registered nurse or midwife working in that area, the legal responsibility remains with the registered nurse or midwife in charge.
6.2.1 All schedule 2 & 3 Controlled drugs are ordered in the Controlled Drug ordering book and must be signed by an authorised signatory.

A copy of the signatures of each authorised signatory should be available in the pharmacy department for validation. New staff must visit pharmacy to leave a sample of their signature for reference.

6.2.2 In most wards or departments only one CD order book and one CD register should be in use at any one time. Where the variety and/or quantity of CDs administered are such that administration and ordering processes would be problematic by having one register then multiple registers can be used by agreement of the Accountable Officer.

6.2.3 Temazepam preparations must be ordered and their use recorded in the CDRB the same way as other controlled drugs.

6.2.4 Tramadol and Midazolam preparations must be ordered in specific Schedule 3 CD Order books, but their use does NOT require recording in the CDRB.

6.2.5 Requisitions must be completed in duplicate. It is essential to ensure the carbon paper is correctly inserted between the white & pink copies and remains there throughout ALL transactions of the order process.

6.2.6 Requisitions must contain the following:-

- Name of the hospital (Non QEH wards)
- Ward/Department
- Drug name, form, strength, ampoule size if more than one available
- Total Quantity
- Signature and printed name of the authorised nurse
- Date

6.2.7 Only one drug must be ordered on each page.

6.2.8 An order that has been written at ward or department level must not be subsequently amended by ward/department staff. If a change to an order is required, the original order must have a line drawn through it, be signed as ‘ordered in error’ and the white copy of the order retained in the CD order book. A new order on new page must be produced.

6.2.9 The complete order book must be sent to pharmacy in the red transit bag kept specifically for this purpose.

6.3 CD Top-up wards

6.3.1 On some wards pharmacy led CD top-up schemes for replenishing stocks of CDs have been established.
6.3.2 For those wards with a CD top up scheme in operation a member of pharmacy staff is responsible for checking the CD balances in the ward Controlled Drug Cupboard against the levels on the agreed stock list and preparing the CD requisition forms for any stock items required. These requisition forms must be signed by an authorised nurse or midwife.

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

6.4 Ward/Department Delivery of Controlled Drugs

6.4.1 Controlled drug orders can be collected at pharmacy by a responsible hospital employee, designated by the nurse in charge of the ward. The person must bear a hospital identification badge.

6.4.2 Authorised hospital porters may also deliver CDs.

6.4.3 The person collecting the drugs must check the order to ensure drug, form, strength and amount supplied correspond to the written order before signing and dating the requisition book to accept responsibility for delivery. In the event of a member of ward staff undertaking this duty for the first time, it is recommended that they ask to be talked through the process by the pharmacist on duty to ensure they understand their responsibilities. Any manufacturer’s tamper evident seals should be left intact.

6.4.4 The drugs must be transferred or conveyed in a secure, locked and sealed tamper-evident red controlled drug transit bag for transportation to the ward. Individually numbered seals will be used to secure the bag and this number must be written onto the order.

6.4.5 The white copy is torn out and retained in pharmacy [for at least 2 years], leaving the pink copy for reference on the ward during the receipt process.

6.4.6 The order book is placed in the bag with the drugs and the bag closed and sealed for delivery to the ward.

6.4.7 When controlled drugs are despatched by hospital transport, the driver will sign the requisition book in the presence of the pharmacist. The number of the seal and the number of the consignment note will both be endorsed on the order page. The process is completed as in 6.4.5 and 6.4.6. Where a commercial courier or taxi driver is responsible for conveying a CD he/she should be asked to show their valid company ID. Taxi drivers should not be made aware that CDs are being transported as this may increase the potential for divergence.

6.4.8 CDs may not be transported by pneumatic tube.
6.5 **Ward Receipt of Controlled Drugs**

6.5.1 When schedule 2 & 3 CDs are delivered they must be taken directly to a registered nurse or Midwife. On no account should they be left unattended. As a matter of good practice the receiving person should not be the same person who ordered the controlled drugs.

6.5.2 Controlled drugs will be recorded in a uniform way on wards throughout the Trust.

It is recognised that some departments may have special requirements but any deviation from standard practice must be agreed in writing with the Accountable Officer.

