TITLE	**CONTROLLED DRUGS MANAGEMENT**
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Equality Impact Assessment has been applied to this policy	None J Watling Clinical Director Medicines Management and Pharmacy (Accountable Officer)
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RATIFIED BY	Medication Safety Committee – December 2007 Professional Advisory Committee – February 2008

AMENDMENTS RECORD

October 2007

Further to the Shipman case Controlled Drugs procedures have been under scrutiny nationally and several DOH reports and new Regulations have been published in recent months.

This policy aims to set out a consistent approach on management of Controlled Drugs across the local health economy, including local PCTs.

This edition has undergone a variety of formatting and minor typographical corrections.
The main substance and principles remain unchanged.

Introduction – reworded
Responsibilities Accountable Officer added (as per 2006 regulations)
Updated referencing/links to current committees, Pacts and policy/ protocol documents,
Changes to legal requirements for CD prescription writing

- handwriting requirement removed
- electronically generated information e.g. ID stickers acceptable
- quantity expressed in dose units

Where relevant assignation of "*doctors*" changed to "*prescribers*" to include non-medical prescribers
Detail on responsibility of HCSW undertaking stock check witness role.
Points added to meet the requirements of NPSA Safer practice Notice 12, Ensuring Safer Practice with High Dose ampoules of Diamorphine and Morphine.

- Wards should not keep high strength unless justified
- Segregation of high strength items
- Naloxone held as stock if opioids stocked

Section on management of Controlled Drugs in operating theatres added
Section on management of Controlled Drugs in pharmacy departments added
Appendix 2: Capitalised case changed to sentence case for easier reading
Ref to Accountable Officer
The electronic "hyperlinks", which when viewed in electronic format, can be "clicked" to give immediate Intranet or Internet access to the reference documents concerned have been checked for functionality

CONTENTS:

APPENDICES:

1. INTRODUCTION / BACKGROUND

This policy gives an overview of English law and good practice relating to Controlled Drugs in hospitals. It gives detailed guidance to ensure that the law is adhered to, including measures to increase the security of Controlled Drugs, and to counter fraud.

2. STATUS

This is a Clinical Policy

3. PURPOSE

The purpose of this policy is to:

- ensure the Trust complies with the legal requirements of the Misuse of Drugs Regulations (1971), all other relevant Controlled Drugs Legislation and NHS Guidance.
- provide clear, standards and procedures for staff carrying out their duties involving Controlled Drugs.

4. SCOPE/AUDIENCE

This policy with associated procedures, applies to all Portsmouth Hospitals NHS Trust, Hampshire PCT (South East) and Portsmouth City PCT staff involved in:

- the safe custody and accountability of Controlled Drugs stored in their area of responsibility
- the ordering and receipt of Controlled Drugs by Wards/Departments
- the prescribing of Controlled Drugs
- the administration of Controlled Drugs to patients
- the handling of patients' own medicines which are classified as Controlled Drugs
- record keeping in the Ward Controlled Drugs Record Book
- the management and checking of Controlled Drugs on Wards/Departments
- disposal of unwanted Controlled Drugs

Staff affected includes, but is not exclusive to, doctors, nurses and midwives, pharmacists, healthcare professionals and associated practitioners.

This policy should be used in conjunction with Policy and Protocol for the Management of Medicines (the "Medicines Policy"). When Controlled Drugs are to be administered via the intravenous, subcutaneous, intramuscular or epidural route, this should be undertaken only by health care professionals, who have undergone specific training and have demonstrated their competence.

5. DEFINITIONS

Controlled Drugs and classes of Controlled Drugs: See "Introduction" in body of Policy

6. PROCESS

See Appendix 1 for full document

0. Introduction
1. Stock, storage and security of Controlled Drugs
2. Ordering and receipt of Controlled Drugs (including Obtaining Controlled Drugs when Pharmacy is closed)
3. Administration of Controlled Drugs
4. Record keeping in the Ward Controlled Drugs Record Book
5. Controlled Drug stock checking on the wards
6. Disposal or return of Controlled Drugs to the Pharmacy Department
7. Patients' own Controlled Drugs
8. Clinical Trials involving Controlled Drugs
9. Prescribing Controlled Drugs
10. Management of Controlled Drugs in in-house operating theatres
11. Management of Controlled Drugs in hospital pharmacies
12. References

7. DUTIES AND RESPONSIBILITIES

Ward/Clinical Department Managers

Ward/Clinical Department Managers are responsible for ensuring adequate dissemination and implementation of policies.

All ward staff

All ward staff must comply with their responsibilities when undertaking their duties involving Controlled Drugs. Incorrect storage or inadequate record keeping is illegal and may lead to disciplinary and/or legal action.

Pharmacy Staff

All pharmacy staff whose duties include Controlled Drugs must comply with the requirements of the Policy to ensure that Controlled Drugs are stored and distributed in accordance with the law, and that proper records of transactions (including destruction) are kept.

Accountable individuals

The registered nurse or midwife in charge of a ward or department

The registered nurse or midwife in charge of a ward or department is responsible for the safe and appropriate management of Controlled Drugs in that area. The registered nurse or midwife in charge can delegate control of access (i.e. key holding) to another, such as a registered nurse or operating department practitioner). However, legal responsibility remains with the registered nurse or midwife in charge. Whilst the task can be delegated responsibility cannot.

Accountable Officer (Controlled Drugs)

A senior officer of the Trust will be appointed to serve in this capacity. This person has overall responsibility to ensure that the Trust operates appropriate arrangements for the securing and safe management of controlled drugs within the Trust, as described in this Policy (and in standard operating procedures used within Pharmacy Departments)

8. TRAINING

All Ward and Clinical Department Managers will need to be aware of the contents of this policy and ensure that their staff are aware of and understand the procedures, roles and responsibilities given. Support and advice will be available from the Pharmacy Department to anyone requiring assistance.

9. ASSOCIATED DOCUMENTATION

- Misuse of Drugs Act, 1971
- Misuse of Drugs (safe custody) Regulations, 1973
- Misuse of Drugs Regulations, 1985
- Misuse of Drugs Regulations, 2001
- The Safe and Secure Handling of Medicines: A Team Approach. A revision of the Duthie Report (1988) led by the Hospital Pharmacists Group of the Royal Pharmaceutical Society of Great Britain March 2005
- Safer practice Notice 12, Ensuring Safer Practice with High Dose ampoules of Diamorphine and Morphine, National Patient Safety Agency (NPSA), May 2006
- Safer Management of Controlled Drugs: Guidance on the Destruction and Disposal of Controlled Drugs new role for accountable officers, Dept of Health, August 2007
- Safer Management of Controlled Drugs: A guide to good practice in secondary care (England) Dept of Health/Royal Pharmaceutical Society of Great Britain October 2007
- Safer Management of Controlled Drugs: changes to requirements for requisitions for the supply of Schedule 1,2 and 3 Controlled Drugs (Interim Guidance) Dept of Health 2007
- Safer Management of Controlled Drugs: changes to record keeping requirements (Interim Guidance Dept of Health 2007
- Statutory Instrument 2006 No. 3148, The Controlled Drugs (Supervision of Management and Use) Regulations 2006, HMSO
- Medicines Ethics and Practice. A Guide for Pharmacists. Royal Pharmaceutical Society of Great Britain. Issue 31. July 2007
- PHT Trust Policy for the Management of Medicines, Feb 2007
- National Prescribing Centre (2004) A Guide to good practice in the management of Controlled Drugs in Primary Care (England)
- Nursing and Midwifery Council, Guidelines for administration of Medicines 2004

Portsmouth Hospitals NHS Trust
Hampshire Primary Care Trust South East
Portsmouth City Primary Care Trust

APPENDIX 1: CONTROLLED DRUGS POLICY

Controlled Drugs Policy

Introduction

This policy is an adjunct to the Medicines Policy to describe in detail the processes, roles and responsibilities in relation to the management of Controlled Drugs (CDs), including:

- Stocks, storage & security of Controlled Drugs at ward level
- Ordering & receipt of Controlled Drugs
- Administration of Controlled Drugs
- Record keeping in the Ward Controlled Drugs Record Book
- Controlled Drugs stock checking on the ward
- Disposal/ return to the Pharmacy Department
- Patients' own Controlled Drugs
- Clinical trials
- Prescribing of Controlled Drugs
- Management of Controlled Drugs in in-house operating theatres
- Management of Controlled Drugs in hospital pharmacies

Within the pharmacy service these activities are the subject of pharmacy Work Instructions (PHPS nomenclature for Standard Operating Procedures). There is a separate policy for dealing with suspected or known possession or use of illegal substances by staff and visitors on Trust premises. Illegal Substances Policy

An overview of the law relating to Controlled Drugs

The Misuse of Drugs Act, 1971 controls certain classes of dangerous drugs, which are listed and known as "Controlled Drugs". Its main purpose is to prevent the misuse of these drugs by imposing a total ban on the possession, supply, manufacture or importation of Controlled Drugs, except as allowed by regulations. The use of Controlled Drugs in medicine is regulated by the Misuse of Drugs Regulations, 2001 (as amended). Separate regulations deal with the safe custody of Controlled Drugs and their supply to addicts.

The 2001 Regulations set out a number of schedules, which classify Controlled Drugs (CDs) according to different levels of control:

Schedule 1 (CD Lic). These drugs have virtually no therapeutic use, e.g. hallucinatory drugs (LSD, "Ecstasy") and cannabis. A special Home Office licence is required for their possession, usually for academic or research purposes.

Schedule 2 (CD). This includes the opiates (e.g. morphine, diamorphine, methadone), synthetic opiates/related compounds (e.g. pethidine, fentanyl), and the major stimulants (e.g. amphetamines). This is the class of drugs to which this policy applies. It should also be noted that medicines that contain these drugs are not only CDs, but also Prescription Only Medicines (POMs), which is also true of schedules 3 and 4.

Schedule 3 (CD No Register). These are drugs less likely to be misused or are considered less harmful than Schedule 2 CDs. Temazepam, midazolam and buprenorphine are included in this class. Safe Custody requirements apply to these two drugs, which means that they must be kept in the CD cupboard. However, there is no legal requirement for records of receipt or administration of Schedule 3 drugs to be kept in the Ward Controlled Drugs Record Book. Apart from the storage requirement, they do not come under the jurisdiction of this policy. Security requirements (e.g. for temazepam) may be increased at the discretion of the Nursing Management.

Schedule 4, Part 1 (CD Benz). This includes most benzodiazepines, (e.g. diazepam, but not temazepam - see above). They are POMs and need to be safely and securely stored and their use carefully controlled by prescribing policy but they do not come under the jurisdiction of this policy.

Schedule 4, Part 2 (CD Anab). This includes many of the anabolic and androgenic steroids. Again, they are POMs and need to be safely and securely stored and their use carefully controlled by prescribing policy, but they do not come under the jurisdiction of this policy.

Schedule 5 (CD Inv). This applies to certain medicines that contain CDs in strengths low enough for them not to require the same degree of control as for other schedules. The name comes from the fact that pharmacies are required to record and retain invoices relating to the procurement of these medicines. They do not come under the jurisdiction of this policy.

Notes:
Storage and security requirements may be increased locally at the discretion and direction of the Nursing Management.

If you are in doubt whether a product is a Controlled Drug or not; if it is in its original manufacturer's pack it should state "CD POM" on the packaging; medicines that are Schedule 2 CDs prepared or repackaged by the Pharmacy Department bear the words "Controlled Drug" on the label.

