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University Hospitals Birmingham NHS
NHS Foundation Trust

Controlled Drugs Procedures

CATEGORY:	Procedure
CLASSIFICATION:	Clinical
PURPOSE:	To describe all aspects of the safe storage and handling of Controlled Drugs under the provisions of the Misuse of Drugs Act 1971, Misuse of Drug Regulations 2001, and subsequent updates; with stringent requirements for supply, storage and administration.
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Distribution: • **Essential Reading for:** • **Information for:**	All Trust staff / departments involved in the handling of controlled drugs. All clinical staff

Contents

1. Introduction

1.1 Purpose

1.1.1 The purpose of this procedure is to describe all aspects of the safe storage and handling of Controlled Drugs (CDs) which are controlled under the provisions of the Misuse of Drugs Act 1971, Misuse of Drug Regulations 2001, and subsequent updates; with stringent requirements for supply, storage and administration.

1.1.2 Within the Trust, the Accountable Officer 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 the management systems and investigation of concerns and incidents related to CDs. The Accountable Officer must ensure a comprehensive audit system is in place.

1.1.3 The Trust Accountable Officer is currently the Chief Pharmacist.

1.1.4 The registered nurse or operating department practitioner (ODP) in charge of a ward or department is responsible for the safe and appropriate management of CDs in that area.

1.2 Definition of Controlled Drugs

1.2.1 The Misuse of Drugs Act 1971, prohibits certain activities in relation to CDs, in particular their manufacture, supply and possession. The penalties applicable to offences involving the different drugs are graded, broadly according to the harmfulness attributable to a drug when it is misused.

1.2.2 The Misuse of Drugs Regulations 2001, define the classes of persons who are authorised to supply and possess CDs while acting in their professional capacities.

1.2.3 CDs are divided into 5 Schedules according to the different levels of control which apply to them:

Schedule 1 - contains preparations such as hallucinogens and cannabis, with limited therapeutic use. Possession and supply are prohibited except in accordance with Home Office authority.

Schedule 2 - contains drugs such as diamorphine and morphine etc. and are subject to the full CD requirements relating to prescriptions, safe custody, the need to keep registers, etc.

Schedule 3 – contains the barbiturates, buprenorphine, midazolam, tramadol, temazepam, pregabalin and gabapentin. The legal requirement is that they are subject to the special prescription

requirements but not to the safe custody requirements (except temazepam, diethylpropion, buprenorphine and flunitrazepam) and the need to keep registers (although there are requirements for the retention of invoices for two years).

Schedule 4 – contains mostly benzodiazepines (see Sativex® section 15.3) and are subject to minimal control. CD prescription requirements do not apply and Schedule 4 CDs are not subject to safe custody requirements. On occasions where deemed appropriate, the Trust may decide to apply additional controls to their use. In such situations the Divisional Associate Director of Nursing will receive notification in writing from the Accountable Officer.

Schedule 5 - contains certain preparations which, because of their strength, are exempt from virtually all CD requirements other than retention of invoices for two years.

1.2.4 For the purpose of this policy the term 'Controlled Drugs' refers to products in Schedules 2 and 3. Outside these schedules this policy also imposes local controls on morphine sulfate oral solution 10mg in 5ml (Oramorph®), strong potassium chloride and sodium chloride products, and some benzodiazepines; though these may be subject to change e.g. if there is a security concern. In these instances staff within the clinical areas concerned will receive confirmation of this decision in writing from the Accountable Officer.

2. Storage

2.1 The registered nurse or operating department practitioner (ODP) in charge of the ward or department for a duty period is responsible for the stock of medicines held in the ward or department and for ensuring that stocks of CDs correspond with the details shown in the register (refer to Medicines Code for the storage of medicines).

2.2 No ward, theatre or department must store CDs unless there is a registered nurse or ODP in Charge responsible for the storage and use of the CDs. The CDs must be stored and records kept according to this procedure.

2.3 Departments where a registered nurse or ODP in charge is not on site when controlled drugs are being handled, must have an agreement from the Trust Accountable Officer and the Chief Nurse.

2.4 Only one set of controlled drugs keys must be held by a ward, each theatre, each imaging room or department, with the exception of wards/departments where Abloy Cliq® is in use where staff will have their own allocated key. Keys must only be available to authorised members of staff. It is NOT necessary for the CD keys to be on a separate key ring from other medicine keys.

2.5 Where Abloy Cliq® is not in use, the registered nurse or ODP in charge is responsible for the CD key. Key-holding may be delegated to other suitably-

trained, healthcare professionals but the legal responsibility rests with the registered nurse or ODP in charge.

2.6 There must be arrangements for keeping the CD keys secure; this is particularly important for areas such as the day surgery unit and wards and departments that are not operational at all times.

2.7 In non Abloy Cliq® areas, if a CD cupboard key cannot be found, urgent efforts must be made to retrieve them (e.g. by contacting relevant staff who have gone off duty) and the following action taken:

- Inform the relevant matron and contact pharmacy
- Complete an incident form and record the reference number
- If the keys are not located during the initial search the Accountable Officer or their deputy must be informed. Depending on circumstance, it may be appropriate to contact the police. This decision will be taken by the Accountable Officer and Trust Security Leads.
- Where relevant, and where pharmacy has not been able to provide a spare key, ward/department managers must contact the estates department to supply a new lock for the CD cupboard.

2.8 Patients' own CDs must not be stored in their bedside lockers (unless special exemption given by the Accountable Officer, or schedule is such that the drugs are exempt from safe custody requirements).

2.9 CD cupboards must:

- be reserved solely for the storage of CDs and other medicines as specified in these procedures only;
- be secured to the wall with rag bolts;
- be constructed of metal (or approved by the CD accountable officer if otherwise)
- be separate from other cupboards; and
- have a lock which is different from any other lock in the hospital.

3. Prescribing

3.1 Prescriptions for CDs must meet the requirements of both the Medicines Act 1968 and the Misuse of Drugs Act 1971.

3.2 Prescribers must adhere to the Trust formulary when prescribing CDs.

3.3 All outpatient and To Take Out (TTO) prescriptions for CDs must comply with the requirements of the Misuse of Drugs Act 1971. Refer to Appendix 1 for full details and examples of how to prescribe CDs for discharge.

3.4 The BNF includes a section about CD prescribing and states that:

Prescriptions for CDs that are subject to prescription requirements[(1)] must be indelible,[(2)] and must be ***signed*** by the prescriber, *be* ***dated****,* and specify the prescriber's ***address***. The prescription must always state:

- the name and address of the patient;
- in the case of a preparation, the form[(3)] and where appropriate the strength[(4)] of the preparation;
- The number (in both words and figures) of dosage units, where appropriate (e.g. if the medicine is a tablet, capsule etc.) to be supplied; in any other case (e.g. liquids), the total quantity (in both words and figures) of the CD to be supplied [(5)];
- the dose;[(6)]

A pharmacist is **not** allowed to dispense a CD unless all the information required by law is given on the prescription. In the case of a prescription for a CD in Schedule 2 or 3, a pharmacist can only amend the prescription at UHB if it specifies the total quantity only in words or in figures and the amendment is to provide the respective missing Total in words or figures provided that such amendments are indelible and clearly attributable to the pharmacist. Failure to comply with the regulations concerning the writing of prescriptions will result in inconvenience to patients and delay in supplying the necessary medicine. A prescription for a CD in Schedules 2, 3, or 4 is valid for 28 days from the date stated thereon[(1)].

(1) All preparations in Schedules 2 and 3.
(2) A machine-written prescription is acceptable*.
(3) The dosage form (e.g. tablets) must be included on a CD prescription irrespective of whether it is implicit in the proprietary name (e.g. *MST Continus*) or whether only one form is available.
(4) When more than one strength of a preparation exists, the strength required must be specified.
(5) The Home Office has advised that quantities of liquid preparations, such as methadone oral solution, should be written in millilitres **and where the total dosage can be expressed as the total number of dosage units to be supplied, the total quantity should be expressed in dosage units.**
(6) The instruction ‘one as directed' constitutes a dose but ‘as directed’ does not.

*TTO prescriptions for CDs in the Trust are generated by the Trust electronic prescribing system. When the TTO prescription is printed there is a requirement for the prescriber to complete the prescription in indelible black ink in accordance with the requirements above (see Appendix 1 for examples).

The printed electronic TTO prescription will list the strengths available of that product to support prescribers in making the appropriate product selection.

Ward stock MUST NOT be used by nurses to issue to patients on discharge prescriptions. A Nurse In Charge can legally give a stock Controlled Drug only for the purpose of administration to a patient in hospital.

3.5 CDs must NOT be authorised as a verbal order unless the request is from an appropriate authorised prescriber and they are present at the time of the request (e.g. preparation of a CD for administration by an anaesthetist). All administrations must be documented.