6.5.3 The registered nurse or midwife receiving the CDs should:

- check the seal on the bag is intact
- opens the bag and check the number written on the order corresponds to the number of the seal
- check the CDs against the requisition for correct drug, form, strength and quantity.
- Any manufacturer’s tamper evident seals on individual packs should be left intact on receipt from pharmacy. This will facilitate routine stock checks.

6.5.4 In the event of any identified discrepancies, either on immediate receipt or at a later time when the pack tamper evident seal is broken, the pharmacy department should be contacted during normal working hours, and the emergency duty pharmacist outside of normal working hours at the discretion of the senior nurse site manager.

6.5.5 When satisfied that the supply of medication agrees with the order the receiving nurse signs and dates the CD order book. The drugs are then written into the controlled drug record book onto the corresponding page to the order book by one registered nurse or midwife. The record of entry must be witnessed by a second registered nurse or midwife. The expiry date of the drugs should be recorded on the title line.

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

6.5.6 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.

6.5.7 Lock the CDs immediately away into the CD cupboard.
6.6 **Key holding, storage and access to controlled Drugs and stationery**

6.6.1 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 or midwife in charge, or another person working under their authority e.g. a pharmacy technician.

6.6.2 All CD stationery should be kept in a locked cupboard or drawer.

6.6.3 Cupboards must be kept locked when not in use.

6.6.4 The lock must not be common to any other lock in the hospital.

6.6.5 Keys may be delegated to other suitably trained, registered healthcare professionals but the legal responsibility rests with the registered nurse or midwife in charge. At any time the key-holder should be readily identifiable.

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

6.6.7 The controlled drug keys should never be given to agency nurses or medical staff.

6.6.8 The CD key must be held separately from the main drug cupboard keys.

6.6.9 No other medicines or items should normally be stored in the CD cupboard.

6.6.10 CDs must be locked away when not in use.

6.6.11 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.

6.6.12 If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as soon as possible. Staff who have recently gone off duty must be contacted at once and requested to return with the key; even if they have left the building.

6.6.13 If after all possibilities for locating the key explored and it remains missing, the senior registered nurse/midwife or matron on duty and the duty pharmacist must be informed.

6.6.14 If the keys cannot be found estates should be contacted to fit a new lock. Estates must not be requested to fit a new lock just because a member of staff has gone off shift with the key. (See 6.6.12) On no account should a spare key be held for the CD cupboard. All new locks are delivered with multiple keys. It is the responsibility of the nurse in charge to ensure any
duplicate keys are destroyed by estates. Spare keys must never be accepted onto the ward.

6.6.15 A Datix incident must be completed each time a new lock is fitted. To ensure the Accountable Officer is informed, this should be documented as a medication incident rather than security and the adverse event category completed as Controlled Drug.

6.6.16 If there is suspected divergence of CDs, it may also be appropriate to contact the police.

6.7 Recording & Administration of Controlled Drugs on wards/departments

6.7.1 Controlled drugs during in-patient stay can only be administered against a prescription on the drug kardex written by a medical practitioner.

6.7.2 All aspects of the administration of schedule 2 and 3 CDs When a controlled drug needs to be administered, two registered Nurses must check the running balance of the controlled drug, then enter the patient’s name, time, date and dose into the CDRB, altering the running balance as appropriate. The drug must be prepared and administered in the presence of both nurses and their signatures entered into the CD register.

6.7.3 For CDs administered the following details should be recorded in the CDRB in ink (stickers must not be used):-

- Name of controlled drug
- Date and time when dose administered
- Name of the patient
- Quantity administered (including quantity wasted if appropriate- see 6.7.6)
- Form (name, formulation and strength) in which administered
- Name/signature of nurse/authorised person who administered the dose
- Name/signature of witness
- Name must be in full
- Balance in stock

6.7.4 The running balance of the amount of drug remaining in stock must be checked after each issue. Any discrepancies in balance which cannot be immediately rectified should be immediately reported to a pharmacist and senior nurse on duty. A Datix incident should be completed for all balance discrepancies which could not easily be rectified eg simple mathematical running balance.

6.7.5 Controlled drugs should not be reconstituted prior to the time of administration, except those products received from pharmacy in that form e.g. PCA syringes.
6.7.6 If part ampoules are administered, the amount given and the amount wasted must be recorded in the CDRB.

eg. Diamorphine 2.5mg given
     Diamorphine 2.5mg wasted.

Both nurses must witness this destruction and sign the CDRB appropriately.