1. Stocks, storage and security of Controlled Drugs in wards and departments

1.1 Stocks of Controlled Drugs

The pharmacy will hold a list of high turnover CDs to be held on wards or departments as stock items. The contents of this list will reflect current patterns of use of Controlled Drugs in the ward or department and be agreed between the pharmacy and the registered nurse or midwife in charge.

The list should be modified if practices change and will be subject to annual review

1.2 Storage of Controlled Drugs

Once CDs, which have been requisitioned from Pharmacy, reach the ward, and the receipt page/form signed, they become the responsibility of the Registered Nurse or Midwife in Charge on duty, and must be immediately stored securely in the CD cupboard.

CDs should be stored in the designated locked CD cupboard. This cupboard must be constructed of metal and securely attached to a wall or floor. Some cupboards may have a warning light to indicate when it is open, but this is not a legal requirement. Fridge items must be stored in a suitable designated locked fridge.

If a discharge prescription (TTO) includes a CD and is not handed to the patient straight away, then the CDs must be stored temporarily in the locked CD cupboard and record entered into the Ward Controlled Drugs Record Book. They must be segregated from ward stock and receipted out when issued to the possession of patient. (see Section 4 Record Keeping).

Ward CD Cupboards should conform to British Standard reference BS2881 or be otherwise approved by the pharmacy department. This minimum security standard my not be adequate for areas, where large quantities of CDs are kept or where there is not 24 hour staffing presence. In these cases a security cabinet that has been evaluated against the "Sold Secure Standard" SS304 should be used.

All CDs must be stored in a locked receptacle which can only be opened by a person that can legally be in possession, such as a pharmacist or the registered nurse or a midwife in charge or a person working under their authority, e.g. a pharmacy technician.

General measures for the storage of CDs include the following:

- Cupboards must be kept locked when not in use
- The lock must not be common to any other lock in the hospital
- Keys must only be available to authorised members of staff
- The cupboard should be dedicated to the storage of CDs
- No other medicines or items should normally be stored in the CD cupboard. Within PHT strong potassium chloride and ketamine injection are treated as CDs in those designated areas allowed to stock them. Some wards choose to treat products as CDs to increase security, e.g. sildenafil (NICU), tramadol (maternity theatres) and midazolam (theatres).
- CDs must be locked away when not in use
- There must be appropriate arrangements for keeping the keys secure (see 1.3 below).

1.3	**Security of Controlled Drugs**

Keys for the CD cupboard should be held by the Nurse or Midwife in Charge of the Ward or Department. The person in charge is responsible for controlling access to the CD keys and access to all CD cupboards on that Ward or Department for that shift.

CD Key holding may be delegated to other Registered Nurses or Midwives, Doctors, Pharmacists (and specified Senior Pharmacy Technicians authorised by the Pharmacist) or Registered Operating Department Practitioners (RODPs). This should be a permanent member of staff wherever possible. The keys must be returned to the Nurse or Midwife in Charge after use. The assigned key holder will challenge members of staff who request the keys to ensure that they have legitimate and acceptable reason to access the CD cupboards.

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 routine CD checks.

The keys for the CD cupboards should not be kept with any keys that may be accessed by staff who are not authorised to hold CD keys.

Security requirements may be increased at the discretion of the Nursing Management.

Missing Keys

- If the CD keys cannot be found urgent efforts should be made to retrieve them, e.g. by contacting relevant staff who have gone off duty.

- The relevant Modern Matron and Directorate Pharmacists should be contacted. They will be responsible for contacting the Facilities Management Company and ensuring security until an alternative lock is fitted.

- If the keys are not located within 24 hours the Accountable Officer will be informed. Depending on circumstances it may be appropriate to contact the police. This decision will be made by the Accountable Officer in consultation with the Trust's Counter Fraud Advisor. If wrong doing is suspected the police should be involved.

1.4 Ward closure

Permanent Ward Closure or Re-designation

If a ward is to close or be re-designated on a permanent basis such that ward stocks of CDs are no longer required a pharmacist should remove stocks from the ward (see below) and return them to the pharmacy. If suitable for re-use the CDs should be "returned" on the pharmacy computer system and value credited to the ward. If the drugs have less than three months shelf life, arrangements should be made to issue the stock to a ward or department actively using the item or it should be written off as expired stock and not credited to the ward.

Temporary ward closure

In the case of a temporary closure or relocation of a ward a pharmacist should agree with the nurse or midwife in charge, whether stocks need to be returned to pharmacy. This will always be the case for temporary ward closure. For a relocation, the pharmacist and nurse in charge may elect to personally and physically remove the stock from one controlled drug cupboard check the stock and move to the new CDs cupboard. Alternatively, if there is likely to be a delay in the move or security is likely to be compromised by the presence of contractors or non-PHT personnel, stock should be removed from the ward CDs cupboard and returned to the pharmacy for secure storage. They may then be returned to the relocated ward when the move is complete and security is ensured.

Entries in the Ward Controlled Drugs Record Book

The pharmacist and nurse or midwife in charge or their authorised deputy should check the CDs stock against the quantities in the Ward Controlled Drugs Record Book (see 5.3).

For each item the record should be annotated with the date and time of the stock check and signed out, "check of stock level and X (number of dose units) returned to pharmacy prior to the move." The new stock level recorded as zero and signed by the pharmacist and nurse or midwife in charge or their authori

A Ward/Department Controlled Drugs Inspection Form (PHPSF 03.005) should be used to record any discrepancies in CD stocks. The Ward, Inspection date and Pharmacist section should be completed and the Storage and Security and Records sections should be completed in the same way as for a normal Ward/Department CDs inspection. The "Problems found" column should be annotated "Stock transferred to pharmacy and dated. The "Proposed Solution/Outcome column should be annotated "quantity." The pharmacist should record the name form and strength of each item to be transferred in the column annotated "Stock transferred to pharmacy and the quantity in the column annotated "quantity." Once the stock check is completed the pharmacist will place the CDs in "Envopack" containers and seal with numbered CD tags. The tag numbers will be recorded on the bottom of the Controlled Drugs Inspection Form.

The pharmacist and nurse or midwife in charge or their authorised deputy plus ward manager will then sign, print name and date the Controlled Drugs Inspection Form. This will be photocopied and a copy retained by the ward or department.

The pharmacist will then deliver the stock to the pharmacy where it will be stored, together with the original or the Controlled Drugs Inspection Form, in a designated Controlled Drug Storage Cupboard until the ward is ready to receive the stock.

The pharmacist will then return the stock to the ward and, with the nurse or midwife in charge or their authorised deputy, check and return the stock to the Ward Controlled Drug Record Book using a process which is the reverse of that described above:

- Check the numbers of the security tags against the record on the Controlled Drugs Inspection Form
- Unpack and organise the stock for checking
- Check the stock
- For each drug form and strength the record should be annotated with the date and time of the stock check, "check of stock level and returned to ward xx after move," the stock level written up to the required level and signed by the and nurse or midwife in charge or their authorised deputy.
- Return the stock to ward Controlled Drugs Cupboard.

On completion of the process, the Controlled Drugs Inspection Form will be endorsed "Ward CD stock transfer completed", dated and signed by pharmacist and nurse or midwife in charge or their authorised deputy.

Any discrepancy throughout this process will be investigated as in 5.5.

During any permanent or temporary ward closure the pharmacy list of signatories for the ward concerned will be annotated by the pharmacist to ensure that pharmacy staff are aware that the ward is closed/re-locating. The list will be returned to "normal state when the stock has been returned to the ward.

For any ward relocation involving a change of ward name. The pharmacist will ensure that all stationery and records are updated at the time of the move, e.g. Ward Controlled Drugs Order and Record books, signatories lists and pharmacy computer records.

1.5	**Security of Controlled Drugs stationery**

The Ward Controlled Drugs Order Book (ref 90-500) and Ward Controlled Drugs Record Book (ref 90-501) should be kept in the CD cupboard when not in use or, if this is impractical, in a securely locked place (e.g. lockable drawer or filing cabinet).

Each Ward Controlled Drugs Order Book and Ward Controlled Drugs Record Book is marked with a unique identification number when supplied by the Pharmacy Department to enable the book to be traced. A record of all issues will be kept in the Ward Controlled Drugs Order Book Index (PHPSF 03.006). Only one Ward Controlled Drugs Order Book per Ward/Department should be in use at any one time.

If the Ward Controlled Drugs Order Book is suspected to be missing, immediately inform the Nurse/ Midwife in Charge who will report it to the Dispensary Manager in the Pharmacy Department as soon as possible. A stop will be put on this Order Book to prevent any unauthorised ordering and interim arrangements may be agreed.

Stocks of CD stationery held in pharmacy departments will be kept in a secure area that is locked when pharmacy staff are not present.

CD stationery will only be supplied by the pharmacy in response to a signed order from the nurse or midwife in charge of the ward or department.

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

- Date,
- Ward or Department
- Name of person ordering stationery
- Type of stationery issued
- Quantity
- Serial numbers of stationery
- Signature of member of staff supplying stationery
- Signature of member of staff receiving stationery.

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

Completed Ward Controlled Drug Ordering and Record books should be dated with the last entry, sealed with tape and retained by the ward for two years from the last entry. If the ward or department closes the Ward Controlled Drug Ordering and Record books should be archived along with other controlled stationery until the due destruction date.

Loss or theft of any controlled stationery, which may be used to order CDs should be reported to the pharmacy department.

1.6	**Writing in ward Controlled Drug order and record books**

Ward Controlled Drug Order and Record Books are of standard bound design with sequentially numbered pages. The Ward Controlled Drug Record Book should have a separate page for each drug and strength, so that a running balance can be maintained. Entries will be made in chronological order.

All entries should be signed by the registered nurse, midwife or RODP and should be witnessed, preferably by a second registered nurse, midwife or RODP.

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

Entries will not be crossed out in CDs records. If a mistake is made it should be bracketed in such a way that the original entry is clearly legible, annotated “in error” and signed, dated and witnessed by a second registered nurse, midwife or other registered professional. A separate correct entry should be made. The witness should also sign the correction.

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

2. Requisitioning & receipt of Controlled Drugs

2.1 Staff authorised to order Controlled Drugs

The Clinical Ward Manager or Midwifery Team Leader (Registered nurse or midwife in charge of a ward or department, operating theatre or theatre suite is responsible for the requisitioning of CDs for the use of that area. Even if the ward or department is managed by someone other than a nurse or midwife, under the present regulations the most senior nurse or midwife present is responsible for Controlled Drugs.

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

Only Registered Nurses who have been authorised by the Clinical Ward Manager and have signed the Ward/ Department Staff Authorised to Sign Ward CD Orders List (PSPSF 03.001), are permitted to order CDs.

The Clinical Ward Manager of each Ward/Department that holds CDs is responsible for ensuring that all Registered Nursing/Midwifery Staff new to their Ward/Department sign the Staff Authorised to Sign Ward CD Orders List, and also that the names/signatures of nurses who have left are deleted from the list.

The Clinical Ward Manager of each Ward/Department is responsible for keeping and updating this list and ensuring that a copy is given to the Pharmacy Department for their reference.

The Pharmacy Department will not supply CDs against requisitions ordered by staff whose name and signature does not appear on the authorised list for that Ward/ Department.

The Pharmacy Department do not supply CDs as part of a ward topping up system. If this was the case, the requisition would still have to be signed by the Clinical Ward Manager or member of staff listed on the ward's Staff Authorised to Sign Ward CD Orders List.

Electronic systems do not apply to Wards or Departments requisitioning CDs in Portsmouth Hospitals.