3.6 A prescriber may not authorise a pharmacist to alter, stop or add a prescription for a CD.

3.7 Supplementary prescribers are permitted to prescribe any CD provided that the CD is included in the clinical management plan.

3.8 Non-medical independent prescribers are able to prescribe any medicine for any medical condition within their competence, except controlled drugs used for treatment of addiction.

3.9 In accordance with British Medical Association (BMA) guidance, prescribers must not prescribe a CD for someone close to them unless:

- No other person with the legal right to prescribe is available to assess the patient's clinical condition and to prescribe without a delay which would put the patient's life or health at risk, or cause the patient unacceptable pain, and

- That treatment is immediately necessary to:

    - save life
    - avoid serious deterioration in the patient's health, or
    - alleviate otherwise uncontrollable pain.

It is expected that this need will occur rarely and only in exceptional circumstances within the Trust. Prescribers must be able to justify their actions by documenting their relationship with the patient and the emergency circumstances in the patient’s notes.

3.10 <u>Prescribing Opioids</u>

3.10.1 When prescribing opioid medicines other than in an acute emergency, prescribers must:

- Confirm previous medical history, any recent opioid does, 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;

- 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, except in palliative care settings); and

- Ensure that persons administering the medicine are familiar with the following characteristics of the medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

3.11 Prescribing Methadone for patients with substance use disorders

3.12 Methadone may be prescribed and administered to patients established on opioid substitution therapy (as methadone oral solution 1mg/ml), as a continuation of their usual prescription whilst in the Emergency Department or on a ward as an inpatient. This should only occur after corroboration of the dose from a medication history.

3.13 Methadone should not be prescribed for the patient on discharge from the hospital as they should revert to their normal supply arrangements after discharge.

3.14 Only in exceptional circumstance should a TTO supply be considered and then only when unavailability of the normal supply mechanism has been confirmed. In such circumstances just one day's supply would normally suffice but with an absolute maximum of three days supply. Supply should only be made after discussion with the patient's usual prescriber (usually the GP or community drug team), usual dispensing pharmacy or drug worker.

3.15 Methadone may also be supplied following local agreed policies that have been approved by Pharmacy and the Accountable Officer.

4. Administration

4.1 Healthcare professionals who have been trained and deemed competent in the administration of medicines in the Trust may administer CDs against prescription. Training may be either in the administration of oral or intravenous medication or both respective to the route of administration of the controlled drug/s administered.

4.2 Controlled drugs may also be administered against a Trust approved Patient Group Direction (PGD) for certain indications. Please refer to the Trust PGD procedure.

4.3 The preparation, administration and destruction of all Schedule 2 CDs and preparation and administration of strong potassium chloride must be subject to a second independent check.

4.4 Medical practitioners or physicians' assistants may administer controlled drugs after preparation or supply by a healthcare professional who has been trained and deemed competent in the administration of medicines in the Trust. In such circumstances, the healthcare professional may prepare the CD and supply to the medical practitioner or physician's assistant, for administration who will second check the medicine.

4.5 In the case of non-parenteral CDs, the healthcare professional administering the CD must be competent in the administration of medicines and the second practitioner must be, a registered nurse, ODP, pharmacist, physician's

assistant or medical practitioner, or role otherwise approved within the Trust Medicines Code for administration of medicines. .

4.6 Midwives have specific provisions in law to possess and administer a defined list of CDs in the course of their professional practice, as outlined in NMC guidance.

4.7 Student nurses and student midwives must not administer CDs under any circumstances. They may observe best practice as a third party.

4.8 If the CD is an intravenous medication then the professional administering the CD must be competent in the administration of IV medication and the other must be a registered practitioner competent in the administration of medicines.

4.9 Both healthcare professionals involved should be present during the whole of the administration procedure and must both witness and document:

4.9.1 The preparation of the CD (on the electronic prescribing system or paper prescription chart and in the CD record book)

4.9.2 The CD being administered (on the electronic prescribing system or paper prescription chart and in the CD record book)

4.9.3 The destruction of any surplus drug. (in the CD record book)

4.10 In the theatre environment it may not be possible for the same two healthcare professionals to be present during the whole of the administration procedure (e.g. incremental doses during a procedure, or in recovery, or patient controlled analgesia (PCAs)). In such cases there must be a separate second check documented for:

4.10.1 The supply of the CD to the individual administering the product (e.g. the anaesthetist)

4.10.2 The destruction or transfer of any surplus

4.11 Entries in a CD record book must not be cancelled or altered. An incorrect entry must be bracketed and amendments made as a footnote, or neatly recorded beside the original entry and signed and dated by the two healthcare professionals involved. Correcting fluid must not be used to amend incorrect entries (see 11.7, Correcting Errors).

4.12 Where more than one patient is due to receive CDs, the medicines administration to each patient must be undertaken as a completely separate process.

4.13 The basic principles of drug administration described in the Medicines Code must be followed and in addition:

4.13.1 Prior to administration:

- the electronic, paper prescription or guidelines for preparation and the controlled drug record book must be taken to the CD cupboard.

- the stock balance of the medicine to be administered must be checked against the balance in the record book by both healthcare professionals.

- the required medicine must be removed from the cupboard, checked and the new stock balance recorded in the record book immediately after removal from the cupboard.

- Doses of liquid medicines must be measured using a purple enteral syringe and must not be decanted into paper tots. Where there is a need to decant into a tot (e.g. patient requests), plastic tots must be used.

4.13.2 Administration against prescription or patient group direction:

Both healthcare professionals must:

- confirm the patient identity – check patient details (patient's name and hospital number and if possible state their date of birth: refer to Trust policy for patient identification CD ref: 382) on the wristband and verbally (if possible)

- independently confirm the medicine identity against the prescription

- be present at the administration to the patient.

4.13.3 Administration by an independent prescriber or of incremental doses

Independent prescribers (e.g. anaesthetists) or individuals administering incremental doses must:

- confirm the patient identity – check patient details (patient's name and hospital number and if possible state their date of birth: refer to Trust policy for patient identification CD ref: 382) on the wristband and verbally (if possible)

- independently confirm the medicine identity

- where possible, the administration should be witnessed and second check performed and documented**.** However a second check is not mandatory.

If the healthcare professional is not familiar with the administration of the drug, the relevant IV monograph must be referred to prior to administration of intravenous CDs.

4.13.4 After administration:

It is the responsibility of the healthcare professionals who have administered the medicine to ensure that the details of the administration are completed in the record book. Full signatures must be used - initials are not sufficient.

4.14 Any discrepancy must be notified immediately as detailed in section 16 of this document.

5. Disposal of Wasted Controlled Drugs in Wards and Departments

5.1 CDs should, as far as is practicable, be returned to pharmacy for safe denaturing and disposal (see 5.4.1).

5.2 **CDs which have expired, are unwanted or are "patients own" and no longer required MUST be returned to Pharmacy.**

5.3 CDs (Schedules 2, 3 and 4) must be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used.

5.4 Disposal **of Wasted CDs**

5.4.1 It is only appropriate to destroy the following in wards or departments:

- Damaged or not fit for use tablets, capsules and vials/ampoules
- the remaining volume of part-used
  - vials
  - ampoules
  - syringes
  - infusion bags
  - PCA Cassettes

5.4.2 Examples of situations where CDs may need to be wasted on wards and departments include:

- the surplus when the dose required is smaller than the total quantity in an ampoule or vial
- when a dose is drawn up but not used
- discontinued infusions

- discontinued patient controlled analgesia (PCA) syringes

5.4.3 The remaining solution or damaged tablets/capsules must be rendered irretrievable by emptying into a blue sharps bin which is already in use or by adding soapy water to the bin (refer to section 7 for details of methods of destruction). The emptied vial, ampoule, syringe or infusion bag must then also be placed in the blue sharps bin. Contents of infusion bags or syringes must NOT be poured down the sink. When the blue sharps bin is sent for destruction, it must be labelled *"contains mixed pharmaceutical waste and sharps – for incineration"*.

5.4.4 Where large quantities of CDs are used and where the volume of part-used vials, ampoules, syringes and infusion bags is high, denaturing kits for use on wards or departments must be requested. Pharmacy must be contacted and a risk assessment must be carried out before a decision is made to supply denaturing kits.

5.5 Documentation of Wastage

5.5.1 Destruction of CDs must be documented on the electronic prescribing system, paper prescription chart or in the appropriate section of the CD record book, against the respective patient's entry at the time of administration (**e.g. "5mg administered, 5mg wasted"**). Discontinued infusions where a quantity still remains in the syringe must be recorded at the back of the CD record book. All entries of wasted CDs in a CD book must include the patient's name, date, the amount administered and the amount wasted. It must be witnessed by a second registered practitioner such as a registered nurse, pharmacist, doctor or ODP. Both persons must sign the CD record book.