6.7.7 The part vial wasted should be rendered irretrievable by emptying into a sharps bin containing a denaturing gel. When the bin is sent for destruction it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration

6.7.8 Individual doses of CDs which have been prepared but not administered should be also destroyed by emptying into a sharps bin containing a denaturing gel. This must be witnessed by both nurses and the reason documented and signed by both in the CDRB.

6.7.9 Entries must be made in chronological order and no deletions may be made or spaces left. Any alterations necessary due to a mistake in an entry must be made by appending putting an asterisk beside the error and appending a footnote or margin note detailing the error eg. error in calculation in quantity administered, entry incorrect

6.7.10 Completed CD order and record books must be retained on the ward for two years from the date of last entry.

6.8 Recording & Administration of Controlled Drugs in Theatre

6.8.1 Accountability and responsibility for theatre controlled drugs is as defined at paragraph 4 above.

6.8.2 No more than two controlled drug registers must be in use at any one time.

6.8.3 When CDs are delivered they must be taken directly to a registered nurse or midwife or Operating Department Practitioner. On no account should they be left unattended. As a matter of good practice the receiving person should not be the same person who ordered the controlled drugs.

6.8.4 The registered nurse or midwife or Operating Department Practitioner receiving the CDs should:-

- check the seal on the bag is intact
- opens the bag and check the number written on the order corresponds to the number of the seal
- check the CDs against the requisition for correct drug, form, strength and quantity.
- Any manufacturer’s tamper evident seals on individual packs should be left intact on receipt from pharmacy. This will facilitate routine stock checks.
6.8.5 In the event of any identified discrepancies, either on immediate receipt or at a later time when the pack tamper evident seal is broken, the pharmacy department should be contacted during normal working hours, and the emergency duty pharmacist outside of normal working hours, at the discretion of the senior nurse site manager.

6.8.6 When satisfied that the supply of medication agrees with the order the receiving nurse or Operating Department Practitioner signs and dates the CD order book.

6.8.7 The drugs are then written into the theatre “style” controlled drug record book. These permit more detailed records of CDs issued, administered and destroyed. The record of entry must be witnessed by a second registered nurse or midwife or Operating Department Practitioner. The running balance must be checked at the time of new drugs receipt.

6.8.8 When Theatres are not in use the CD keys are stored in a key press. When required these are logged out and carried by the authorised Anaesthetic Nurse/Operating Department Practitioner.

6.8.9 Prior to each planned/emergency operating session an authorised Anaesthetic Nurse must check, with another Anaesthetic Nurse/ Operating Department Practitioner, the total stock of controlled drugs in each Theatre. This check must be recorded in the Controlled Drug register and both people involved identified.

6.8.10 Controlled drugs must only be issued on request to an Anaesthetist.

6.8.11 After each operation the Anaesthetist must record in the CDRB the following, where appropriate, for all controlled drugs used:
- Patient’s name
- Dose of controlled drug administered
- Dose of controlled drug wasted.

6.8.12 The Anaesthetist must sign each entry in the controlled drug register. The Anaesthetic Nurse/ Operating Department Practitioner must countersign each entry in the controlled drug register, indicating that the correct quantity of drug remains in stock.

6.8.13 Where part vials are wasted, the remainder should be rendered irretrievable by emptying into a sharps bin containing a denaturing gel. When the bin is sent for destruction it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration.

6.8.14 Individual doses of CDs which have been prepared but not administered should be also destroyed by emptying into a sharps bin. This must be witnessed by two practitioners and the reason documented and signed by both in the CDRB. This applies equally to part used syringes. Small volumes...
remaining must never be placed beneath the patient’s pillow in case a “top up” is required in recovery.

6.8.15 The controlled drug register must be completed fully by all parties by the end of the operating session.

6.8.16 If there is a change of Anaesthetic Nurse/ Operating Department Practitioner during operation sessions the controlled drugs in use must be checked before the changeover.

6.8.17 A separate register must be maintained for each individual theatre. A stock list should be agreed for each theatre.

6.8.18 At the end of each session the Anaesthetic Nurse must check with another Anaesthetic Nurse/ Operating Department Practitioner the remaining balance of all controlled drugs. This check must be recorded in the controlled drug register and both people involved identified.