2.2 Use of the Ward Controlled Drugs order book

Controlled Drug orders for stock supplies to wards and departments will only be written on the Ward Controlled Drugs Order Book. The nurse ordering the CD stock must ensure that the requisition in the Ward Controlled Drugs Order Book is completed in ink and that the carbon copy has printed correctly.

The following must be completed

- Hospital
- Ward/ Department
- Name of drug e.g. not just "PCAs"
- Pharmaceutical form e.g. injection, capsules etc
- Formulation e.g. modified or sustained release or long acting (MR, XL, SR)
- Strength e.g. mg or mg/ml
- Quantity - total number of dose units required e.g. 10 amps, 100ml etc.
- Do not request by the box or bottle because the pack sizes can vary.

The requesting nurse must sign and also PRINT his/her name in capital letters to facilitate the checking of the nurse's signature against the authorised list.

Each different CD preparation or strength must be ordered on a separate page.

Wards/departments may NOT order diamorphine and morphine ampoules of 30mg or more *unless* there is a patient whose current prescribed dose of these drugs justifies it. Unjustified stocks should be returned to pharmacy or the department's ward pharmacist as soon as possible.

Orders no longer required or containing errors can be cancelled by drawing a line through the whole page and writing "cancelled" and sign and print name, checking that the carbon has printed correctly.

Alternatively an error in quantity or strength on the CD order can be corrected by bracketing the incorrect information and writing a brief explanation adjacent to it (e.g. "written in error"). Changes must be signed next to the alteration, by the nurse making the change or alteration. If altering another nurse's order, the nurse altering must also sign & print his/her name next to the original signature and must also check that the carbon copy has printed correctly, including alterations and signatures. Changes must NOT be made directly on the pink carbon copy.

Liquid paper correction fluid (e.g.Tippex™) must never be used to change orders.

The pink carbon copy pages must never be torn out of the Ward Controlled Drugs Order Book.

The used pink carbon copies in the Ward Controlled Drugs Order book may be kept together using a rubber band around the front cover of the book so that earlier pages can easily be checked. The used pink carbon copies should not be folded as this discourages inspection of previous orders.

A new Ward Controlled Drugs Order Book should be requested from Pharmacy Department only when less than 5 blank pages are left in the current Ward Controlled Drugs Order Book.

The issuing Pharmacy Department maintains a written record of Controlled Drugs Order Books issued to each Ward/ Department. Duplicate books will not be provided. See Section 1.3 Security of CD Stationery.

When the Ward Controlled Drugs Order Book is completed, the date of completion should be written on the front cover and then stored securely at Ward/ Department level. It is a legal requirement that the Ward Controlled Drugs Order Book is kept for 2 years from the date of the last entry. It may then be destroyed as confidential waste.

2.3 Ordering Days and Quantity of Controlled Drug order

Each ward should agree with Pharmacy Dept suitable designated days on which to routinely order their CDs. This will be indicated on the front of the Ward Controlled Drugs Order Book. Wards should order routinely only on their designated ordering days and should anticipate requirements for weekends and Bank Holidays, to avoid ordering on these days.

Unless specific arrangements are agreed with the Pharmacy Department, CD Orders should be sent to the Pharmacy Department or be ready for collection as early as possible or **by 10am**. This will enable completed orders to be delivered and avoid the need for ward staff to collect them later from the Pharmacy Department.

To help prevent under or over-ordering each Ward/Department will keep a list specifying a standard stock level and re-order quantities for each drug that reflects their usual routine usage. This list should be kept in the CD cupboard or with the Ward Controlled Drugs Order Book to facilitate the ordering process.

2.4 Collection/ delivery of Controlled Drug from Pharmacy

After the CD is dispensed and checked as per relevant Pharmacy Department Work Instructions, the checking pharmacist or technician selects a numbered CD Envopak security tag and records this number on the "accepted for delivery" line of each corresponding CD order sheet. The white top copy is retained for filing in the Pharmacy Department. The consignment of CD items together with the Ward Controlled Drugs Order Book (where applicable) are placed in a CD Envopak bag and sealed with the corresponding numbered tag.

The initial part of the Receipt for Collection/Delivery of Controlled Drugs Form (PHPSF 03.008) is then completed for each CD order, entering onto the form:

- Date
- Ward/ Department
- Serial (page) number(s) of each CD order in that consignment
- CD Envopak tag number

- Signature of pharmacist/ pharmacy technician sealing the Envopak

The Receipt for Collection/Delivery of Controlled Drugs Forms are bound into a booklet for each month and a separate page is used each day. This booklet and all the top copies of the CD orders are filed at the end of each month and archived in the Pharmacy Department for 2 years to ensure a complete audit trail.

The Pharmacy Department retains responsibility for CDs until the sealed CD Envopak bag is signed for receipt, either:

- at ward level, by the Nurse in Charge if delivered by Pharmacy Staff.
- at the pharmacy hatch, by the Nurse or member of ward staff collecting the CDs, who is then responsible for the safe transfer and delivery to the Nurse/ Midwife in Charge of the Ward/ Department.

Thereafter, the Nurse/ Midwife in Charge is responsible for checking the delivered stock against the order(s), recording receipt of the new stock in Ward/ Department Controlled Drugs Record Book and the safe transfer of stock into the ward CD cupboard.

2.5	Collection and delivery of Controlled Drugs by pharmacy on PHT sites

For Wards/ Departments on the PHT hospital site, the Pharmacy Support Worker (PSW) will routinely deliver the CDs supplied by the Pharmacy Department.

Before commencing the delivery round, the PSW signs the Receipt for Collection/Delivery of CDs Form (PHPSF 03.008), ensuring the Envopak tag numbers on the bags correspond with the delivery location stated on the bag and the Form. Any discrepancies should be notified to the designated CD technician, senior technician or dispensary manager.

The Pharmacy Support Worker will then take the booklet of receipt forms, together with the CD Envopak bags on their delivery round to obtain nurse signatures for receipt of the CDs at ward level.

CDs should generally be delivered using a trolley that can be securely closed whilst in transit between delivery points. Throughout the delivery round, the PSW should never leave the trolley unattended. Smaller deliveries may be carried by hand but must never leave the hand of the person delivering until signed for by an authorised member of ward staff.

When the Pharmacy Support Worker arrives at the Ward/ Department, the CD Envopaks are handed directly to the Nurse in Charge who accepts the intact bag and signs the “received by” entry on the Receipt for Collection/Delivery of CDs Form. If there is no nurse available to sign for CDs, the PSW should annotate the Form “unable to deliver” and return the sealed bag(s) to the Pharmacy Department.

At the end of the delivery round the PSW returns to the Pharmacy Department and returns the Receipt for Collection/Delivery of CDs Form booklet and any undelivered CDs, to the designated CD technician, senior technician or Dispensary Manager.

If a CD is required before the pharmacy delivery, the Nurse/ Midwife in Charge may ask any permanent member of the ward staff to collect the CDs from the pharmacy hatch. They will need to show their PHT identification badge and sign and print their name on the receipt for Collection/Delivery of CDs Form. They should immediately return to the ward and hand the intact CD Envopak bag directly to the Nurse/Midwife in Charge who will then open the bag, check the contents and sign for receipt on the pink copy of the Ward Controlled Drugs Order Book, following the procedures as in Section 2.6.

The person who conveys the Controlled Drug as described in the paragraph above, acts as a messenger, i.e. they carry a sealed container and are responsible for delivering an intact container.

The person acting as a messenger should

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

Messengers for CDs will be PHT staff with valid PHT staff identity badges. This excludes agency nursing staff but includes Healthcare Support Workers employed by PHT.

Current guidance states that CDs may not be transported in pneumatic tubes.

2.6	**Checking and signing for the receipt of a Controlled Drug on the ward/ department**

After the Nurse/ Midwife in Charge accepts the delivery of the CDs on the ward, they should open the CD Envopak bag immediately and check the contents to ensure that the delivered CDs correspond to the order on the pink carbon copy of the Ward Controlled Drugs Order Book. They then sign the "received by" section of the pink carbon copy for each requisition to confirm they have received the stock.

If any discrepancy, breakage of tamper evident seal or suspicious alterations are found on opening the sealed Envopak bag, the nurse should not sign, but should immediately phone the Pharmacy Dispensary and discuss the issue with Pharmacy Dispensary Manager or designated deputy to resolve the matter.

The person who has signed the pink carbon copy to receive the CDs is responsible and accountable for them until the CDs are signed into the Ward/ Department Controlled Drugs Record Book and securely locked away in the CD cupboard.

The CD stock items are then entered into the Ward/ Department Controlled Drugs Record Book (as described in Section 2.7). In PHT, a second Registered Nurse should be available to check the CDs and countersign the entry/ entries in the Controlled Drugs Record Book. In wards/ departments where there is **no second trained nurse available,** registered healthcare professionals (e.g. RODPs, pharmacists) or HCSWs who have been assessed as competent, may witness and countersign the entry.

Empty CD Envopak bags are retrieved on subsequent pharmacy delivery/collection visits to wards and departments.

The CDs are immediately placed inside the CD cabinet. Morphine and diamorphine ampoules of 30mg or more should be physically segregated from lower strength ampoules within the CD cabinet. This can be done by keeping them (in their original packaging) on a separate shelf/compartment, or by placing them within a separate container.

2.7	**Entering received stock in the ward Controlled Drugs record book**

After the Ward Controlled Drugs Order Book has been signed to confirm receipt of the order, the stock must be entered into the Controlled Drugs Record Book.

The correct page must be found for that drug, dose, strength and form.

The following particulars should be recorded by the nurse on the correct page of the Controlled Drugs Record Book:

- Date received
- Time received (in 24 hour clock)
- Name of pharmacy making supply (for hospitals without on site pharmacy only)
- Quantity received (in dose units)
- Serial (page) number of the order
- Signature of Registered Nurse/ Midwife completing the entry
- Signature of witness
- New resulting total balance

The stock balance must be checked to ensure that it agrees with the actual stock present in the CD cupboard.

All entries for a given preparation in the Ward Controlled Drugs Record Book (including receipt, administration and return) must run **in strict chronological order**; therefore it is imperative that entries are made **at the time** a transaction takes place.

2.8. Special rules for high-strength diamorphine and morphine

Wards/departments should NOT hold diamorphine or morphine ampoules of 30mg or more, UNLESS there is a patient whose dose justifies it. Unjustified stocks should be returned to pharmacy/the ward pharmacist, as soon as possible.

If high-strength ampoules are kept, they should be physically segregated from other medicines within the CD cabinet. This can be done by having a shelf/compartment dedicated to high strengths, or by having a small tray, box or re-sealable bag to contain them.

Before drawing up a dose of an injectable opiate, always read the label very carefully. Different strength ampoules and their packaging may look very similar.

2.9 Stock of Naloxone

Ensure at all times that the ward/dept has a readily accessible stock of the opiate reversal agent, naloxone injection. This applies if ANY strength of diamorphine or morphine injection is kept.

2.10 Interim storage of Controlled Drug discharge medicines (TTOs)

When CDs form part of discharge medication and are sent to the wards in advance of the patient leaving the hospital, the medicines should be stored in the CD cupboard. These medicines should be segregated from the ward CD stock and remain in a sealed bag clearly marked with the name of the patient.

In order to maintain an audit trail they should be entered in the ward controlled drug record book and booked out when given to the patient.

2.11 Obtaining Controlled Drug stock when pharmacy is closed

CDs should never be obtained from other Wards/ Departments during normal Pharmacy opening hours. If the request is very urgent the dispensary should be contacted and asked to prioritize and expedite the supply of the order needed.