5.5.2 Where a risk assessment has been undertaken by pharmacy, a separate book may be used to record destruction e.g. in areas where large amounts of PCAs or syringe drivers are wasted.

NB. Where morphine has been administered to a patient and the pump or bag has delivered the entire contents of the syringe or bag to the patient, any tiny amounts of overage remaining in the bag or syringe need not be documented as wasted but require safe disposal in the blue sharps bin.

5.6 Disposal of Broken/Defective CDs

5.6.1 Where there is accidental breakage of ampoules, other fragile containers and damage to tablets and capsules (e.g. dropped on the floor), the CD involved must be safely disposed of in the clinical area in the presence of two registered practitioners. If a second registered practitioner is not available in the clinical area at the time, a matron, the Clinical Site Manager or a registered nurse summoned from another clinical area must witness the breakage/damage and subsequent destruction.

5.6.2 The ampoule(s)/tablet/capsule needs to be accounted for, so must be signed out of the respective CD record book by the two registered practitioners, stating the reason as accidental damage.

5.6.3 In all cases of broken ampoules and damaged tablets/capsules, the registered nurse or ODP in Charge of the Ward/ Department must be informed and an incident form must be completed and referenced in the CD record book.

5.6.4 If a CD is found to be defective (e.g. ampoules already broken or cracked, the contents appear cloudy or appear to contain contamination), the item(s) must be clearly marked “do not use,” and retained in the CD cupboard. The Pharmacy Department or ward pharmacist must be contacted as soon as possible during normal working hours . A pharmacist must assess the problem, removing the defective items if necessary and making appropriate entries in the CD record book. The pharmacist must return the stock to the Pharmacy Department or destroy the item(s) on the ward. If necessary, they will also report the problem to the manufacturers and check any remaining pharmacy stocks.

6. Controlled Drug Returns to Pharmacy

6.1 CDs which are no longer required or have expired must be returned to pharmacy. Ward/ departmental stock close to expiry date should remain on the ward/ department. It should not be returned in order to expire in the Pharmacy Department.

6.2 CDs belonging to a patient may be returned to pharmacy but the patient or their carer must first agree to destruction.

6.3 Pharmacy should be notified, in order that they may arrange for the pharmacist, registered pharmacy technician or a pre-registration pharmacist (Pharmacy staff) to return the CDs to Pharmacy.

6.4 An entry must be made on the relevant page of the CD record book showing:

- “Returned to Pharmacy for Destruction”
- Date and time
- Reason for return
- Description of item
- Quantity removed
- Balance remaining

- Name and signature of the registered nurse or ODP removing the CD from the CD cupboard

- Name and signature of the pharmacy staff witnessing removal from the cupboard.

6.5 Pharmacy staff must check the quantity of the CD to be returned, the remaining balance and countersign the record book.

6.6 Pharmacy staff must return directly to the Pharmacy, transferring the CDs to the pharmacy in a safe and secure manner.

6.7 On receipt within the Pharmacy, the member of pharmacy staff must record the drugs in the Pharmacy department CD registers or destruction registers as appropriate, with a second signature from another member of pharmacy staff in accordance with Pharmacy department standard operating procedures.

6.8 Morphine sulfate 10mg/5ml (Oramorph®) may be destroyed by a registered pharmacist or pharmacy technician without the presence of an authorised person. However it is good practice to have another member of staff as a witness.

7. METHODS OF DESTRUCTION FOR DIFFERENT FORMS OF CONTROLLED DRUGS IN PHARMACY AND WASTED/ BROKEN/ DEFECTIVE CDs ON WARD

Wear gloves and dispose of all controlled drugs in a blue sharps bin with blue lid containing cat litter* or a destruction of old pharmaceutical (DOOP) bin.

CD form	Confirm quantity against register/record book entry	Method of adding to Sharps or DOOP bin
Ampoules containing liquid	Count the number of ampoules	Break open ampoule. Withdraw contents and add to cat litter or CD Destruction Jar (Doop Jar, "DOOP"). Dispose of ampoule in blue sharps bin.
Ampoules containing powder	Count the number of ampoules	Break open ampoules and reconstitute with water. Withdraw contents and add to cat litter or DOOP. Dispose of ampoule in blue sharps bin.
Capsule	Count the number of capsules whilst in the blister. Remove from blister and count again.	Open capsule and add straight into cat litter or DOOP.
Cartridge from epidural or intrathecal pump	Confirm the volume that is in the pump with the register.	Draw the volume out of the pump using a syringe and add straight to cat litter or DOOP
Liquids	Measure volume in a measuring cylinder or syringe.	Pour straight into cat litter or DOOP
Oral Lozenges	Confirm the number of lozenges	Remove from packaging and dissolve in boiling water. Add resultant liquid to cat litter or DOOP
Powder sachets	Count the number of sachets.	Open sachet and add straight to cat litter or DOOP.
Syringes from syringe driver	Confirm the volume that is in the syringe with the register (or PICs on wards).	Add straight to cat litter or DOOP
Spray	Remove top and withdraw volume.	Add straight into cat litter or DOOP.
Tablet	Count the number of tablets whilst in the blister. Remove from blister and count again.	Crush before adding to cat litter or DOOP
Transdermal patch	Count the number of patches	Peel backing off patch and fold the patch over on itself before adding to blue sharps bin or DOOP bin.
Vial containing liquid	Count the number of vials	Use needle and syringe to withdraw contents and add to cat litter or DOOP. Dispose of vial in blue sharps bin.
Vial containing powder	Count the number of vials	Reconstitute with water. Use needle and syringe to withdraw contents and add to cat litter or DOOP. Dispose of vial in blue sharps bin.

***Where cat litter is not available preparations must be rendered irretrievable by emptying into a blue sharps bin which is already in use or by adding soapy water to the bin.**

8. Summary of Disposal of Controlled Drugs

Type of drug	Where destruction should take place	Person who should destroy drug	Person who must witness destruction	Register entry	Notes
Patient's own – unsuitable for use	Pharmacy	Pharmacist or Registered Technician	Pharmacist or Registered Technician	Clinical area's CD record book and Pharmacy CD destruction register	The patient must consent to the destruction.
Patient's own – unsuitable for use (handed in directly to Pharmacy by patient	Pharmacy at which they have been handed in	Pharmacist or Registered Technician	Pharmacist or Registered Technician	Pharmacy CD destruction register	The patient must consent to the destruction.
Patient's own – patient deceased **(must only be destroyed following authorisation from an ADN, since may be required for examination by the police or coroner)**	Pharmacy	Pharmacist or Registered Technician	Pharmacist or Registered Technician	Clinical area's CD Record book and Pharmacy CD Destruction Register	Patient's own CDs for deceased patients can only be destroyed if consent is received from the patient's estate / relatives
Clinical area's stock – unfit for use	Pharmacy	Pharmacist or Registered Technician	Authorised Witness	Clinical area's CD record book and Pharmacy CD Destruction Register	
Wastage from part doses drawn up on ward for individual patient, e.g. when giving 5mg dose from 10mg ampoule	In the respective clinical area	Registered Nurse, doctor or ODP	Registered nurse, ODP, doctor, pharmacist	Clinical area's CD Record book	Ward record book must show name of patient and details of dose/wastage e.g. 5mg given/5mg wasted.
Dose drawn up in clinical area for individual patient but not given	In the respective clinical area	Registered Nurse or ODP	Registered nurse, ODP, doctor or pharmacist	Clinical Area's CD Record book	Clinical area's record book must show name of patient and reason for non-administration.
Wastage from discontinued parenteral dose in infusion bag or syringe	In the Pharmacy, or in the clinical area	Registered nurse or ODP	Registered nurse, ODP, doctor, pharmacist or registered technician	Pharmacy CD destruction Register and/or clinical area's CD record book	Name of patient, details of amount administered and amount discarded must be recorded at the back of the clinical area's CD record book or on PICS
Pharmacy stock unfit for use (schedule 1 and 2 only)	Pharmacy	Pharmacist or Registered Technician	Authorised Witness	Pharmacy CD Destruction Register	

9. Handling of Substances of Misuse

9.1 On occasion healthcare professionals will be asked to deal with suspected illegal substances that a patient has in their possession. Acceptance of these items must only be for the purpose of destruction. It should be noted that it is not possible to positively identify these substances as Schedule 1 and therefore this guidance reflects that. The patient's confidentiality should normally be maintained. However, if the quantity is so large that it could not be purely for personal use, the greater good of the public may demand that the source be identified to the police. Such a decision should be taken by the consultant involved in the patient's care in discussion with the Trust Accountable Officer and the Trust's legal advisor.