6.8.19 Anaesthetic Nurses/ Operating Department Practitioners should not be involved in the process of drawing up controlled drugs into syringes in the Anaesthetic Room. The only exception is when an Anaesthetist requests the Anaesthetic Nurse/ or Operating Department Practitioner to draw up a controlled drug under his/her supervision. The controlled drug must be checked and documented as above.

6.8.20 In Theatre Recovery, the procedure for custody, administration and recording of controlled drugs will be the same as outlined in this policy for wards across the Trust.

6.9 Out-of-hours supply

6.9.1 Under the current Regulations a registered nurse or midwife may only supply CDs to a patient on that ward, theatre or department in accordance with the written instructions of an authorised prescriber. Whole packs of controlled drugs must not be loaned to another ward.

6.9.2 If a controlled drug is required from another ward, a single dose may be taken from their drug cupboard at the time of drug administration.

6.9.3 The entry must be made in the lending ward’s controlled drug register and an authorised nurse from the lending ward must be one of the two nurses involved in the administration of the dose. This mandates that this nurse must attend on the borrowing ward at the time the dose is given. The patient’s ward number must also be entered next to the name in the CDRB.

6.9.4 Every effort should be made to ensure that adequate stocks are maintained at ward level to meet likely needs. Further advice can be obtained from the on-call pharmacist. At the pharmacist’s discretion a supply may be made out of hours.
6.10 Temporary ward closure or relocation

6.10.1 When a ward will be closed for a period of time pharmacy must be advised as the periods for which ward premises will be unoccupied and the security of drugs during this time may result in varied decisions. The drugs may be uplifted and stored in pharmacy during the period of the closure.

6.10.2 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 lists and whether it is a permanent or a temporary relocation. Pharmacy should be contacted for advice.

6.11 Controlled drugs for homebirths in the community

6.11.1 For planned homebirths, a registered midwife will undertake a risk assessment from 36 weeks, when the potential requirement for opiates will be discussed with the mother.

6.11.2 If the mother wants opiates to be available at the homebirth, then the GP will be contacted to write a prescription in the mother’s name for the drugs required: diamorphine or pethidine.

6.11.3 The mother will take the prescription to a community pharmacy to be supplied with the controlled drugs.

6.11.4 The registered midwife will administer the controlled drugs, if required by the mother, using midwife exemptions under the Medicines Act 1968.

6.11.5 It is the responsibility of the mother to return any unused controlled drugs to the Community Pharmacy for destruction.

6.12 Return of Controlled drugs to pharmacy and destruction

6.12.1 Controlled drugs can only be returned to pharmacy once a pharmacist has signed the ward CDRB indicating medication has been returned.

6.12.2 The pharmacist will book stock for return from the ward CDRB and record this in the pharmacy return transit book. This is required to ensure there is a full audit trail of CDs returned to pharmacy.

6.12.3 The following details should be recorded on the pharmacy transit record when CDs are returned to pharmacy.

- Date
- Name, form, strength and quantity of the drug being returned
- Reason for return
- Confirmation that these were ward stock items
• Name and signature of the registered nurse or midwife

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

• Date
• Reason for return
• Name and signature of the registered nurse or midwife
• Name and signature of the registered pharmacist uplifting the stock
• Quantity removed
• Name, form and strength of drug
• Balance remaining

6.12.5 If a pharmacist is unavailable to go to the ward, a qualified nurse can bring the expired drugs and the register to the pharmacy.

6.12.6 On return to pharmacy the pharmacist will either:
- return the item to pharmacy
  The item will be written into the appropriate register and returned onto the pharmacy computer system, the ward book being marked appropriately
- destroy stock not fit for re-use
  The pharmacist will ensure that the medicines are destroyed and rendered irretrievable using a CD destruction kit. The destruction will be witnessed by a registered colleague. Both will sign the ward returns book

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<tr>
<th>Type of Drug</th>
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<tbody>
<tr>
<td>PODs</td>
<td>In the pharmacy</td>
<td>Pharmacist or registered technician</td>
<td>Pharmacist or registered technician</td>
<td>Ward returns CD destruction record book</td>
</tr>
<tr>
<td>Ward stock unfit for use</td>
<td>In the pharmacy</td>
<td>Pharmacist</td>
<td>Pharmacist or registered technician</td>
<td>Ward returns CD destruction record book</td>
</tr>
<tr>
<td>Pharmacy stock unfit for use</td>
<td>In the pharmacy</td>
<td>Pharmacist</td>
<td>Medical Director</td>
<td>Pharmacy CD destruction book</td>
</tr>
</tbody>
</table>

6.13 Discrepancies and Diversion

6.13.1 The balances in the CDRBs should always tally with the amounts of CDs in the cupboard. If they do not, the discrepancy must be investigated and
ideally resolved. It is important to remember that a discrepancy can indicate misuse.