In exceptional circumstances when the medication is required urgently and the Pharmacy Department is closed, CDs sufficient for a single dose only may be obtained from another ward.

To obtain a CD from another ward, the Unit Bleep Holder or Clinical Site Manager should be contacted to authorize and oversee the transaction. Alternatively the on-call pharmacist can be contacted via switchboard.

The nurse requesting the supply should go to the ward where the required drug is held, taking the patient's drug chart to demonstrate the need for the supply.

The procedure must then follow Section 3.2 for administering and witnessing administration of CDs. This means that the nurse from the ward from where the drug is obtained will accompany the requesting nurse, to the ward where the patient is, to witness the administration.

They must both then sign the Ward Controlled Drugs Record Book to document that the drug has been administered, stating the patient's name and the patient's ward. Thus, no entry will be made in the Ward Controlled Drugs Record Book of the patient's own ward.

It is NOT permitted to transfer ward stock CDs from one Ward/ Department's CD cupboard, and Ward Controlled Drugs Record Book, to another. This would be seen as the nurse supplying a stock of a CD and would therefore be illegal.

If there is any doubt as to the circumstances or the intention of the requesting nurse at any stage, refer back to the Unit Bleep Holder or Clinical Site Manager, without hesitation.

2.12 Self administration of Controlled Drugs

Self administration of CDs should only be allowed in exceptional circumstances because of the security and reconciliation issues concerning CDs. Where this is allowed it should be agreed between a senior pharmacy manager, the consultant in charge of the patient and modern matron for the area concerned.

Patient's own supplies of CDs should be checked by a member of pharmacy staff before use (see section 7).

When patients who self administer CDs require further supplies, these should be dispensed as discharge medication (TTOs).

A separate Ward Controlled Drugs Record Book should be used for recording CDs that have been self-administered.

Supplies of CDs for self administration should be entered in the Ward Controlled Drugs Record Book to ensure that there is an auditable record of their arrival on the ward.

CDs for patients who are to self administer their medicines should be stored in the ward Controlled Drugs cupboard and supplied to the patient, one dose at a time and signed for by the nurse supplying the dose and the patient self administering it. In the case of Morphine Sulphate oral solution (Oramorph), which is schedule 5 CD Inv this may be stored in the patients POD locker.

2.13 Transfer of Controlled Drugs – patient controlled analgesia (PCA)

The transfer of Patient's Own Controlled Drugs is generally dealt with in section 7.

When a patient is set up with a syringe driver (device) for Patient Controlled Analgesia (PCA), the clinician, nurse or midwife setting up the device will ensure the CD preparation is recorded on the inpatient Prescription Record Chart, the PCA record chart and the Ward Controlled Drugs Record Book (see 3.3)

If the patient is then transferred to another ward or department the PCA chart provides detail of the name, form, strength and volume of CD set up for the patient.

No further record is currently required of the exact volume transferred with the patient to the receiving ward or department.

When the receiving ward need to set up additional doses in the device, they will use CD stock from their own ward, in the usual way and record the administration on the inpatient Prescription Record Chart, the PCA record chart and the Ward Controlled Drugs Record Book (see 3.3).

Any surplus CD prepared but not administered will be disposed of (see 3.3 and 3.4)

2.14 Controlled Drugs for Community Midwives

Acquisition of CDs by midwives

- Pethidine used for home confinement by Community Midwives may be obtained from GP Units.
- All stock transactions that occur and administration(s) must be recorded in accordance with the following procedures:
- A Community Midwife who practises from a community unit may obtain a total of pethidine 200mgs (in 2 x 100 mg ampoules) from a supply especially set aside at community units.
- The pethidine must be signed out by two midwives (Community Midwife and Community Unit Midwife). If the pethidine is not used, it is returned to stock at the maternity unit and re-entered in the record book.
- An Inspector of the Home Office Drugs Branch may inspect the drugs and record book of a Community Midwife at any time, as may the Supervisor of Midwives.
- Should a Community Midwife experience difficulty with carrying out the above procedure, she should contact her Maternity Manager or Supervisor of Midwives.
- A list of signatures of each Community Midwife is kept on the Controlled Drugs Book at each GP Unit, and countersigned by the Supervisor of Midwives once a year.

Storage and records

- Records of Pethidine received and administered to a patient must be recorded in the Community Midwife Personal Register/Controlled Drugs Book in the community unit as required by the Supervisor of Midwives
- Once medicines are received by a midwife they become the responsibility of the midwife and should be stored safety and securely.
- Where it is necessary for midwives to keep medicines in their homes, the medicines should be placed in a secure, locked receptacle. If necessary, this should be provided by the Trust.
- Administration of CDs by midwives should be in accordance with locally agreed procedures
- A record of administration of CDs should also be kept in the woman's records.

Returns and disposal

- In addition to the returns procedure above if stock is no longer required by the Supervisor of Midwives or date expired they should be returned to the pharmacy as in 6.1 and the appropriate entry made in the Controlled Drugs Register.

- When a Schedule 2 CD has been prepared/drawn up but is no longer required it should be destroyed as in 3.4 and 6. Where possible the midwife should ask a member of the family to witness the destruction.

- The midwife should be supplied with sharps boxes for the purpose of disposal of syringes and needles, including those containing small quantities of CDs. These will be disposed of through the Trusts clinical waste disposal system and never placed in the domestic waste stream.

- CDs that have been prescribed for a woman, whom the midwife is attending, by a doctor for use in her home confinement are her own property and are not the midwife's responsibility. Even if they are no longer required they will not be removed by the midwife, but the woman should be advised to return them to her local community pharmacy for destruction.

3. Administration of Controlled Drugs

3.1 Staff authorised to administer and witness Controlled Drugs administration

CDs must be administered only by a Registered Nurse/ Midwife, doctor or Registered Operating Department Practitioner (RODP).

Two people (preferably two Registered Nurses/Midwives, but a minimum of one Registered Nurse/ Midwife) must witness the entire procedure from the removal of the drug from the CD cupboard through preparation of the dose, its administration to the patient and the destruction of any surplus dose not required. Most acute PHT ward areas should have at least two Registered Nurses available. Outside of the acute Trust setting, or in wards/departments where there is no second registered nurse, or in an emergency, other registered healthcare professionals (e.g. RODPs, pharmacist), or Healthcare Support Workers, who have completed a competency training pack and been assessed as competent, may witness the administration.

It is not acceptable for two staff to select and prepare a dose of a Controlled Drug for administration by a third person.

CDs must be administered only in accordance with the written directions of a suitably qualified prescriber. The only exception to this is Midwives who have provisions in law to possess and administer certain CDs in the course of their professional practice, (section 2.13).

3.2 Procedure for administering and witnessing administration of Controlled Drugs

General good practice procedures for the preparation and administration of medications should be followed as per the Medicines Policy and associated supporting documents.

Additionally:

- CDs should **not** be administered as part of the routine drug administration round. Regularly prescribed CDs are usually administered separately before the start or after completion of the routine drug round.

- Two Registered Nurses (or staff as described in 3.1) go to the CD cupboard with the patient's prescription record chart.

- The correct page in the Ward Controlled Drugs Record Book relating to the drug/ form/ strength to be administered is found.

- The correct stock is identified and selected from the CD cupboard. Labels should be read very carefully, as different strengths of medicines and their packaging can look very similar.

- The stock level is checked to ensure it is correct and amount required removed, returning the remaining stock to the CD cupboard, noting the balance.

- The dose to be given is then prepared against the prescription, carefully checking all details on the prescription record chart as below.

- Verbal orders for administration of CDs are not acceptable.

1. Check drug / preparation
Drug Name
Drug Form (e.g. tablet, oral liquid, injection etc.)
Dose/ Strength/ Formulation (e.g. MR)
Expiry date
Details of preparation

.

2. Check the patient
Both staff attend to the patient's bedside for the administration of the dose
Positively confirm the patient's identity and date of birth with that on the prescription record chart. If the patient is unable to provide a verbal response, the patient's wristband or photograph (if used) MUST be checked.
Provide an explanation to the patient about the process, thus gaining implied consent
One person will administer the drug whilst the other person witnesses the act.

- **Both** staff then complete the entry and sign the Ward Controlled Drugs Record Book.

3.3 Recording administration in the ward Controlled Drugs record book

The following information is recorded in the Ward Controlled Drugs Record Book after administration

- The date. This must be stated. Ditto marks or arrows to indicate the same day or time are NOT acceptable.
- The time of administration in 24 hour clock notation, e.g. 19.15
- Patient's first name and surname, Mr or Mrs X alone is not acceptable.
- Drug (name formulation and strength) in which administered (this will already be recorded on the header of the sheet used to record the administration.
- Amount administered. If only part of the CD is given, the amount administered and the amount wasted must be witnessed and fully documented in the Ward Controlled Drugs Record Book. For example, if only 2.5mg diamorphine is required from a 5mg ampoule this must be documented as 2.5mg given, 2.5mg wasted.
- If a patient refuses or spits out the medication, record this fact in the Ward Controlled Drugs Record Book and on the prescription record chart. Discard any remains of the dose in a sharps bin as below (Section 3.4).
- The "administered by" and "witnessed by" columns must be signed. Staff may prefer to take the Ward Controlled Drugs Record Book with them to the patient so that they can sign immediately.
- The prescription record chart must also be signed as per the Medicines Policy.
- The new stock balance must be calculated and checked.

- Individual doses of CDs prepared but not administered should be destroyed by a registered nurse, midwife or registered health care professional on the ward or department in the presence of a witness and reason documented in the Ward Controlled Drugs Record Book. For methods for disposal of small quantities of CDs see 3.4 below.

NB: In the rare situations where CDs need to be signed out to a patient on another ward the ward name must be recorded next to the patient's name in the Ward Controlled Drugs Record Book (see section 2.9)

Community Midwives using pethidine for home confinement must keep their own detailed records of administration and stock accountability (section 2.10).

3.4 Disposal of wasted part of Controlled Drug doses

This applies only to parts of CD doses that are to be wasted after being prepared for administration to a patient. Expired or unwanted CDs must be signed out and taken for destruction as per Section 6.

Wasted part of CD doses should be rendered irretrievable on disposal

- Small quantities of liquid should be soaked onto either a tissue or other absorbent material, which is then disposed of in a clinical waste bin or sharps box.
- Larger quantities of liquid should be put into a sharps box together with a handful of cat litter (Request from Pharmacy if required)
- Solid dosage forms should be dropped directly into a sharps box to prevent the drug being recovered.

All transactions should be correctly accounted for.

4. Record keeping in the Controlled Drugs record book

4.1 The Controlled Drugs record book

At any given time, each ward should have only **ONE** Ward Controlled Drugs Record Book for ward stock, and, if applicable, **ONE** for patients' own CDs (see also Section 1.3 Security of CD Stationery and Section 7 Patients Own Controlled Drugs) unless by prior arrangement with the Ward Pharmacist.

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

4.2 Page headings

Each different preparation or strength should have its own dedicated page

The approved name, form and strength of the preparation should be written at the top of each page of the Ward Controlled Drugs Record Book. However, where similar products exist it is important to distinguish between e.g. modified release and plain formulations, the brand name should also be included in brackets.

Example

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

4.3 Indexing

Each Ward/ Department Controlled Drugs Record Book should have a dedicated index page.

Each preparation recorded in the Ward Controlled Drugs Record Book should also be entered on the index page.