9.2 Under no circumstances should these be returned to a patient as this may represent the illegal supply of an illegal substance and constitute a criminal offence.

9.3 Please refer to the Handling of Illegal Substances on Trust Premises procedure (Controlled Document No. 965)

10. Controlled Drug Stationery

10.1 CD stationery includes the ward/department order book ,ward record book and patient's own controlled drugs record book (or destruction book where a Pharmacy risk assessment has approved its use). On wards and departments the CD stationery must be kept in a locked cupboard or drawer when not in use. In theatres during the list, the CD stationery need not be locked away.

10.2 Stocks of CD stationery held in pharmacy must be kept in a secure area..

10.3 Loss or theft of any CD stationery must be reported as soon as possible to the Accountable Officer on the next working day by informing a pharmacist. Any suspected misuse of CD order or record books (e.g. unauthorised amendments or ripped pages) should also be reported to the Accountable Officer through the pharmacy team immediately.

10.4 A record must be kept in Pharmacy, of the supply of CD stationery; this must include the following information:

- Date
- Ward/department supplied to
- Type of stationery
- Serial number

- Quantity
- Name of individual ordering CD order or record book

10.5 Only one CD order book per ward or department must be in use at any one time.

10.6 Completed ward order books and CD record books must be retained by the ward/department for a minimum of 2 years after the last entry. Refer to section 11.6 for more detail about retention of CD record books.

11. Documentation (See Appendix 2 for Summary).

11.1 Entries in the ward CD record book must be:

- clear and legible
- made in strict chronological order
- made at the time of the transaction (receipt, administration, wastage or removal by a pharmacist).
- made in black ink. Exception can be made for receipts of CD stock from the Pharmacy Department which may be made in red ink.

11.2 Index Page

11.2.1 Each ward/ department CD record book must have a dedicated index page.

11.2.2 Each preparation recorded in the ward CD record book must be entered on the index page.

11.2.3 Page numbers for each preparation must be kept up to date on the index page.

11.2.4 When starting a new ward CD record book it is useful to try to anticipate how many pages will be needed for each preparation by looking at the previous ward CD record book and ensuring that sufficient pages are left for frequently used items. This enables recording to take place on sequential pages rather than having to find blank pages elsewhere in the record book.

11.2.5 It is good practice to draw 15-20 vertical lines on the index page after the name of the drug, producing columns in which to

record the corresponding page numbers, making the audit trail easier to follow.

11.2.6 It is good practice to separate different strengths of the same product in the record book. This should prompt segregation of different strengths of the same CD in the CD cupboard.

11.3 **Page Headings**

11.3.1 Each different drug preparation and each strength of the preparation must have its own dedicated page.

11.3.2 The approved drug name, form and strength of the preparation must be written at the top of each page of the ward CD record book. Where similar products exist it is important to distinguish between them e.g. modified release and standard formulations. The addition of the brand name in brackets will aid this distinction.

Example:

Name	Form/Brand	Strength
Morphine sulfate	Injection	10mg
Morphine sulfate	Oral solution	10mg/5ml
Morphine sulfate	MR capsules (Zomorph®)	10mg
Oxycodone	Capsules (Oxynorm®)	10mg
Oxycodone	MR tablets (Oxycontin®)	10mg

11.4 Starting a New Page for a Drug in the Ward CDs Record Book

11.4.1 A new page must be started only when the current page has no further room for new entries. The bottom line of the ward CD record book must not be used to record administration or stock checks. The bottom line must be reserved for documenting the trail for balance transfers from page to page and also when a new ward CD record book is started.

11.4.2 Where books or pages are damaged or spoiled any remaining blank spaces on a page must be crossed through with a single diagonal line, therefore preventing any further entries, and the transfer to a new page or a new book may be witnessed, dated and documented as in 11.4.3.

11.4.3 When a new page is started, cross-reference must be made on both the old and the new pages.

For example:

Bottom of completed page (p.14): "balance transferred to page 20"

Top of new page (p.20) "balance transferred from page 14"

11.4.4 When transferring the balance to another page or book, this must be witnessed by a second registered nurse or ODP with both individuals signing the record book and the entry dated.

11.4.5 When the balance for a preparation reads 'zero', this is not an indication to start a new page the next time the preparation is held on the ward.

11.4.6 It may be useful to start a new page for new bottles (or a consignment) of oral liquid preparations. This prevents small overage volumes accumulating which can cause measuring discrepancies. Refer to the ward Pharmacist for advice if balances appear to require adjustment.

11.4.7 The index page must be updated to reflect the new page number.

11.5 Starting a New Ward/Department Controlled Drug Record Book

11.5.1 A new CD record book must be started only when no further blank pages are left in the current CD record book. All controlled drug balances must then be transferred from the old CD record book to the new one. This must be carried out by two registered nurses or ODPs and documented in both the new and old record books. In departments where there is no second registered nurse or ODP, another registered healthcare professional (e.g. pharmacist or medical practitioner) may check and countersign this process.

11.5.2 date of the last entry must be written on the front cover of the old CD record book, and the date of starting must be written on the front cover of the new one. All CD record books must be numbered sequentially.

11.5.3 Appropriate cross-references must be made in both old and new CD record books for each balance transferred

For example:

In Book 3 (just completed) "balance transferred to book 4, page 10"

In Book 4 (new book) "balance transferred from Book 3, page 54"

Any remaining blank space on pages in the old CD record book must be crossed through with a single diagonal line, therefore preventing any further entries.

11.6 Retention of Ward/Department CD Record Books which are no longer in use

11.6.1 Old CD record books must be locked in a secure place at ward/ department level. It is a legal requirement that CD record books are kept for 2 years from the date of last entry and can only then be destroyed as confidential waste.

11.6.2 Where the record book contains details of CD destruction/wastage, the book must be retained for 7 years after the last date of the entry. (This includes all individual doses of CDs, which are prepared, but not administered such as part ampoules and unused Patient Controlled Analgesia or infusions.)

11.6.3 If a ward/ department has been decommissioned, the CD record book must be sealed with sticky tape and signed, dated and returned to Pharmacy for archiving.

11.7 Correcting Mistakes

11.7.1 Entries must be clear, unambiguous, and must contain no crossings out. Errors must NEVER be altered, scribbled over or obliterated. **Do not cross out or attempt to delete anything in the CD record book; not even with a single line.**

11.7.2 Any errors must be bracketed and the correct entry made in an adjacent space or next line. A brief explanation (e.g. “entered in error”) must be made in the margin or at the bottom of the page and then signed and dated.

11.7.3 Liquid paper correction fluid (e.g.Tippex™) must NEVER be used.

11.7.4 Pages or part-pages must NEVER be torn out of the CD record book.

11.8 Controlled Drug Stock Checks

11.8.1 The controlled drug stock checking procedure detailed below must be followed ONCE as a minimum on each day of the week. More frequent checking is at the discretion of the ward/department manager.

11.8.2 Within the Operating Theatres CDs must be checked at the beginning and end of each shift (i.e. at the time of a change of the person in charge), by two registered nurses/ODPs or at least once a day whichever is the more frequent.

11.8.3 The check must take account of the following points:

- Checking of CDs involves checking the balance in the register 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.

11.8.4 Controlled drug stock checks must be recorded, with both practitioners identified, in the back of the CD record book or a separate bound record book specifically for the purpose.

11.8.5 Where a department is closed and locked for periods of up to 48 hours (72 hours in the case of Bank Holidays), CD stock checks are not required for that period. Stock checks, however, must occur before closing the department and when re-opening.

11.8.6 If a discrepancy is found it must be investigated without delay according to section 16.

12. Ordering Controlled Drugs

12.1 The responsibility for the ordering, receipt and safe storage of controlled drugs is that of the Ward or Department Manager.

12.2 Clinical areas should only order controlled drugs from Monday to Friday inclusive.

12.3 Where a CD is required on a Saturday or Sunday due to a clinical emergency, the Pharmacy department should be contacted prior to sending the requisition.

12.4 The CD duplicate order book must be used when ordering CDs. Each item required must be ordered on a separate page using consecutive order numbers in the CD order book.

12.5 All requisitions for CDs must comply with legislation and contain:

- Ward or department name and hospital

- Name, form, strength, ampoule size if more than one available of CD

- Total quantity to be supplied

- Signature and printed name of the registered nurse or ODP ordering the item
- Signature of the person issuing the item from pharmacy
- Signature of the person in receipt of goods for transit
- Signature of the person in receipt of goods on ward or department
- Date

12.6 The name of the person ordering the CDs must be clearly printed next to their signature.

12.7 The signature of the registered nurse or ODP ordering the CDs must appear on the approved signatory list at the front of the ward/department order book. Agency or locum staff are not authorised to order CDs.