6.13.2 In the first instance the following should be carefully checked:-

- All requisitions received have been correctly entered into the CDRB
- All CDs administered have been entered into the CDRB. This may require retrieval of medical notes for recently discharged patients
- Re-check contents of all boxes of drugs against the balance on each page
- Items have not been accidentally put into the wrong place in the cupboard
- Arithmetic to ensure the balances have been correctly calculated
- Check contents of waste bins within the parameters of H & S to ensure drugs have not been disposed of in error.

6.13.3 If the error or omission is traced, the registered nurse or midwife or Operating Department Practitioner in charge should make an entry and the corrected balance. This entry should be witnessed by a second registered nurse or midwife, ODPs, pharmacists and doctors could also be the witness. Both persons will sign the CDRB.

If no reason for the discrepancy can be identified then the CD stock loss must be reported. During normal working hours 09.00 – 17.00 the ward pharmacist and Modern Matron should be informed for advice. Out of hours, contact bleep 1200 for the nurse with site responsibility and the on-call pharmacist. The incident must be reported through Datix which will alert the Accountable Officer. Depending on the severity of the discrepancy the Accountable Officer may involve the police. All Datix incidents are subject to regular review to identify areas of concern and where practice can be improved. Trends/concerns will be reported to the Local Intelligence Network.

6.13.4 Where there are concerns about Diversion take advice from personnel if it is deemed necessary to interview staff about the incident.

6.14 Controlled drug stock checks

6.14.1 The stock balance of all CDs 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 minimum frequency for general ward areas is weekly and it is up to the discretion of the Ward/department Head if there is a need to check the drugs more frequently. Where volume of CD usage is higher, e.g. Theatres and CCD, checks must be done once every 24 hours. The check must be undertaken by two qualified nurses (see MM01).
6.14.2 The check should take account of the following points:-

- Remove all items from the cupboard and return them as they are checked off against each page in turn. This method of checking balances in the CDRB against the contents of the cupboard, not the reverse, ensures 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. Periodic volume checks for slower moving lines may be helpful. The balance must be confirmed to be correct on completion of a bottle.

6.14.3 The weekly check must be recorded in the margins of the pages in the controlled drug register. The date the check is undertaken must be recorded and then signed for by the two nurses undertaking it. Any discrepancies must also be recorded, investigated and signed for. Where discrepancies cannot be reconciled the Senior Nurse in Charge must be informed as described in above. Where daily checks are retained these should be recorded in the separate ward controlled drug check book, to be held in the controlled drug cupboard.

6.14.4 The pharmacist will also routinely check the controlled drugs once every 3 months. Any out of date stock or stock no longer required can only be returned to pharmacy by a pharmacist. (As described in 6.12 above). The check should always be done with a member of ward staff present to act as a witness. The method of checking is as described in 6.14.2 above.

6.14.5 The night site managers will also check all controlled drug cupboards every six months. This will monitor that controlled drug cupboards are not being used for the storage of anything other than controlled drugs and that all the checks listed in paragraphs 6.14.1 to 6.14.3 have been undertaken. A summary report will be completed and given to the deputy Director of Nursing & Midwifery.

6.14.6 If there are any material concerns regarding controlled drug stock discrepancies these should be reported via DATIX. In such instances it is recommended that the frequency of CD checks is increased to daily, pending review of the incidents and understanding of reasons for the discrepancies.

6.15 Patient’s Own Controlled Drugs

6.15.1 When the patient has been admitted and the medicines inspected by medical staff, they should ideally be handed to a relative or carer to take home.
6.15.2 If a relative or carer cannot take the Controlled Drugs home then the details of the medicine must be entered into the Patient’s Own Controlled Drug Record Book.

6.15.3 The Controlled Drug’s and this record book must be stored in the patient’s own section of the controlled drug cupboard.

6.15.4 This book MUST be used to record any doses of patient’s own controlled drugs which need to be administered before a supply can be obtained from pharmacy.