Page numbers for each preparation should be kept up to date on the index page. When starting a new Ward Controlled Drugs Record Book it is useful to try and anticipate how many pages will be needed for each preparation by looking at the previous Ward Controlled Drugs Record Book and leave more pages for high usage items. This will help to enable entries to be entered in sequential order rather than having to find blank pages later.

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.

4.4 Starting a new page for a drug in the ward Controlled Drugs record book

A new page should be started only when the current page has no further room for new entries. Do not use the bottom line of the Ward Controlled Drugs Record Book to record administration or stock checks. This should be reserved for use to complete the audit trail for balance transfers from page to page and also when a new Ward Controlled Drugs Record Book is started.

When a new page is started, cross-reference should 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”

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

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 your Ward Pharmacist for advice if balances appear to require adjustment.

The index page should be updated to reflect the new page number

4.5 Correcting mistakes

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 Ward Controlled Drugs Record Book; **not even with a single line**.

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”) should be made in the margin or at the bottom of the page and then signed and dated.

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

Pages or part-pages must NEVER be torn out of the Ward Controlled Drugs Record Book.

4.6 Starting a new Ward Controlled Drugs record book

A new Ward Controlled Drugs Record Book should be requested from the Pharmacy Department only when no further blank pages are left in the current Ward Controlled Drugs Record Book.

The issuing Pharmacy Department maintains a written record of Controlled Drugs Record Books issued to each Ward/ Department. Duplicate books will not be provided. See Section 1.3 Security of CD Stationery.

All Controlled Drug balances should then be transferred from the old Ward Controlled Drugs Record Book to the new one. This should be carried out by two Registered Nurses/ Midwives. In Wards/ Departments where there is no second Registered Nurse, another registered healthcare professional (e.g. pharmacist, RODP), or HCSW who has been assessed as competent, may check and countersign this process. The date of the last entry should be written on the front cover of the old Ward Controlled Drugs Record Book, and the date of starting should be written on the front cover of the new one.

Appropriate cross-references should be made in both old and new Ward Controlled Drugs 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 Ward Controlled Drugs Record Book should be crossed through with a single diagonal line, therefore preventing any further entries.

Once decommissioned, the Ward Controlled Drugs Record Book should be sealed with ward ID sticky tape and signed and dated. Old Ward Controlled Drugs Record Books must be locked in a secure place at ward/ department level. It is a legal requirement that Ward Controlled Drugs Record Books are kept for 2 years from the date of last entry and can then be destroyed as confidential waste.

5. Controlled Drug stock checks

5.1 Frequency of Controlled Drugs stock checking

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

Two Authorised Persons (see 5.2) should check the actual quantity of CD stocks present in the CD cupboard against the balances in the Ward Controlled Drugs Record Book and reconcile discrepancies **at least once a week**. The frequency of CD stock checks depends on perceived security issues, such as the number of CD transactions per day. On busy wards and departments the frequency of stock checks may be increased to **once a day** (or more often) at the discretion of The Nursing Management Team or Nurse in Charge.

5.2 Persons authorised to carry out stock checks

The person carrying out the ward stock check must be a Registered Nurse.
The person witnessing the stock check will be a second Registered Nurse or other registered healthcare professional (e.g. pharmacist, RODP),

OR

In wards/departments where, or during times when, wards/departments operate using only one qualified nurse, a HCSW who has been assessed as competent may sign to witness the stock check.

When undertaking a stock check with a HCSW:

- The Registered Nurse leading the check remains professionally accountable for accurate checking procedures and for follow up action if a discrepancy is discovered;
- The HCSW must be suitably trained and competent to undertake the check;
- The HCSW must understand their responsibility in the checking process. This is defined as "to confirm that the balance recorded in the CD Record Book accurately reflects the total stock held."

5.3 Procedure for stock checking

Starting at the front of the Ward Controlled Drugs Record Book work systematically turning through the pages.

Checks should take account of the following points:

- Checking the balance in the Ward Controlled Drugs Record Book, not the reverse, to ensure all balances are checked, i.e. each item with a positive balance should be checked in turn, counting the quantity of that drug, strength and formulation in the CD cupboard.
- It is not necessary to open packs with intact tamper evident seals.
- Stock balances of liquid medicines should generally be checked by visual inspection but the balance must be confirmed correct at the completion of each bottle.

Each stock item balance check should be recorded on the relevant page of the Ward Controlled Drugs Record Book. This should state: date and time of stock check, "Check of Stock Level" and be signed by the two authorised members of staff concerned.

If a discrepancy is found it should be investigated without delay (see 5.5 below)

During the stock check, all pages of the Ward Controlled Drugs Record Book should be checked to ensure there are no missing pages.

5.4	**Controlled Drugs stock inspections by pharmacy staff**

A pharmacist or authorised technician should make an independent check of the CD stocks held in each Ward/ Department at least once every 3 months using the Ward/ Department Controlled Drugs Inspection Form (PHPSF 03.005).

The stock check will include the following:

- A check of sample CD requisition copies to ensure that they have been entered correctly in the Ward Controlled Drugs Record Book
- A review of security and quality of record keeping
- Checking and updating the list of authorised signatories for CD requisitions
- A check of exceptional usage of CDs
- A check of the physical security arrangements for CDs, CD stationery and the key holding policy

The procedure may also include a check of patient's own CDs held on the ward at the time to ensure that they have been properly entered into the Ward Controlled Drugs Record Book, administration is properly recorded and that there are records of them being handed back to the patient via the pharmacy on discharge.

Records of the stock check should be clearly in ink in the Ward Controlled Drugs Record Book and on the Ward/Department Controlled Drugs Inspection Form PHPSF 03.005. These should be signed by the person who carried out the inspection.

A copy of the Ward/Department Controlled Drugs Inspection Form should be handed to the nurse or midwife in charge.

This should be documented by an entry for each item checked in the Ward Controlled Drugs Record Book as "Pharmacy stock check", dated and signed by the Pharmacy staff.

The Ward/ Department CD Inspection Form is to be signed by the checking Pharmacist or Pharmacy Technician and the Witnessing Nurse/ Midwife in Charge. Checks carried out by Pharmacy Technicians must be discussed with, and the Form countersigned by, the Ward Pharmacist.

Any action points or recommendations arising from the inspection will be noted on the CD Inspection Form.

The completed CD Inspection Form should be photocopied and the copy given to the accountable Clinical Ward/ Department Manager to review, sign and keep as a record. The original of the completed Form should be given to the Principal Pharmacist Operations Manager.

Any concerns or discrepancies should be noted and discussed with the Nurse/Midwife in Charge. Discrepancies which cannot be resolved should be notified at once to the Pharmacy Operations Manager, who should consider informing the Trust's Accountable Officer for Controlled Drugs.

Summaries of these inspections should be made available to the Trust's Accountable Officer for CDs periodically, and/or at his/her request.

5.5 Procedure for dealing with stock discrepancies

If any discrepancy in a Controlled Drug quantity is discovered:

Every possible step should be taken to identify the cause of the loss and/or correct the omission(s) in the Ward Controlled Drugs Record Book.

See Appendix 2: Flow diagram of the procedure to follow when a discrepancy is discovered in the Ward Controlled Drugs Record Book.

If the discrepancy cannot be clarified and corrected during the shift having performed a preliminary investigation, the Clinical Ward/ Department Manager should be informed. Out of hours the Clinical Site Manager should be contacted and the matter reported to the Principal Pharmacist Operations Manager or Dispensary Manager the next working day.

An adverse incident report form should be completed and sent to the Trust Risk Management Department (and copied to the Principal Pharmacist Operations Manager).

The Police should be informed of major or suspicious CD Incidents as per Appendix 3, (Flow diagram of the procedure to follow when a discrepancy is discovered in the Ward Controlled Drugs Record Book), at the discretion of the Nursing/ Midwifery/ Pharmacy Management and/or the Counter Fraud Specialist.

The Trust's Accountable Officer for CDs should be informed in the case of all major incidents or those where there is suspicion of wider fraud/misuse.

6. Disposal or return of Controlled Drugs to the pharmacy department

6.1 Return of expired Controlled Drugs or unwanted Controlled Drugs stock

Within PHT and PCT managed wards on the QAH, SMH and SJH sites Controlled Drugs will not be destroyed at ward level. On PCT managed wards on community hospital sites Controlled Drugs may be destroyed at ward level at the discretion of the Accountable Office for the PCT which manages the ward in question.

Where Controlled Drugs are to be returned to a PHT Pharmacy Department they should never be included amongst consignments of unwanted medicines. CDs should be returned to the pharmacy if:

- The CD has expired
- The CD is no longer required on the ward (e.g. the patient's drug treatment has changed, patient has been discharged or deceased)
- A CD dispensed for an individual patient, including patient's own CDs are required by the pharmacy for review and relabelling for discharge medication.

If CDs are no longer needed, the ward pharmacist should be asked to sign the CDs out of the Ward Controlled Drugs Record Book and take the stock back to the Pharmacy Department. For Wards or Departments who do not have a regular pharmacist visit, a pharmacist can be asked to attend or a Registered Nurse/ Midwife must take the unwanted drug and Ward Controlled Drugs Record Book to the Pharmacy Department. A pharmacist will sign the stock out of the Ward Controlled Drugs Record Book, witnessed and countersigned by the nurse/ midwife. The pharmacist will then deal with the returned CDs as below.

In all cases the return must be documented in the Ward Controlled Drugs Record Book to indicate that the stock has been removed. The pharmacist and nurse/midwife will both sign the entry in Ward Controlled Drugs Record Book stating the:

- Date
- Time
- "Returned to pharmacy" and reason for return (e.g. out of date)
- Quantity returned
- A new total balance must be entered, even if this is zero

The pharmacist will then remove the stock and take it back to the Pharmacy Department. Stock previously issued by the Pharmacy Department that meets suitability criteria may be returned into pharmacy stock in accordance with PHPSWI 14.002. Otherwise, expired or unwanted CDs will be signed into the pharmacy CD Destruction Register to be ultimately disposed of as per PHPSWI 03.001.

Messengers other than registered nurses or midwives and pharmacists or pharmacy technicians may not be used to return CDs to the pharmacy department.

The pharmacy department may be telephoned for advice concerning return of CDs in specific areas and, on occasions, a pharmacist may need to be sent to collect CDs for disposal, e.g. in community hospitals.

6.2 Disposal of broken/defective ampoules

Accidental breakage of ampoules and other fragile containers has been known to occur from time to time. In this circumstance the drug can be discarded and safely disposed of on the ward in the presence of two Registered Nurses as described in Section 3.3 for wastage. If a second Registered Nurse is not available on the ward at the time, a senior nurse, the Clinical Site Manager or a Registered Nurse summoned from another ward will witness the breakage and subsequent destruction.

The ampoule(s) need to be accounted for so should be signed out of the Ward Controlled Drugs Record Book by the two Registered Nurses, stating the reason.

In all cases of broken ampoules the Nurse/ Midwife in Charge of the Ward/ Department should be informed and an adverse incident form should be completed.

If a CD medicine is found to be defective (e.g. ampoules already broken or cracked, the contents appear cloudy or appear to contain contamination), the item(s) should be clearly marked "do not use," and retained in the CD cupboard. The ward pharmacist should be contacted to return the stock to the Pharmacy Department as soon as possible during normal hours. The pharmacist will then assess the problem, removing the offending items if necessary and make appropriate entries in the Ward Controlled Drugs Record Book. If necessary, they will also report the problem to the manufacturers and check any remaining pharmacy stocks.

6.3 Denaturing and disposal of Controlled Drugs

The method of disposal of CDs within the pharmacy department will be within the current Home Office guidance, Waste Management Regulations and Environment Agency guidance.