12.8 A request for a Controlled drug that is not a stock item for a ward/clinical area will require a pharmacist counter signature

13. Transportation and Delivery of Controlled Drugs

13.1 CDs must be transported in sealed, tamper evident, transit bags; they must not be transported via the pneumatic tube system or placed in secure collection areas.

13.2 Controlled Drugs for Ward/Department stock

13.2.1 The registered nurse or ODP in charge can delegate the collection from Pharmacy of Controlled drugs required as **stock** to a member of the ward/department team or a porter, providing that the individual is aware of the extra responsibility involved.

13.2.2 When collecting the medicines the individual will need to prove their identity by displaying their Trust identification badge or an alternative Trust approved form of identification e.g. student nurses with an identity badge from Birmingham City University.

13.2.3 A request for a Controlled drug that is not a stock item will require a pharmacist counter signature

13.3 Discharge Medicines containing Controlled Drugs

13.3.1 The law requires a pharmacist to ascertain whether, a person collecting Controlled Drugs which form part of the discharge medication for a patient, is the patient, patient's representative

or a member of healthcare staff acting in their professional capacity on behalf of the patient.

13.3.2 Where the person collecting the controlled drug on behalf of the patient is a member of the Trust's healthcare staff (including porters) the pharmacist must obtain the healthcare professional's name and see their Trust identification badge or an alternative Trust approved form of identification.

13.3.3 Where the person collecting the controlled drug is the patient or the patient's representative the member of pharmacy staff should ask for proof of identity, for example, ask to see photo-ID or a credit or debit card. If the patient or representative has no proof of ID, the member of staff may ask the Responsible Pharmacist for advice.

13.3.4 Where the person collecting is a healthcare professional who is not employed by the Trust the member of pharmacy staff must obtain the person's name and address and must ask for proof of identity.

13.3.5 The Responsible Pharmacist may still supply the CD even if ID is not provided.

13.4 <u>Staff Responsibilities when transferring CD's</u>

13.4.1 Pharmacy Staff are responsible for ensuring that:

- CD transit bags are only issued to authorised personnel with a valid ID badge
- A record is made for each CD transit bag issued as per Pharmacy standard operating procedures
- A portering sheet is completed for each CD transit bag issued
- All CD transit bags issued are sealed with a numbered tamper-proof seal
- All portering sheets are returned to the pharmacy department and are filed with its corresponding pharmacy copy
- Any CD portering sheets not returned to pharmacy within 24 hours (or the next working day if weekend/bank holiday) are investigated.

13.4.2 Delivery personnel (porters/nursing staff/couriers etc.) are responsible for:

- Checking that the number on the tamper-proof seal matches the entry on the CD portering sheet before signing

- The safe custody of the CD transit bag until it is delivered to, and the CD portering sheet is signed by, a **registered nurse or ODP** on the appropriate ward/department

- Ensuring the CD portering sheet is returned to pharmacy within 24 hours (or the next working day if weekend/bank holiday).

13.4.3 Registered practitioners accepting delivery of CD transit bag on the ward/department are responsible for:

- Checking the number on the tamper-proof seal matches that written on the CD portering sheet when accepting delivery of a CD transit bag

- Signing the CD portering sheet to accept delivery if all details on the CD portering sheet are correct

- Opening the CD transit bag and checking the medicines against the requisition book pink copy (copies). If correct, the practitioner must sign the 'Received' section on the appropriate requisition pink copy
- Ensuring the CD portering sheet is returned to pharmacy within 24 hours (or the next working day if weekend/bank holiday) if the delivery person is unable to do this

- Entering the received items in the CD record book and securing the CDs with a second registered practitioner.

13.4.4 The delivery person must only hand over the CD transit bag to a registered **nurse or ODP**. Only a registered nurse or ODP may sign the CD portering sheet.

13.4.5 When signing the CD portering sheet for the delivery person – the registered practitioner is signing to confirm acceptance of the CD transit bag and that the number on the tamper-proof seal matches the entry on the CD portering sheet.

13.4.6 Once the CD portering sheet has been signed by a registered nurse or ODP the delivery person is free to go as the contents of the CD transit bag are not the responsibility of the delivery person.

13.4.7 If a registered practitioner finds a discrepancy when checking the received medicines against the appropriate requisition pink copy (copies) he/she must contact the Pharmacy Dispensary Manager

as soon as possible in working hours and the on-call pharmacist out-of-hours.

NB. Boxes of controlled drugs sealed by the manufacturer with tamper evident seals need not be opened on receipt to confirm the contents. Sealed boxes need only be opened at the point of use. In the case of any discrepancy, the pharmacy must be noted at this point.

14. Receipt of Controlled Drugs

14.1 Controlled drugs must be receipted in the duplicate order book by a registered nurse/ODP in the clinical area.

14.2 It is the responsibility of the registered nurse or ODP accepting delivery in the clinical area to check that the name, form and quantity of medicine supplied against the order and if a discrepancy exists, immediately bring this to the attention of Pharmacy department. It is not necessary to open packs with intact tamper-evident seals to count individual ampoules on receipt.

14.3 The registered nurse/ODP is responsible for:

- signing the “received by” section on pink copy of the requisition in the order book to confirm receipt of the medicines
- making a record of the new stock received in the CD record book in the clinical area
- ensuring that the record book balance is correctly amended and witnessed by another registered nurse/ODP or where this is not possible by another registered practitioner e.g. pharmacist, doctor
- locking away the medicines in the CD cupboard immediately.

14.4 The entry made in the CD record book should show the following information:

- Date of receipt
- Requisition number
- Words “Received from Pharmacy”
- Quantity received
- New balance

- Signatures of the healthcare professional making the entry and the witness.

14.5 CD order books must be retained in the clinical area for 2 years from the date of the last receipt. They must then be destroyed as confidential waste.

14.6 The white copy of the CD requisition must be retained in Pharmacy for 2 years.

15. Patients' Own Controlled Drugs Brought into Hospital

15.1 <u>On admission:</u>

15.1.1 The patient's family should be encouraged to take patient's own CDs (CDs brought into hospital by a patient) home if they are safe and appropriate for use. Temporary storage of patient's own CDs may be necessary whilst awaiting collection; these should be clearly separated from all ward stock CDs.

15.1.2 Patient's own CDs that are subject to Safe Custody requirements (see section 24.1) must be stored in the ward CD cupboard and not in the patient's bedside medication lockers. Wherever possible ward stock should be used for the administration of controlled drug doses.

15.1.3 A record must be made of all patient's own CDs brought with them into the Trust (including syringe drivers in situ prior to admission). The entry must be witnessed by a second registered practitioner.

15.1.4 A separate CD record book should be used to record the receipt, administration and return or transfer of patient's own CDs.

15.1.5 When patient's own CDs have been entered into the register, and require destruction (for example if they are unsafe or inappropriate for use), the pharmacist for the ward must be informed as soon as practically possible. The pharmacist will endeavour to return stock to pharmacy for destruction within 48 hours if possible (see section 6 for returns to Pharmacy).

15.1.6 Wherever possible, consent must be obtained from the patient and documented in the patient's notes prior to destruction of patient's own controlled drugs. This is mandatory for conscious patients who have capacity.

15.1.7 Under no circumstances should Patient's own Drugs be used to treat another patient or be added to the ward stock.

15.2 <u>On Discharge</u>

15.2.1 Patients' own medicines should be returned to patients, where this is not appropriate, the ward pharmacist must be contacted to arrange collection of CDs requiring destruction at the earliest opportunity.

15.2.2 These drugs must be signed out of the CD record book in the clinical area by a registered nurse/ODP and a pharmacist.

15.2.3 Only part ampoules or partially used syringes containing CDs may be destroyed on wards, all other CDs must be returned to pharmacy for destruction (see section 5 for destruction of wasted CDs).

15.3 Patient's Own Sativex®

15.3.1 Sativex® is a Schedule 4 controlled drug which is a cannabinoid oromucosal mouth spray for use by patients with multiple sclerosis to alleviate symptoms such as neuropathic pain, spasticity or overactive bladder.

15.3.2 Sativex® is not available for issue from Pharmacy in the Trust, however, patients may bring Sativex® into the Trust as patients' own CDs from home.

15.3.3 Sativex® requires storage in the fridge and as such the Home Office have issued specific regulatory requirements to allow appropriate, safe and secure storage.

15.3.4 Sativex®:

- does not require storage in a CD cupboard
- requirements specific to CD prescriptions do not apply
- destruction of Sativex® should be made in the usual way as for all patients own CDs as detailed in section 5. Records must be kept for a minimum of 2 years
- may be prescribed as a "when required" medicine and should be given to the patient by the registered nurse for use when requested. The patient therefore acts as a witness to the administration and as such a second practitioner is not required as a witness
- Documentation of usage should be in a CD record book and as such entries must be made in the usual manner with the exception of the requirement for a second signature.