6.15.5 When the patient is discharged the drugs should be returned to the patient and the book signed to indicate this.

6.15.6 If the patient is deceased or the drugs are no longer required, a pharmacist must collect them from the ward and sign the book to indicate that this has been done.

6.16 Prescriptions for Controlled Drugs

6.16.1 Prescriptions for Controlled Drugs must be written in ink or computer generated. Although the body of the prescription no longer needs to be in the doctor’s own `handwriting, scripts must be signed and dated by the prescriber and state:

- The name and address of the patient**
- The form (eg. tablets, injection, solution etc).
- The strength of the preparation (where appropriate).
- The dose and frequency of administration.
- The total quantity to be dispensed in both words AND figures.

**Although the Home Office have confirmed that technically addressographs could be used, these would need to be tamper evident and signed across by the prescriber to ensure another label could not be stuck on top of the original. As some Trust prescriptions are in duplicate and these can become separated so each would need to be signed through. This is likely to be impractical to administer and therefore the Trust pharmacy will not accept these scripts with addressograph labels.

6.16.2 Examples of suitable working for controlled drug prescriptions

6.16.2.1 Where a product is supplied in dose units (eg. tablets)

**Pethidine tablets**

50mg bd

Please supply 14 (fourteen) tablets.
6.16.2.2 Where a product is not supplied in dose units (eg. solution)

**Methadone 1mg/ml solution**
40mg daily
**Please supply two hundred and forty mls (240)ml**

6.16.2.3 Where more than one strength is needed to give the required dose eg. for a 50mg dose morphine sulphate in modified release tablets

**Morphine sulphate m/r tablets**
50mg bd
**Please supply as 28 (twenty eight) 30mg tablets and 56 (fifty six) 10mg tablets**

6.16.3 Important Points

- Stating the number of doses supplied or the duration of treatment in words and figures **does not** meet legal requirements.

- Likewise stating the total quantity of the controlled substance itself (eg. 1800mg morphine sulphate) is unacceptable unless it is being supplied in its pure form (eg. morphine sulphate powder) and not a preparation.

- The strength of the medicine does not need to be stated in words and figures.

- Under no circumstances will prescriptions for Controlled Drugs be dispensed in advance of a valid prescription signed and dated by the prescriber.

6.16.4 Prescriptions written for Schedule 2, 3 & 4 CD prescriptions are only valid for 28 days.

6.16.5 Ideally the quantity prescribed should not exceed 30 days. In exceptional circumstances when the prescriber can identify a clinical need which poses no risk to patient safety a longer supply may be deemed appropriate. The pharmacist MUST satisfy themselves that it is clinically appropriate prior to dispensing and the prescriber must record the reasons in the patient’s notes.

6.16.6 Prescribers should not prescribe controlled drugs for themselves or a member of their family.

6.16.7 The Trust will not dispense private prescriptions for controlled drugs, as there is a requirement to:

- use special prescriptions forms not normally held by the Trust
• to send off copies of the prescriptions to the NHS Business Service Authority.

6.16.8 Pharmacists are allowed to make minor technical adjustments after the prescription has been signed by the prescriber, but only where the intent is absolutely clear. This will NOT allow completion of significant elements of the requirements in 6.16.2 and could result in delay in supply where prescriptions are not correctly written.

6.17 Collection of Controlled Drug Prescriptions Dispensed for Patients

6.17.1 In patients

6.17.1.1 All controlled drug prescriptions for schedule 2 and 3 medicines are returned to the ward in a special “controlled drug” bag which has a tamper evident seal and is numbered. Each bag has a corresponding tear off strip which is signed by the person delivering the medicine and left in pharmacy

Schedule 2 and 3 drugs

Must be collected by a member of ward staff who signs the tear off audit strip to accept responsibility for delivery

6.17.2 Out patients

6.17.2.1 Pharmacists must ascertain whether the person collecting the CD prescription is the patient, the patient’s representative or a healthcare professional.

6.17.2.2 If it is a healthcare professional, the pharmacist MUST ask for proof of identity and it is also recommended as good practice to ask this of patients and their representatives too.

6.17.2.3 The person collecting the prescription will be asked to sign the declaration on the back of the prescription and if they are a healthcare professional they must put their address.

6.17.2.4 Should the person collecting the prescription refuse to provide identity or to sign the form, the pharmacist must use their discretion whether or not to supply.