This includes any pharmacy stock of obsolete, expired or unwanted schedule 2 CDs, stock returned from wards and Patients Own CDs returned to the pharmacy for destruction.

CDs awaiting destruction will be entered into the Pharmacy Controlled Drugs Destruction Register by the pharmacist receiving the CD or identifying that stock is out of date etc. in accordance with Pharmacy Work Instruction PHPSWI03001 Controlled Drugs Transactions and Record Keeping

CDs awaiting destruction will be stored in a segregated section of the Pharmacy CDs Cupboard. Approximately monthly this will be boxed in numbered packages and decanted to a separate CDs Cupboard prior to denaturing and disposal.

Denaturing of CDs, which have been returned from wards and departments or patients, will be undertaken by a pharmacist, independent of the pharmacy department involved, nominated for the purpose by the PHT Authorised Officer for Controlled Drugs.

Denaturing of CDs, which have remained as pharmacy stock, including retention samples etc in pharmacy manufacturing, will be undertaken by a pharmacist, independent of the pharmacy department involved plus an independent non-pharmacy manager nominated for the purpose by the PHT Authorised Officer for Controlled Drugs sanctioned by the General Manager for Clinical Support Division.

When Schedule 2 CDs are denatured the following details must be entered onto the Controlled Drug Destruction Register:

- Reference number of the package being denatured
- Drug, name, form and strength
- Quantity being destroyed
- Date of denaturing
- Signatures of the authorised person carrying out the denaturing plus the departmental witness

The denaturing process will be in accordance with the Pharmacy Work Instruction PSS&PTWI016 Denaturing of Controlled Drugs and will always be witnessed by an authorised member of pharmacy staff from the pharmacy department concerned. Both the designated pharmacist and departmental witness will sign off each page of the Controlled Drugs destruction register during the checking and denaturing process.

Destruction of CDs should take place with sufficient frequency to ensure that excessive quantities are not stored to await denaturing and disposal.

Once denatured the CDs will be sent to the PHT clinical waste contractor labelled as “Contains Pharmaceutical Waste – for incineration,” placed in a designated yellow Eurobin and stored within the pharmacy prior to collection by the PHT Clinical Waste Porter

Thereafter the Yellow Eurobin will be stored in the secure clinical waste storage area prior to collection by the PHT Clinical waste contractor

7. Patients' Own Controlled Drugs

7.1 Dealing with Patients Own Controlled Drugs

Patients' Own CDs (POD CDs) must be kept securely in the ward's Controlled Drugs cupboard and **not** in the patient's possession, nor in a bedside POD locker, nor in the drugs trolley. The only exception to this is where patients are to self administer their CDs (see 2.10).

A separate Ward Controlled Drugs Record Book should be used to record receipt of patients' own CDs. There should be one page for each drug belonging to each patient. In Wards or Departments where patient's own CDs are rarely brought in, it is acceptable to record receipt in the back of the Ward Controlled Drugs Record Book. However, care must be taken to leave sufficient room after each entry so that clear records are made when the CDs are administered, or signed out to be returned, either to patients or to Pharmacy, or transferred with the patient to another ward.

The following information should be recorded:

- Date that the CD was received onto ward
- Patient's first name and surname
- Patient's address and/or hospital number
- Approved name of drug
- Pharmaceutical form (e.g. tablets/ injection etc)
- Formulation (e.g. modified release)
- Strength
- Quantity (in dose units)
- Signature of Registered Nurse completing the entry
- Signature of witness (Registered Nurse or other staff as authorised in Section 3.1)

If there is ward stock available, then this should normally be routinely used. On occasions it may be necessary to use a patient's own CDs (e.g. because the medication is non-formulary or needed before pharmacy is open). If possible PODs should be checked for suitability for use by a member of pharmacy staff prior to administration. If necessary, ward staff may do this referring to the Medicines Policy referring to "criteria for suitability of PODs for continued use. Administration must be recorded, together with quantity of that patient's own CDs remaining.

If a patient is transferred between wards, the POD CD should be signed out of the Ward Controlled Drugs Record Book and sent on with the patient and handed to the Nurse in Charge to sign in to the Ward Controlled Drugs Record Book on the new ward.

On discharge, the POD CD may be returned to the patient, if still appropriate, but care should be taken to ensure that the preparation is still currently prescribed on a TTO, and that the dose and directions are still the same. The safest way to achieve this is to ask the pharmacy to collect the CDs along with other PODs and sign them out of the Ward Controlled Drugs Record Book. Alternatively they may be returned to pharmacy along with other PODs, the Discharge Prescription sheet and the Ward Controlled Drugs Record Book for signing out by a registered nurse and a pharmacist.

If the medication is no longer appropriate this should be explained to the patient and, with their permission, the CD returned to the Pharmacy Department for destruction. See Section 6.1

An entry must be made in the Ward Controlled Drugs Record Book if the POD CD is returned to the patient on discharge. This should be witnessed and countersigned by staff as authorised in Section 3.1.

Patient's own Drugs will never be used to treat another patient.

Illicit substances should be handled according to the Trust Policy and Procedure for Dealing with Suspected Possession of Illegal Substances on Trust Premises Illegal Substances Policy

7.2	**Child Protection**

Parents who are substance misusers sometimes bring CDs on to hospital premises. On request and in exceptional circumstances - agreed between a senior pharmacy manager, the consultant in charge of the patient and modern matron for the area concerned. Parent's Own CDs may be stored in the ward CD cupboard and dealt with in the same way as Patients Own CDs (section 7.1). However the CDs will only be kept in the Ward CDs Cupboard, they will be clearly labelled and segregated to other CDs. Records will be kept as in section 7.1.

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

8. Clinical Trials

Procedures for the use of controlled drugs in clinical trials must comply with the Misuse of Drugs Regulations (MDR) and local policies for the management of clinical trial medicines, in addition to clinical trials legislation and MHRA guidance on clinical trials.

8.1	**Storage and records**

Within the pharmacy, clinical trial CDs will be stored separately from routine CD stocks. They do not have to be stored in a separate CD cupboard but must be clearly segregated from routine stock. Separate pages in the register should be used to record receipts and issues, in addition to clinical trial documentation, so that a running balance of trial stock can be maintained.

If a discrepancy is identified an adverse incident report form should be completed as above (section 5.5). A record of any investigation should be kept with any clinical trial documentation. The sponsor of the clinical trial and investigator should be informed of any discrepancies.

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

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

Clinical trial material containing CDs, returned by patients, clinical trials nurses or other authorised staff, stock which is date expired or surplus to requirements will be booked into the pharmacy Controlled Drugs Destruction register in the normal way (sections 6 1, 8.3, 8.4) and stored in a segregated section of the Controlled Drugs Storage Cupboard prior to destruction.

8.2 Labelling

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

8.3 Disposal

Clinical trial CDs must be destroyed in the same way as other CDs (see section 6.2). However this destruction may need to be carried out following the monitoring instructions with the trial sponsor. For example the sponsor may wish to carry out an independent reconciliation prior to any destruction. The pharmacy department will ensure that this is facilitated.

8.4 Clinical trial material returned by patients

Clinical trial material containing CDs, returned by patients, clinical trials nurses or other authorised staff will be booked into the pharmacy Controlled Drugs Destruction register in the normal way (section 6 1)

Drug accountability records should be completed promptly on return of the above.

8.5 Arrangements for research departments

If PHT supplies a research department or other third party organisation, e.g. Rowans Hospice, SMH ISTC, the same governance arrangements for safe use will apply as for elsewhere in the organisation. All the activities should be covered by SOPs and processes should be robust and auditable.

9. Prescribing

9.1 Prescribing Controlled Drugs for inpatients

Prescribers must adhere to the general guidance on prescribing in the Medicines Policy. Prescriptions will be written on the inpatient Prescription Record Chart (PMP458) or PCT equivalent.

Medical Doctors who have achieved full registration with the GMC and suitably qualified registered non-medical prescribers are allowed to prescribe discharge medication for inpatients and for outpatients. In addition, Medical Doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other Prescription Only Medicines [POMs]) on these forms for inpatient use.

The following must be stated:

- drug and dosage form (e.g., capsules, modified-release capsules, oral liquid, injection, patch etc.), even when it is implicit in the proprietary name. The following must be stated:
- The route of administration
- The strength
- The dose and frequency (if prescribed “when required” e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours and a maximum total quantity to be administered in 24 hours)
- Start date
- Signature and bleep number of prescriber.

Include a finish date where appropriate

9.2 Prescribing Controlled Drugs for outpatients and on discharge prescriptions

Prescriptions will be written on the Discharge Prescription Sheet (WKN1006, PMP 871) or Outpatient Prescription sheets (MR 601) as appropriate.

Only Medical Doctors who have achieved full registration with the GMC and suitably qualified registered non-medical prescribers are allowed to prescribe discharge medication for inpatients and for outpatients.

Up to a maximum of 30 days supply should be prescribed.

There may be circumstances where there is a genuine need to prescribed for more than 30 days. Where the prescriber believes that it is in the clinical interest to prescribe for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a note of the reasons on the patient's notes an explanatory note on the patient's prescription would be helpful.

Prescribers must adhere to the general guidance on prescribing in the Medicines Policy. In addition to this, when prescribing Schedule 2 and 3 CDs (with the exception of temazepam and preparations containing it) for outpatient or discharge prescriptions, they must conform to all the requirements of the Misuse of Drugs Regulations for a Controlled Drugs prescription.

Since a change in the Misuse of Drugs Regulations 2001, which came into force on 14th November 2005, the entire prescription no longer has to be written in the doctor's own handwriting but the following must be included on the prescription

- The name and address of the patient and preferably the patient identification number.
- The drug and dosage form must be stated (e.g., capsules, modified-release capsules, oral liquid, injection, patch etc.), even when it is implicit in the proprietary name.
- The strength
- The total quantity of the preparation (e.g. number of tablets/ capsules, millilitres of liquid, or number of dose units) must be written in words and figures.
- The dose and frequency
- Doctor's signature – the only remaining requirement to be in the doctor's own handwriting. The prescriber should also sign any manuscript changes.

Full guidance on CD prescription writing is given in the "Controlled Drugs and drug dependence" section of the current BNF http://www.bnf.org/bnf/bnf/49/openat/29424.htm?q=%22cd%22

Information required	Example
Name of patient	Archibald Smith
Address of Patient	1 High Street, Portsmouth
Drug	Morphine Sulphate
Strength	10mg
Dosage Form	SR Capsules
Dose	20mg
Frequency	Bd
Total Quantity IN WORDS AND FIGURES	One hundred and twenty (120) capsules
Doctor's Signature	M Jones
Date	1/1/2007

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

Controlled Drugs on a prescription will not be released from the issuing Pharmacy for a patient until all the legally required information has been provided. This is a legal requirement and enables all the necessary records to be completed.

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

The use of pre-printed sticky labels with the name, form, strength etc of the drug is not approved within PHT.

9.3 Supplementary prescribers

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

For PHT outpatients only outpatient prescription forms (MR 601) can be used for this purpose.

9.4 Non-medical independent prescribers

Community Nurse Prescribers

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

Nurse Independent Prescribers (formerly Extended Formulary Nurse Prescribers)

Following amendments to the Medicines Regulations, which came into force in January 2006 the range of drugs that nurse independent prescibers are able to prescribe independently has been extended. From 1st May 2006 the nurse prescribers' Extended Formulary was discontinued and qualified nurse independent prescribers are able to prescribe any licensed medicine for any medical condition within their competence, including some CDs for specific conditions. The 2001 Misuse of Drugs Regulations were amended, with effect from 1st May 2006 to reflect the change in terminology relating to nurse independent prescribers (see table below).