- Patients own Cannabis based products for medicinal use and cannabinoid oils

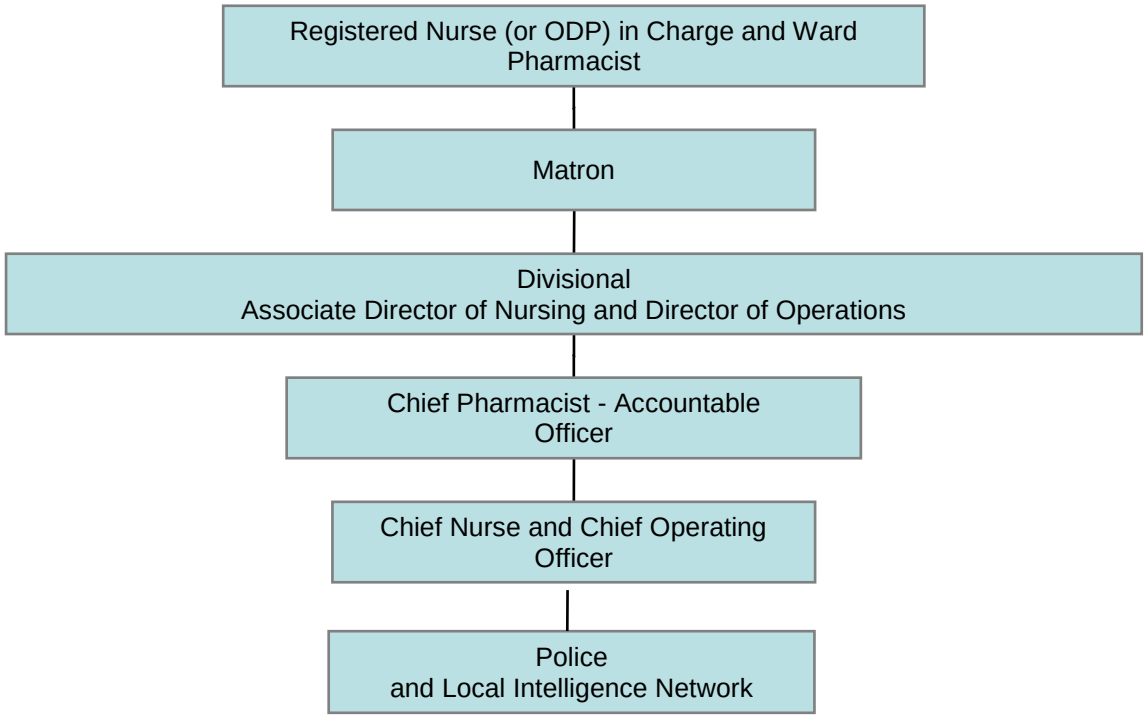
    - Please refer to the Trust procedure for the management of Cannabis-based products for medicinal use.

16. Dealing with Controlled Drug Discrepancies

16.1 In the event of a discrepancy between the stock balance and register for Controlled Drugs, the Registered Nurse or ODP in Charge must immediately investigate the loss.

16.2 The possibility of a missing or incorrect entry or arithmetical error must be investigated first and corrected if found. When correcting the error in the record book no crossing out or Tippex® may be used on previous entries. A full explanation must be recorded in the CD record book. Any recording must be signed and dated by the Registered Nurse or ODP in charge and a second registered nurse or ODP.

16.3 If unresolved then the following escalation process must be followed **within 24 hours:**



16.4 In the case of theft, the escalation process in 16.3 must occur immediately.

16.5 Out of hours the Clinical Site Manager must be notified who will contact the on-call pharmacist. The Clinical Site Manager and on-call pharmacist will determine if the incident warrants contacting the ADN and Accountable Officer out of hours.

16.6 In the event the Accountable Officer and ADN are NOT notified out of hours in section 16.5, they must be informed by the on-call pharmacist and Clinical Site Manger respectively, the next working day.

16.7 A Trust incident form must be completed.

17. Transfer of Controlled Drugs

17.1 Clinical areas must not offer to supply controlled drugs to other wards or departments, unless transferring Patients Own Controlled drugs between areas when a patient is transferred.

17.2 When Pharmacy department is closed, and an urgent dose is needed, a single dose only of the controlled drug may be administered directly to a patient in another clinical area. This should only occur after a discussion with the on-call pharmacist.

17.3 In such circumstances, both a registered nurse or ODP from the clinical area lending the dose and a registered nurse or ODP from the clinical area receiving the dose must witness the administration to the patient.

17.4 The CD record book from the lending area must be signed by both the registered nurse or ODP from the lending and receiving areas detailing the name of the patient and the clinical area where the patient is located.

17.5 Controlled drugs must not be transferred for use as stock in another clinical area unless approved by the Accountable Officer. The on-call pharmacist may be contacted for further advice.

18. Controlled Drugs in Unmanned Units

18.1 Controlled drug usage in unmanned units should be avoided wherever possible unless clinically justified, and agreed between the Accountable Officer for controlled drugs and the relevant Clinical Service Lead. CD stocks (range and quantity) must be kept to a minimum. The controlled drug cupboard must be alarmed.

18.2 In addition to once daily checking, CD checking must also occur at the end of every out-of-hours attendance unless those individuals entering the unit are not permitted to access the CD cupboard.

18.3 Where a department is closed and locked for periods of up to 48 hours (72 hours in the case of Bank Holidays), CD stock checks are not required for that period. Stock checks, however, must occur before closing the department and immediately upon re-opening.

18.4 Where a department is to remain closed for more than 48 hours (72 hours in the case of Bank Holidays),CDs must be returned to Pharmacy together with the department's CD record book and order book.

18.5 The practitioner in charge must ensure that all balances are correct at the time of closure and have the balances confirmed by a second registered nurse, ODP or a pharmacist (investigating any discrepancies as detailed within this procedure).

18.6 The practitioner in charge must remove all CDs and place with the CD register and order book in a transit pharmacy bag and seal using a pharmacy tamper evident seal.

18.7 The practitioner in charge must then take the bag to the pharmacy department where the seal number will be recorded and signed and dated by the pharmacist accepting the CDs for storage and the practitioner handing them over.

18.8 When the ward/department re-opens, the practitioner in charge must collect the transit bag from Pharmacy containing the CDs, checking that the seal is intact.

19. Controlled Drugs in Operating Theatres

19.1 The responsibility for the safe custody of CDs lies with the registered nurse or ODP in charge of the individual theatre.

19.2 Keys (where Abloy Cliq® is not in use) may be entrusted to registered nurses or ODPs at the discretion of the registered nurse or ODP in charge at that time. The responsibility for administering and recording in the CD record book lies with the registered nurse, ODP or doctor.

19.3 Within the Operating Theatres CDs must be checked at the beginning and end of each shift (i.e. at the time of a change of the person in charge), by two registered nurses/ODPs or at least once a day whichever is the more frequent.

19.4 Operating Theatres and Recoveries have their own theatre style record books. Use of these registers must be in line with the Trust theatre standard operating procedure.

20. Monitoring Controlled Drug Storage and Use

20.1 Clinical matrons, or in those areas not covered by a clinical matron a senior member of staff who has been identified and documented as the responsible person, are responsible for ensuring a monthly audit of CD daily stock checks is being carried out.

20.2 The Pharmacy Department carries out a rolling programme of quarterly Controlled Drug audits. .

21. Management of High Dose Opiates

21.1 Nationally there have been a number of reports of deaths and harm due to the administration of high dose (30mg or greater) diamorphine or

morphine injections to patients who had not previously received doses of opiates (NPSA, 2006).

21.2 The major risks are:

- Dosing errors can arise because the packaging of different strengths of morphine and diamorphine ampoules is similar; the outer carton and ampoule labelling are poorly differentiated so that 5mg, 10mg, 15mg, 20mg and 30mg products have similar appearances

- Higher strength ampoules of morphine or diamorphine (30mg or above) stored alongside lower strength products (10mg, for example) in clinical areas, partly due to lack of space within the controlled cabinet to segregate them or due to custom and practice to store alphabetically

- Insufficient therapeutic training and understanding on the part of the healthcare staff of the risks and precautions when prescribing, dispensing and administering higher doses of morphine injections.

21.3 Procedures to be followed:

21.3.1 Safe Prescribing of Opiates

(a) The prescribing of high dose morphine (30mg or greater) should only be undertaken by an approved Trust prescriber and it must be prescribed in the Trust electronic prescribing system or on approved stationary.