6.17.2.5 Identification is not required if the person collecting the prescription is well known to the pharmacist.

6.18 Patient Controlled Analgesia Devices (More detail available in OP49)

6.18.1 Controlled drugs for administration via a PCA device will usually be prescribed by an Anaesthetist on the prescription specifically designed for
this purpose, stating lock out time and rate of background infusion if appropriate. The initial infusion is normally commenced in Theatre recovery or Critical Care Area.

6.18.2 The prescribed drug may only be administered by patient request via the push button device. Under no circumstances may nursing staff personnel administer the drug by the push button system.

6.18.3 The contents of part used PCA syringes should be rendered irretrievable by emptying into a sharps bin containing a denaturing gel. When the bin is sent for destruction it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration. The amount destroyed must be signed for and witnessed by the two qualified nurses involved in the relevant section of the PCA prescription chart.

6.18.4 In the event of uncontrolled pain or when the patient for mechanical reasons is unable to use the press-button device, drugs may be prescribed separately by the medical staff and administered as a stat bolus via the PCA device by nursing personnel competent to administer intravenous drugs. (See OP49 6.12)

6.19 Substances Obtained Illegally and Brought into Hospital by Patients

6.19.1 Illegally obtained substances brought into hospital by patients upon admission or during in-patient stay is a matter of serious concern and should be treated accordingly.

6.19.2 Although not a frequent occurrence it does occasionally arise and is more likely to be discovered during the admission procedure. The following advice is designed to protect the nurse and all other health staff.

6.19.3 Where a situation of a patient bringing illegal substances into hospital is discovered the most senior nurse midwife on duty for the directorate and the responsible Medical officer must be notified.

6.19.4 The drug substance will almost certainly be the property of the patient and the Trust cannot allow patients to continue possession of illegally obtained substances in hospital.

6.19.5 Substances referred to include cannabis, heroin, cocaine, LSD and barbiturates and are unlikely to be readily identifiable. The responsible nurse and doctor must make a judgement as to the status of suspected substances.

6.19.6 For any material believed to be illegal, the patient must be asked to hand over the substances for destruction.

6.19.7 If this is acceptable to the patient, the material must be securely sealed, labelled as the patient’s property and stored in the ward controlled drug
cupboard. However, as it would be illegal for any member of hospital staff to return this to the patient it must also be clearly labelled ‘Not to be Returned to the Patient’. Should the patient refuse to hand over the material then the patient must be advised that the police would have to be notified (see 6.19.10 below).

6.19.8 The pharmacy must be contacted to arrange for destruction of the material following the procedure for Patient’s Own Controlled Drugs. If the incident occurs when the pharmacy is closed the material may be held on the ward until the pharmacy is next open. The on-call pharmacist can be contacted for advice.

6.19.9 The Medical Officer contacted is responsible for the clinical management of the patient and providing any advice felt necessary to other doctors involved in treating the patient.

6.19.10 Further advice can be sought from the Business unit Associate Director/Service Line Manager or the Chief Pharmacist during normal working hours of the Senior Nurse with Site Responsibility at other times, who can in turn refer to a member of the Central Team if deemed necessary.

6.19.11 It is not necessary to inform the police unless:-

- the patient is unwilling to hand over the material
- the quantity of material is excessive
- the patient is thought to be a drug dealer
- it is not definitively known which patient the material belongs to (e.g. found in a bathroom, on the floor between beds).

Advice as detailed in paragraph 6.19.10 should be sought before the police are involved on any occasion.

6.19.13 Nursing and medical staff are only allowed to handle a Class 1 controlled drug, with the direct intention of handing it over for destruction. It is illegal to POSSESS a Class 1 controlled drug. All transactions should be documented. It is illegal to hand the substance back to the patient as the healthcare professional would then be liable for supply, and a custodial sentence could ensue. Likewise pharmacists are allowed to handle Class 1 controlled drugs when the intention is to destroy them. Documentation should be made in pharmacy of any such substances destroyed.

6.20 Prescribing and supply of methadone to addicts/others thought to be misusing controlled drugs.

6.20.1 If a patient is admitted and is thought to be misusing a controlled drug it should be brought to the attention of the ward pharmacist as soon as possible.
6.20.2 The pharmacist will try to ascertain if the patient is part of a community substance replacement program by contacting the GP and community pharmacy where appropriate.