NB Within Portsmouth and SE Hampshire qualified nurse independent prescribers are only allowed to prescribe medicines included within the District Prescribing Formulary.

Nurse independent prescribers are permitted to prescribe, administer, or direct to administer the following CDs solely for the medical conditions indicated. Details of the appropriate route of administration for these CDs can also be found in the table below. The Misuse of Drugs Regulations were amended in 2005 to permit a supplementary prescriber, when acting under and in accordance with the terms of an agreed individual clinical management plan (CMP) to prescribe and administer/or supply or direct any person to administer any CD provided that the CD is included in the CMP.

For PHT outpatients only outpatient prescription forms (MR 601) can be used for this purpose.

Controlled Drugs that can be prescribed and administered for specified indications by Nurse Independent Prescribers

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

9.5 Pharmacist independent prescribers

Pharmacist independent prescribers are not allowed to prescribe CDs.

9.6 Prescribing Controlled Drugs for administration by community nurses

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

- name of drug
- dosage
- frequency,
- route / method of administration.
- any special precautions/instructions

10. Management of Controlled Drugs in in-house operating theatres

10.1 Accountability and responsibility

Accountable individuals

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

The registered nurse, midwife or ODP in charge can delegate control of access (i.e. key-holding) to the CD cupboard to another, such as a registered nurse or ODP. A nurse or 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, midwife or ODP in charge or doctor. However, legal responsibility remains with the registered nurse, midwife or ODP in charge: the task may be delegated but the responsibility cannot. The person to whom the task has been delegated is still professionally accountable for his/her actions.

Similar conditions apply to requisitioning and checking CDs.

Standard Operating Procedures (SOPs)

Written Operating Procedures for the management of CDs in in-house operating theatres and recovery wards are a PHT requirement and all staff, including anaesthetists should be aware of them. Procedures are finalised only after a period of consultation to ensure ownership and practicality within the confines of compliance with legal requirements and Department of Health Guidance.

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

10.2 Controlled Drugs stocks

The pharmacy department holds a list of CDs that are held in each theatre as stock items. The contents of the list should reflect patterns of use in the theatre and should be agreed between the pharmacy technician or pharmacist responsible for stock control of medicines in the theatre and the operating department manager, appropriate medical staff and the registered nurse or midwife in charge.

The list should be modified with the agreement of the above parties and should, at least, be reviewed annually.

10.3 Requisitioning of Controlled Drugs

The registered nurse, midwife or ODP in charge of an operating theatre or theatre suite is responsible for the requisitioning of CDs for use in the theatre.

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

Wherever practicable there should be separation of duties with regard to ordering and receipt of CDs.

Ward Controlled Drugs Order Books will be used for requisitions for CDs (Section 1.4). Requisitioning and Receipt of CDs will comply with general requirements for requisitioning and receipt of CDs (section 2).

10.4 Storage of CDs

The storage arrangement for CDs in Theatres will conform to the general requirements for storage of CDs on wards and departments (section 1.2) and security of CDs (section 1.3)

Controlled Drugs refrigerators will be provided to ensure secure maintenance of cold chain for aseptically prepared Controlled Drug injections.

10.5 Record keeping

The records of receipt and administration of CDs in theatres will conform to the general provisions for writing in Controlled Drug Order and Record Books (section 1.5), entering received stock in the Ward Controlled Drugs Record Book (section 2.7) and Administration of CDs (section 3).

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

10.6 Controlled Drug stock checks

Stock balances of CDs entered in the Controlled Drugs Record Book should be checked in accordance with the general procedure for stock checking (section 5.3)

The frequency of stock checking will comply with general requirements for frequency of CD stock checking (section 5.1). Frequency should be determined by the registered nurse or midwife in charge and should be sufficiently frequent to ensure that discrepancies can be readily identified and investigated.

10.7 Archiving of Controlled Drugs records

The archiving of CDs records should conform to the general provisions for Archiving of Controlled Drugs records (section 1.5)

10.8 Prescribing of Controlled Drugs

The anaesthetist on duty is usually responsible for prescribing CDs but other prescribers may also be involved. Nurse independent prescribers may also be responsible for prescribing or administration of diamorphine or morphine for post-operative pain.

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

Prescribing of CDs will follow the general provisions for prescribing of Controlled Drugs for inpatients (section 9.1)

10.9 Administration of Controlled Drugs

The Practice of issuing "active stock" to the anaesthetist then returning the unused portion to stock, recording both issues and returns in the theatre CD record book should be avoided. An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed and witnessed (section 3.3).

Any surplus drug should be rendered irretrievable following the general provisions for Disposal of wasted part of CD Doses (section 3.4)

Injectables should be treated as intended for single use only unless the label specifically states that they are licensed for multiple use or to provide more than a single dose on any one occasion.

A record of administration should be made on the appropriate chart immediately after administration by the person who administered the CD. This should include the date, the identity of the person, the dose administered and the time of administration.

10.10 Patient controlled analgesia (PCA)

The Trust has a special "PCA Prescription Chart (Adult)." This defines the PCA Device to be used, the drug (morphine) and concentration, the initial volume, the lockout time, the PCA bolus and limit in mg or ml. In addition the chart has space for date, time and signature of prescriber and space for recording syringe changes.

This documentation is clipped to the inpatient prescribing record chart when the patient is moved from theatre to a surgical ward.

Stock of morphine for PCA syringes will be kept on acute surgical wards to ensure continuity of treatment.

Any surplus CDs should be disposed of in the ward receiving the patient (section 3.4)

10.11 Returning Controlled Drugs to the pharmacy

The disposal of CDs in theatres will conform to the general requirements for Disposal or Return of CDs to the Pharmacy Department (section 6)

Time-expired, no longer fit for use and surplus CD stock (particularly of high strength diamorphine and morphine) should be returned to the pharmacy by the Registered Nurse/Midwife in Charge or authorised deputy as described in section 6.1.

11. Management of Controlled Drugs by hospital pharmacies

11.1 Accountability and responsibility

The Clinical Director Medicines Management and Pharmacy is responsible for management of Controlled Drugs in the Pharmacy. Day-to-day management of CDs, e.g. receipt and issue of dispensary stock, will normally be delegated to a competent registered pharmacist or pharmacy technician. Legal responsibility for CDs remains the responsibility of the Clinical Director.

11.2 Security of Controlled Drugs

In addition to this Policy, the pharmacy has work instructions covering each of the aspects of the safe management of CDs.

The Clinical Director is responsible for ensuring that this Policy and Pharmacy Work Instructions are up-to-date and reflect current legislation and good practice guidance.

Work Instructions are approved by the Clinical Director, who is also the Accountable Officer for Controlled Drugs. The Accountable Officer remains finally responsible for all the systems for the safe management of CDs.

11.3 Ordering and receipt

The ordering of CDs from wholesalers and manufacturers and receipt of CDs should follow the principles of good procurement. Pharmacy Work Instructions and computer records ensure that there is a robust audit trail and that opportunities for diversion are minimised.

There is a Pharmacy Work Instruction PHPSWI 03.001 Controlled Drugs Transactions and Record Keeping, which deals with

- Use of Controlled Drugs Registers,
- Issue of CDs from the Drug Purchasing Centre and Pharmacy Manufacturing Unit, Receipt of CDs
- Issue of CDs as Ward/Departmental Stock,
- Issue of CDs against Prescriptions,
- Extemporaneous Dispensing,
- Supply of CDs to Community Units
- Return of CDs from Wards and Departments,
- Expired Pharmacy CDs

Ordering

Routine orders to wholesalers and manufacturers are placed using the JAC pharmacy system.

Stock levels are determined by need and the nature of the product concerned. Stock levels may be increased prior to known busy periods, where there is uncertainty of supply or, in rare cases prior to known international tension or infectious disease outbreak, e.g. pandemic flu.

Receipt

PHPSWI 03.001 Controlled Drugs and Record Keeping includes a section dealing with receipt of CDs into the pharmacy. This work instruction includes:

- Who should sign for receipt,
- Checking of goods
- Non removal of tamper evident seals
- Dealing with discrepancies
- Arrangement for storage of incorrect items prior to return
- Specifications of the entries required in the Controlled Drugs Register

Recording of receipt will be undertaken immediately on receipt, and in any event no later than 24 hours after receipt.

The balance of stock will be checked and recorded as correct by the person making the entry. Stock is immediately put away into the appropriate section of the Pharmacy Controlled Drugs Cupboard

11.4 Storage

Pharmacy Controlled Drugs Cupboards must, as a minimum, comply with the Misuse of Drugs (safe Custody) Regulations.

11.5 Issuing of Controlled Drugs to wards and departments

PHPSWI 03.001 Controlled Drugs and Record Keeping, includes a section dealing with Issuing CDs to Wards and Departments. This includes

- The procedure for checking that a requisition is valid (complete and signed by an authorised signatory.
- The mechanism for correcting an incomplete or inaccurate requisition
- Specifications for details required on labels
- Specification of entries required in the register including who should make the register entry.
- Arrangements for transfer of CDs to the ward or department.

Electronic systems

Electronic systems are not currently in place for requisitioning of CDs. If they are introduced, safeguards will have to be in place to ensure that:

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

Labelling of Controlled Drugs

PHPSL 05.001.Labelling Standards provides details for labelling of CDs. The label states

- Drug, name , form and strength;
- Quantity
- “Store in A CD cupboard”
- Department/Ward name or number
- Date of issue
- Expiry Date (may be original pack expiry date but some products have a reduced expiry once opened)
- “Keep out of the reach and sight of children”
- Address of pharmacy

11.6 Record keeping

Controlled Drugs registers

The pharmacy service keeps registers of receipt and supplies of Schedule 2 CDs using standard Astron Issue CDs registers and inserts (ref 90-521 for receipts and ref 90-520).

Register entries will be made in consecutive, chronological order. All entries will be made prospectively, i.e. before the stock is taken into or taken from stock. Entries will be in ink or otherwise indelible.

If a mistake is made the entry will not be crossed out but bracketed and an amendment made such that the original and new entries are clearly visible. Amendments will be authorised by a clearly recognisable signature and dated. Where appropriate a footnote should be added to explain the alteration.

The following staff may complete a Pharmacy Controlled Drugs Register

- A pharmacist employed by Portsmouth Hospitals NHS Trust or locum employed on behalf of Portsmouth Hospitals by a locum agency. The latter being authorised to complete Pharmacy Controlled Drugs Registers by the Pharmacy Operational Manager.
- Any pharmacy technician or competent member of pharmacy staff employed by Portsmouth Hospitals NHS Trust or locum employed on behalf of Portsmouth Hospitals by a locum agency. The latter being authorised to complete Pharmacy Controlled Drugs Registers by the Pharmacy Operational Manager or Departmental Pharmacy Manager.
- Any person (including student pharmacy technician or pre-registration pharmacist) who is being trained by a competent member of pharmacy staff (see above), under their supervision. The supervisor should counter sign each entry.

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

For CDs supplied the register entry will include:

- Date of supply/transaction;
- Name and address of ward, person or firm supplied
- Details of the authority to possess, prescriber or licence holder
- CD requisition reference number
- Licence or authority of person supplied
- Amount/quantity supplied
- Name of patient if individually dispensed

For CDs received into stock the register entry will include:

- The date received
- The name and address of the supplier, e.g. wholesaler or Drug Purchasing Centre
- The quantity received
- The name form and strength of the Controlled Drug

The stock balance in the register should be checked against both the quantity in the CD cupboard and the balance shown on the pharmacy stock control system. Stock levels should be checked each time stock is booked into the pharmacy or weekly, whichever is less.