(b) The lowest clinically appropriate dose must be prescribed. Specialist advice may be obtained from the Urgent Care and Acute Pain (UCAP), Chronic Pain or Palliative Care Teams. Any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient must be confirmed.

(c) When prescribing high dose opiates, Naloxone must be prescribed as required (See Trust Guidelines for the Use of High Dose Opiates http://uhbpolicies/assets/HighDoseOpiates.pdf).

21.3.2 Ordering Diamorphine and Morphine

(a) The following strengths of diamorphine and morphine may be kept as stock and must be ordered in the “CD order book” which must be sent to the Pharmacy department:

- diamorphine ampoules 5mg/ml

- morphine ampoules 5mg/ml and 10mg/ml

(b) Low dose ampoules (5mg/ml and 10mg/ml) must be used for all bolus dose administration and for patients newly commenced on morphine infusions and those requiring less than 30mg in 24 hours.

(c) High dose ampoules (20mg and 30mg/ml) must only be stocked routinely in

- Critical care
- Oncology wards
- Theatres

(d) In all other areas, should a specific clinical need arise, high strengths can be obtained from pharmacy on a named patient basis – e.g. for the management of a palliative care patient requiring greater than 30mg morphine in 24 hours.

21.3.2 Pharmacy Supply of Diamorphine and Morphine

(a) High dose ampoules of both drugs will be stored in a separate location to lower strength formulations.

(b) Low strength ampoules can be supplied against a standard "CD order", in line with standard pharmacy procedures.

(c) High strength ampoules will only be supplied when there is a specific clinical need (see examples above).

(d) A record of all wards receiving high dose preparations will be maintained within pharmacy. The continuing need for these should be assessed on a weekly basis.

(e) High strength ampoules no longer required should be removed and returned to pharmacy via a pharmacist, pre-registration pharmacist or registered pharmacy technician (See section 6).

21.3.3 Ward Storage of High Dose Opiates

(a) Low dose and high dose opiates must ALWAYS be segregated within the cupboard.

(b) At the end of treatment any remaining high dose opiate ampoules must be returned to pharmacy at the earliest practical opportunity.

(c) Naloxone must be stocked in all areas that administer high dose opiates. It should be stored with the other injectable medicines on the ward or department under “n”.

22. Management of Oramorph® (Morphine Sulfate Solution 10mg/5ml)

22.1 Morphine sulfate 10mg/5ml is a schedule 5 controlled drug which means that controls on the handling of this product are not as restrictive as for morphine sulfate in higher concentrations.

22.2 TTOs and outpatient prescriptions for oramorph need NOT be written according to the controlled drug requirements.

22.3 The following local management has been approved by the Accountable Officer:

22.3.1 Ward/department orders for **Oramorph®** must be made using a controlled drug order book.

22.3.2 When issued from Pharmacy **Oramorph®** stocks must be transported in a sealed bag, to highlight to nursing staff that a signature is required for stock.

22.3.3 When **Oramorph®** is issued from Pharmacy as part of a TTO, it may be transported in Pharmacy transit bag.

22.3.4 When received into the clinical area, full stock bottles of oramorph must be signed into the CD record book in the usual manner and stored in the CD cupboard.

22.3.5 Once a dose is required, the whole bottle (100ml) may be booked out of the register and into the ward drug trolley (where more than one trolley is in use on a ward then the trolley must be identified by number or location e.g. **“100ml booked to trolley bay 2”**). The bottle must be booked out of the register by registered nurse or ODP and witnessed by a second registered healthcare professional.

22.3.6 When in use, the bottle of **Oramorph®** may be used in the same way as all other liquid medicines but must remain in the trolley into which it was booked. **No second signature is required to witness the administration and no running total of the quantity remaining in the bottle need be made**.

23. Management of Tramadol, Pregabalin and Gabapentin

23.1 Tramadol, pregabalin and gabapentin are schedule 3 controlled drugs.

23.2 The following local management has been approved by the Accountable Officer:

23.2.1 Ward/department orders must be made using the controlled drug order book.

23.2.2 When issued form pharmacy as stock these must be transported in a CD transit bag, to highlight to nursing staff that a signature is required.

23.2.3 When issued from pharmacy as part of a TTO, it may be transported in a pharmacy transit bag.

23.2.4 When received into the clinical area, whole packs must be signed into the CD record book in the usual manner and stored in the CD cupboard.

23.2.5 Once a dose is required, the whole pack may be booked out of the register into the ward medicines trolley. Where more than one trolley is in use on the ward, then the trolley must be identified by a number (e.g. 100 capsules booked into Trolley Bay 2). The whole pack must be booked out of the register by a registered nurse or ODP and witnessed by a second registered practitioner.

23.2.6 When in use, the pack may be used in the same way as all other medicines, but must remain in the trolley into which it is booked. No second signature is required to witness the administration and no running total of the quantity remaining in the bottle need be made.

23.2.7 Patients own supply from home does not need to be stored in the CD cupboard

24. Community Services

24.1 **Prescribing CDs for Administration by Community Nurses**

24.1.1 A community nurse must have the written directions on an official drug card signed and dated by a medical practitioner.

24.2 **Administration of CDs by Community Nurses**

24.2.1 The vast majority of administration of CDs by community nursing is for palliative care patients. The processes and documentation outlined in the Guidelines for the Use if McKinley T34 Syringe Drivers in Palliative Care (Community) should be followed.

24.2.2 The Authorisation to Administer Subcutaneous Palliative Medications chart should be completed by the prescriber for administration of subcutaneous CDs in the community.

24.2.3 A stock count of the CDs should be done at each administration session and documented on the CD record sheet.

24.2.4 Due to the nature of working in the community in patient's own homes, two nurses are not routinely required to witness administration.

24.3 **Disposal of CDs by Community Nurses**

24.3.1 Medicines are the property of the patient and as such cannot be removed without permission. If a patient no longer needs CD medication due to either a change in medication or death, the patients' carers or relatives should be directed to return drugs to a community pharmacist, who will denature and dispose of the drugs. Yellow lidded sharps bins are suitable for disposal of sharps used for the administration of controlled drugs. Small amounts of drug remaining in the syringe driver may be similarly disposed of in a yellow-lidded sharps bin as well.

24.3.2 Whilst community nurses should not routinely transport controlled drugs, this can be undertaken acting as the patient's representative in exceptional circumstances where there is no other reasonable mechanism available or where there is a perceived significant risk in leaving the drugs in the home.

24.3.3 In such circumstances:

24.4 Drugs are only to be removed if there is a local pharmacy open to receive them the same day

24.5 Details of the drugs to be removed for disposal by a community pharmacist must be made in the patient notes

24.6 A pro-forma detailing the drugs, quantities and date and reason removed must be completed and signed by the patient/relative/carer/witness.

24.7 The same pro-forma to be signed by the community pharmacist upon receipt. In rare circumstances when there is no other witness available; the community nurse can provide the pharmacy with a copy of the CD record sheet so that the pharmacist can cross check the quantity with what has been returned. The pro-forma should be faxed team managers and the original copy placed in the patient notes.

24.8 All drugs should be kept out of sight during transportation.

24.8.1.1 The drugs must be taken directly to the community pharmacy.

24.8.1.2 For full details see protocol for SCS community nurses on disposal of CDs.

24.9 **CDs in Community Services Clinics bases**

24.9.1 CDs must be ordered and collected from pharmacy using the processes described in section 12. When staff pick up the CDs from Pharmacy, the CDs must be taken directly back to base and logged into the CD record book and stored securely straight away. Midazolam may be stored in a

non CD drug cupboard but this must be approved with the community services pharmacist and the Accountable Officer.