6.20.3 The doses can be confirmed with the prescriber or community pharmacy before being written on the inpatient drug chart.

6.20.4 It is important for the pharmacist to contact the pharmacy as the patient on the program will have a contract with them which will be breached if they do not attend for their supply. It also ensure the community pharmacist is aware and knows supplies should not be made whilst the patient is in hospital.

6.20.5 If the patient is not part of a community substance replacement program, then the pharmacist will contact the Drugs and Alcohol Team to see if they are aware of the patient and to ask advice on an individual patient basis on prescribing to avoid withdrawal on the ward.

6.20.6 If it is outside of pharmacist working hours it is the responsibility of the doctors and nursing staff to identify the substance being taken and the dose if on a program, before writing the drug chart, if at all possible this should be confirmed with either the prescriber or the pharmacy.

6.20.7 Again outside of hours, if the patient is not part of a community substance replacement program, then the doctors on the ward should contact the Drugs and Alcohol Team for advice before prescribing anything.

6.20.8 The pharmacist will follow up these patients on the next working day.

6.20.9 No substance replacement drugs will be supplied on discharge as either the patient will have a supply/prescription at home or otherwise if not on a program will not have access to a follow up supply, these patients should again be referred to the Drugs and Alcohol Team if in agreement.

6.20.10 If the doctor writing the discharge prescription believes that the patient should be supplied with a substance replacement drug they should contact pharmacy to discuss this. It is essential to ensure that there is no duplication with primary care substance misuse supply programmes.

7. Training

7.1 As MM01

8. Equality and diversity

8.1 An equality analysis has been undertaken for this policy, in accordance with the Equality Act (2010) as described in MM01.
9. **Process(s) for monitoring compliance with the policy**

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10. **Consultation and review of this policy**

Members of the Medicines Governance Group and the Equality and Diversity Co-ordinator.

11. **Implementation of policy (including raising awareness)**

All members of staff will be informed via e-mail and the Medicines Management Newsletter as and when the policy is reviewed and re-implemented.

12. **References**

- Medicine Act 1968
- Misuse of Drugs Act 1971
- Misuse of Drugs Regulations 2001
- Misuse of Drugs Safe Custody Regulations 1973
- Health Act 2006
- Equality Act 2010
- Controlled Drug (Supervision of Management and Use) Regulations 2006
- The Government’s response to the Shipman Inquiry’s Fourth Report
- The Duthie Report – Guidelines for the Safe and Secure Handling of Medicines (March 2005 revision The Safe and Secure Handling of medicines: A Team approach RPSGB
- NMC Standards of Conduct, Performance and Ethics for Nurses and Midwives
- NMC Standards for Medicines Management
- NMC Midwives Rules & Standards
- NMC Standards for proficiency for Nurse and Midwife Prescribers
- The Best Medicine - Health Care Commission 2007
• British National Formulary,, BMJ Group & RPS Publishing, UK
• A Spoonful of Sugar: Medicines Management in NHS Hospitals.
• Audit Commission 2001
• Building a Safer NHS for Patients – improving medication safety (DH 2004)
• NHS Litigation Authority
• An Organisation with a Memory (DoH, 2000)
• Medicines Management: Everybody’s Business
• A guide for service users, carers and health and social care practitioners (DH,2008)
• Medicines Adherence: involving patients in decisions about prescribed medicines and supporting adherence. NICE Clinical Guideline 76 (2009)
• National Prescribing Centre, Mixing of medicines prior to administration in clinical practice – responding to legislative changes, May 2010
• Department of Health, Mixing of medicines prior to administration in clinical practice: medical and non-medical prescribing, May 2010
• Thames Valley Y-Site Intravenous Drugs Compatibility Chart (March 2011), Thames Valley critical care network pharmacists group
• Palliative care Formulary
• The Syringe Driver: Continuous Subcutaneous Infusions in Palliative Care
• National Cancer Peer Review Programme – Chemotherapy Measures
• Updated national guidance on the safe administration of intrathecal chemotherapy
• NCEPOD Systemic Anti-Cancer Therapy: For better, for worse? (2008)
• NCAG Chemotherapy Services in England: Ensuring quality and safety (2009)

13. Associated documents

This policy relates to

Medicines Management Policies MM01 – MM07
Standard operating policies with in pharmacy and on the wards
OP66 Medical Gases
IC09 Waste Policy