11.7 Liquid preparations

The pharmacy will usually issue only original packs of liquid medicines.

In exceptional circumstances, e.g. individual supplies to addicts, part packs may be issued but running balances will be checked in completion of a bottle, any adjustments will be made to running totals at this stage and verified (section 11.6)

When spillages occur the remaining volume should be checked by a person authorised to complete a Pharmacy Controlled Drugs Register (section 11.6) and an entry accounting for the amount made and countersigned by them.

11.8 Computerised registers

Portsmouth Hospitals Pharmacy Service does not operate computerised Controlled Drugs Registers. It does hold computerised stock levels which drive the ordering system. Checking computerised stock levels is include on part of PHPSWI 03.001 Controlled Drugs Transactions and Record Keeping (para 5.15).

11.9 Checks of Controlled Drugs stocks kept in the pharmacy

All CDs held as pharmacy stock must be checked every three months. The Pharmacy Operations Manager is responsible for managing this process. PHPSWI 03.001 "Controlled Drugs Transactions and Record Keeping (para 5.15)," defines how this process will be carried out and PHPSWI 16.002 "Resolving JAC Stock Discrepancies," defines how stock discrepancies are to be investigated.

CDs stock checks will be carried out by a competent person (section 11.6)

The check will be recorded in the register by means of signature, date and an appropriate entry, e.g. "Stock checked, balance correct."

11.10 Checks of Controlled Drugs stocks held on wards, theatres or departments

Please refer to section 5.4 CD stock inspections by pharmacy staff

11.11 Dealing with Controlled Drugs stock discrepancies within the pharmacy

If during a CDs stock level check a discrepancy is found this must be investigated and resolved without delay. The discrepancy should be reported to the pharmacy operations manager for the department concerned, who will lead the investigation. Any discrepancy, which is not easily resolved, should be reported to the Clinical Director Medicines Management and Pharmacy within one working day.

There should be a careful check of transactions in the register and pharmacy stock control system, (any discrepancy may provide a clue to the potential cause of error).

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

If no error is traced then the Clinical Director Medicines Management and Pharmacy/Accountable Officer will be informed and will decide on whether further action is necessary.

As a minimum an untraced error will require the preparation of an adverse event form. If diversion is suspected this should be copied to the Trust's Counter Fraud Officer.

In cases of suspected diversion the Clinical Director Medicines Management and Pharmacy /Accountable Officer will normally advise involvement of the police.

11.12 Archiving pharmacy Controlled Drugs records

Every requisition, order, private prescription on which a controlled drug is supplied must be preserved by the pharmacy department for a minimum of two years from the date on which the last issue under it was made.

The time periods for archiving CDs Documentation are:

o Requisitions	2 years
o Registers and Controlled Drugs Record Books	2 years
o Extemporaneous work sheets	13 years
o Aseptic worksheets (adult)	13 years
o Aseptic worksheets (paediatric)	26 years
o External Orders and Delivery notes	2 years
o Prescriptions (inpatients)	2 years
o Prescriptions (outpatients)	2 years
o Clinical Trials	5 years minimum
o Destruction of CDs	7 years

Future regulations may increase the period for storage of records. This policy will be updated as additional requirements come into effect.

11.13 Supply of Controlled Drugs outpatients and discharge patients

Patients or their representatives may collect prescriptions containing CDs from the pharmacy department

Pharmacy Staff are required to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in their professional capacity on behalf of the patient.

Where the person is the patient or their representative, the member of pharmacy staff will obtain positive proof of their identity (name, address, date of birth or photo identity) and may refuse to supply the medicine if identity cannot be confirmed.

Where a healthcare professional is acting in a professional capacity on behalf of the patient the member of pharmacy staff must obtain positive proof of their identity (name address and photo identity) and may refuse to supply the medicine if identity cannot be confirmed.

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

- Whether the person who collected was the patient, the patient's representative or a healthcare professional acting on behalf of the patient
- If the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address
- If the person who collected was the patient, or their representative, whether evidence of identity was requested and whether evidence of identity was provided by the person collecting the drug.
- Outpatients or their representatives will sign a receipt to record the number of doses (tablets, capsules, ampoules or volume of liquid) received.

The postal service will not be used for the delivery of CDs to patient's homes

11.14	**Supply of Controlled Drugs to external units (i.e. other health and social services bodies)**

Portsmouth Hospitals Pharmacies hold a wholesaler dealers' license and are, therefore, legally entitled to supply CDs to external organisations.

Portsmouth Hospitals Pharmacies may only make supplies to NHS healthcare or social services bodies and the following non NHS organisations:

- The Rowans Hospice
- St Mary's ISTC

Before making a supply to an external unit other than the above the pharmacy service would need to satisfy itself that the recipient may lawfully possess CDs. A private hospital that is not maintained by voluntary funds or by a registered charity requires a Home Office Licence for each of the CDs that it wishes to stock.

Where the external unit or body is a "designated body" as defined in the Regulations the PHT Authorised Officer must ensure that this designated body has up-to-date SOPS for the use and management of CDs.

Where a service level agreement (SLA) is drawn up for the PHT Pharmacy Service to supply CDs to an external body or unit, the SLA should specify the Work Instructions/SOPs that are to be followed (i.e. those of the provider or purchaser). The SLA will include all elements laid down in section 7.11.2 of Safer Management of Controlled Drugs (October 2007).

If the external body does not have an Accountable Officer then the SLA should specify that this Policy and relevant Work Instructions/SOPs should apply.

11.15	**Ordering of stock Controlled Drugs to external units (i.e. other health and social services bodies, the Rowans Hospice and SMH ISTC)**

CDs are supplied to off-site Wards/ Departments only following the receipt of the original prescription or order in or from the Ward Controlled Drugs Order Book.
In very exceptional circumstances, and on the specific agreement of the Dispensary Manager or designated deputy with a named senior member of nursing staff, stock CDs may be supplied against a faxed copy of the page from the Ward Controlled Drugs Order Book, provided the requestor undertakes to provide the original document to the Pharmacy Department within 24 hours. This does not apply to prescriptions for patients.

CD prescriptions and CD orders must comply with all the legal requirements stated in sections 8 and 2.2 respectively of this policy, and be signed by an authorised signatory, whose name and signature appear on that Ward/ Department's current Staff Authorised to Sign Ward CD Orders List (PHPSF 03.001).

Locally designed and approved prescription record cards and discharge prescription sheets may be used for prescribing a patient's discharge medication. The pharmacy service will manage these prescription forms in the same way as internal prescription forms.

Stock CD orders for Registered Nursing Homes must be countersigned by a doctor working there, whose signature should also appear on the approved list of signatures for that Nursing Home.

CDs should be supplied in a clearly addressed CD Envopak bag, sealed with a numbered tag. The checking pharmacist or technician records the tag number on the "accepted for delivery" line of each corresponding CD Order page, retains the white top copy for filing and places the CDs and Ward Controlled Drugs Order Book in the CD Envopak bag.

An Itemised CD Receipt is produced by photocopying the CD Receipt Memo (PHPSF 03.010) and order page(s). This is enclosed in the CD Envopak bag with the consignment and must be dealt with promptly as described below to confirm receipt and accuracy of the consignment.

For CDs collected by Hospital District transport, a District Transport Despatch Form (PHPSF 15.00X) is also completed, and the tag number recorded in the Envopak column. This Form is then signed by the driver on collection and a photocopy of the Form given to the driver. On arrival, staff accepting the CD delivery should check that the tag number corresponds with that recorded on the District Transport Despatch Form and sign and print name confirming the safe delivery of the package by the driver.

Where CDs are collected by staff or other agencies (e.g. taxis or drivers), the identity/bona fides of the collector should first be verified. Ad Hoc Transport/ Despatch Log (PHPSF Form 04.001) should be used to obtain a signature of receipt for the sealed bag and taxi driver's badge number recorded and the tag number recorded.

With all deliveries to Outside Units, a Record should be made on the CD Despatch to Outside Units Tracking Record (PHPSF 03.009), which is kept in the Pharmacy Department and used to track when the arrival of the CDs has been confirmed by faxing back to the pharmacy of the signed copies of the CD receipts and, also if the faxed CD receipts are not returned promptly, to document when any reminders are given.

With all deliveries to Outside Units, on arrival the Nurse in Charge should check the contents of the enclosed CD consignment against the original order and cross-reference with the Itemised CD Receipt provided. A telephone call should be made to the Pharmacy Department immediately to confirm that the CD consignment has arrived and that the order(s) is/are correct. Each part of the Itemised CD Receipt should then be signed on the "Received by" line and returned via internal mail to the issuing Pharmacy Department, within 3 working days.

In the event of the consignment not arriving when expected or a discrepancy with the contents of the order, the Nurse in Charge should inform and alert the Dispensary Manager to the situation immediately so that any necessary action can be taken promptly.

The CDs should be received into stock in the Ward/ Department Controlled Drugs Record Book and secured in the CD cupboard, as described in Section 2.6.

If the member of staff collecting CDs in person from the Pharmacy Department for an Outside Unit is qualified/authorised to receive CDs on the ward, they may open the sealed bag at the time of collection, inspect the contents, sign the enclosed Itemised CD Receipt and hand it to pharmacy staff. Having signed for the receipt of the CDs they are then responsible and accountable for them until the CDs are signed into the Ward/ Department Controlled Drugs Record Book and securely locked away in the CD cupboard as in Section 2.

11.16 Management of Controlled Drugs returned from wards

PHPSWI 03.001 "Controlled Drugs and Record Keeping," includes a section dealing with Management of CDs returned from wards.
The process of return of unwanted CDs is described above (section 6.1)

12. References

1. Misuse of Drugs Act, 1971
2. Misuse of Drugs (safe custody) Regulations, 1973
3. Misuse of Drugs Regulations, 1985
4. Misuse of Drugs Regulations, 2001
5. The Safe and Secure Handling of Medicines: A Team Approach. A revision of the Duthie Report (1988) led by the Hospital Pharmacists Group of the Royal Pharmaceutical Society of Great Britain March 2005
6. Safer practice Notice 12, Ensuring Safer Practice with High Dose ampoules of Diamorphine and Morphine, NPSA, May 2006
7. Safer Management of Controlled Drugs: Guidance on the Destruction and Disposal of CDs, Dept of Health, October 2006 (Interim Guidance)
8. Safer Management of Controlled Drugs: A guide to good practice in secondary care (England) Dept of Health/Royal Pharmaceutical Society of Great Britain May 2007
9. Statutory Instrument 2006 No. 3148, The Controlled Drugs (Supervision of Management and Use) Regulations 2006, HMSO
10. Medicines Ethics and Practice. A Guide for Pharmacists. Royal Pharmaceutical Society of Great Britain. Issue 31. July 2007
11. Royal Pharmaceutical Society of Great Britain (2002) Factsheets on Controlled Drugs. http://www.rpsgb.org.uk/pdfs/factsheet1.pdf and http://www.rpsgb.org.uk/pdfs/factsheet2.pdf
12. PHT Trust Policy for the Management of Medicines, Feb 2007
13. National Prescribing Centre (2004) A Guide to good practice in the management of Controlled Drugs in Primary Care (England)
14. NMC Guidelines for administration of Medicines 2004

Appendix 2 Procedure when a discrepancy is discovered in the ward Controlled Drugs record book