25. Summary of Controlled Drug Requirements for Specific Controlled Drugs

25.1 The following table summarises some of the controlled drug requirements for some controlled drugs which commonly cause confusion due to specific exceptions under the legislation and/or local restrictions:

Name of Controlled Drug:	Midazolam	Temazepam	Tramadol	Pregabalin and Gabapentin	Phenobarbital	Morphine Sulfate 10mg/5ml (Oramorph)	Buprenorphine	Ketamine	"Strong" potassium Chloride and Sodium chloride 30%	Sativex®
Prescription CD requirements apply?	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Storage in CD cupboard required?	No	Yes	Yes for original packs. No for packs in use	Yes for original packs. No for packs in use	No	Yes for full bottles. No for bottles in use	Yes	Yes	Yes	No
Must be ordered from Pharmacy in a CD order book?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not available from Pharmacy
Must be recorded in a ward/dept. CD record book?	No	No	Yes for original packs. No for packs in use	Yes for original packs. No for packs in use	No	Yes for full bottles. No for bottles in use	No	Yes	Yes	Good practice but another book used solely for the purpose may be used
Must be transported in a CD transit bag?	Yes	Yes	Yes	Yes	Yes	Yes- for stock bottles No – when dispensed as TTO	Yes	Yes	Yes	NA
Clinical areas must return to Pharmacy for destruction?	No - but the destruction must be witnessed by a second registered practitioner and the product rendered irretrievable by opening the ampoule and disposing of the contents into an in use sharps bin	No - but the destruction must be witnessed by a second registered practitioner and the product rendered irretrievable by crushing the tablet and disposing of the contents into an in use sharps bin	No - but the destruction must be witnessed by a second registered practitioner and the product rendered irretrievable by opening the capsule/ampoule and disposing of the contents into an in use sharps bin	No - but the destruction must be witnessed by a second registered practitioner and the product rendered irretrievable by opening the capsule and disposing of the contents into an in use sharps bin	No - but the destruction must be witnessed by a second registered practitioner and the product rendered irretrievable by opening the capsule and disposing of the contents into an in use sharps bin	No - but the destruction must be witnessed by a second registered practitioner and the product rendered irretrievable by disposing of the contents into an in use sharps bin	No - but the destruction must be witnessed by a second registered practitioner and the product rendered irretrievable by crushing the tablet or folding the patch on itself and disposing of the contents into an in use sharps bin	Yes	No - but the destruction must be witnessed by a second registered practitioner and the product rendered irretrievable by opening the ampoule and disposing of the contents into an in use sharps bin	Yes – as will be patients own CDs

26. References/ Bibliography

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Appendix 1

Examples of appropriately prescribed CD prescriptions:

Example 1: Fentanyl 25micrograms every 72 hours

Date	Medicine Name	Form	Strength	Dose	Route	Frequency	Total quantity in words	Total quantity in figures
14/7/06	Fentanyl	Patch	25 micrograms per hour	One patch	Topical	Every 72 hours	Five	5

Example 2: Diamorphine 60mg SC infusion

Date	Medicine Name	Form	Strength	Dose	Route	Frequency	Total quantity in words	Total quantity in figures
14/7/06	Diamorphine	Injection	30mg	60mg	sc infusion	Daily over 24 hours	Six	6
In this example only 6 ampoules of 30mg will be supplied. (60mg ampoules not available)								

In any other case (where there is no preparation e.g. for a powder), the total quantity (in both words and figures) of the Controlled Drug to be supplied must be written on the prescription.

e.g. Cocaine Powder (5mg) (five milligrams).

Care must be taken when prescribing morphine for parenteral use as errors have occurred where high strengths have been used in error when the lower strength was intended. Ensure the patient/carer is aware of the strength they will be receiving.

Although not a legal requirement, the Department of Health has issued a strong recommendation that as good practice the quantity of CDs prescribed should not exceed 30 days' supply.

Examples of appropriately prescriped CD prescriptions on the Trust Electronic Prescribing System:

Example 1

Ann NewPatient *Hospital No: EM0000040*

University Hospitals Birmingham NHS
NHS Foundation Trust

Controlled drug prescription for Discharge and OPD patients

Surname:	**NewPatient**	Ward:	**Ward 625 (QEHB)**
First name:	**Ann**	Consultant:	Dr SA Abudabeeb
Registration No.:	EM0000040		
NHS number:	*Unavailable*		
Date of Birth:	27/03/1953		
Address:	1 High St District Town County Z0 0ZZ		

Morphine Sustained Rel. [Capsule, Oral]
20mg Twice a Day (BD)

Please supply

Strength of Formulation (see below *)	Formulation (e.g. tablet, syrup)	Number to be administered at each dose (e.g. 2 tablets)	Frequency	Total supply quantity of formulation in words (e.g. TEN tablets)	Total supply quantity of formulation in figures (e.g. 10)
10 milligrams	Slow release Capsule	2 capsules	TWICE DAILY	FIFTY SIX	56.

* **[Available strengths:** 10 mg Slow Release Capsule, 30 mg Slow Release Capsule, 60 mg Slow Release Capsule, 100 mg Slow Release Capsule, 200 mg Slow Release Capsule]

Signature	PRINT NAME	Contact number	GMC number	Date
A. Doctor	A. DOCTOR	Bleep 6627	N15263	28/3/13.

Can ONLY be dispensed in a Pharmacy within University Hospitals Birmingham NHS Foundation Trust
Prescriptions for duration of greater than 30 days MUST include an annotation describing the clinical justification

Pharmacy use only
Authorised for supply by:
PRINT NAME:

Signature:

Example 2

Ann NewPatient *Hospital No: EM0000040*

University Hospitals Birmingham NHS
NHS Foundation Trust

Controlled drug prescription for Discharge and OPD patients

Surname:	**NewPatient**	Ward:	**Ward 625 (QEHB)**
First name:	**Ann**	Consultant:	Dr SA Abudabeeb
Registration No.:	EM0000040		
NHS number:	*Unavailable*		
Date of Birth:	27/03/1953		
Address:	1 High St District Town County Z0 0ZZ		

50microg/spray Fentanyl [Nasal Spray, Both Nostrils]
2Spray Four Times a Day (QDS)

Please supply

Strength of Formulation (see below *)	Formulation (e.g. tablet, syrup)	Number to be administered at each dose (e.g. 2 tablets)	Frequency	Total supply quantity of formulation in words (e.g. TEN tablets)	Total supply quantity of formulation in figures (e.g. 10)
50 Micrograms	Nasal Spray	2 Sprays each nostril	four times daily	ONE Bottle	1 Bottle.

* **[Available strengths:** 50 microgram spray, 100 microgram spray, 200 microgram spray, 400 microgram spray]

Signature	PRINT NAME	Contact number	GMC number	Date
A.Doctor.	A.DOCTOR	Bleep 6527	N15263	28/3/13

Can ONLY be dispensed in a Pharmacy within University Hospitals Birmingham NHS Foundation Trust
Prescriptions for duration of greater than 30 days MUST include an annotation describing the clinical justification

Pharmacy use only
Authorised for supply by:
PRINT NAME:

Signature:

Printed on Wed. 20 Jun. 2012 12:58 by Dr A. Doctor (Bleep 12323213123) **Page 3 of 6**
Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Edgbaston, Birmingham, B15 2WB

Appendix 2 **Summary of Documentation Relating to Controlled Drugs (CDs) and CD Record Book.**

1. An entry must be made in the CD record book whenever a CD is received, administered, destroyed or removed from stock.

2. Stock balances must be checked every time after a CD is received, administered, destroyed or removed from stock.

3. Any CD prepared and not used, or only partly used, must be destroyed by the registered nurse or ODP in the presence of another healthcare practitioner. An entry must be made in the CD record book and signed by both individuals e.g. 5ml given, 5ml wasted (at the back of the book for discontinued infusions and PCAs).

4. CDs no longer required must only be removed by a registered pharmacist or pharmacy technician and witnessed by a registered nurse or ODP. A full record must be made in the CD record book.

5. Patient's own CDs, must be entered in a CD record book on separate pages specifically allocated for that individual patient's own CDs. One product per page.

6. Stock balances of all CDs, including patient's own CDs, must be checked at least once daily against the actual stock held. Two registered nurses or ODPs, or one registered nurse and one ODP must perform the check.

7. A record indicating this check has been carried out must be made to confirm the stock is correct. This record may be a single entry at the back of the record book or in a separate bound book used solely for that purpose. The record must be dated and signed by both individuals involved. **The Ward or Team Manager must ensure that these checks are carried out.**

8. In the event of a discrepancy being found, the Registered Nurse or ODP in charge must immediately and thoroughly investigate it as per section 16.1.

NAME, FORM OF PREPARATION AND STRENGTH……*Morphine Sulphate MR (MST) tablets 30mg ……..*									
AMOUNT(S) OBTAINED			**AMOUNT(S) ADMINISTERED**						
Amount	**Date Received**	**Serial No. of Requisition**	**Date**	**Time**	**Patient's Name**	**Amount given**	**Given by (signature)**	**Witnessed by (signature)**	**STOCK BALANCE**
28	*1/3/10*	*21*	*-*	*-*	*Received by A Nurse*	*-*	*-*	*-*	*28*
			1.3.10	*18.00*	*Mrs A Patient*	*1*	*A Nurse*	*B Nurse*	*27*
			2.3.10	*07.10*	*Mrs A Patient*	*1*	*D Nurse*	*B Nurse*	*(25)**
			2.3.10		**Arithmetical error corrected*	*A Nurse*	*W Manager*		*26*
			2.3.10	*18.05*	*Mrs A Patient*	*1*	*A Nurse*	*W Manager*	*25*

9. If this investigation is unsuccessful the discrepancy must be reported as soon as possible. *See section 16 of these procedures for more details.*