Clinical

Management of Controlled Drugs in the Hospital Pharmacy Department: Standard Operating Procedures

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1. Introduction
The management of controlled drugs (CDs) will be in line with guidance produced by the Department of Health (Safer Management of Controlled Drugs: a guide to good practice in secondary care (England), May 2007) and NHS England (The Controlled Drugs (Supervision of Management and Use) Regulations 2013). The Accountable Officer for any contracted Pharmacy service will be responsible for the standard operating procedures for the provision of CDs, and the Accountable Officer for SSHFT will be responsible for standard operating procedures for receipt of CDs.

2. Purpose
This policy is required to ensure the safe and transparent supply of controlled drugs within SSHFT.

3. Scope
This policy applies to any member of staff involved with the handling of controlled drugs.
4. Management of Controlled Drugs (CDs) in the hospital pharmacy

**Management of CDs in the hospital pharmacy providing a service via a contract**

Management of CDs will be in line with Safer Management of Controlled Drugs: a guide to good practice in secondary care (England), May 2007. The Accountable Officer for any contracted Pharmacy service will be responsible for the standard operating procedures for the provision of CDs, and the Accountable Officer for SSHFT will be responsible for standard operating procedures for receipt of CDs.

**Management of CDs in the in-house hospital pharmacy**

**Accountability and responsibility**

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

**Security of CDs**

The pharmacies should have standard operating procedures (SOPs) covering each of the aspects of the safe management of CDs such as ordering, receipt, recordkeeping etc. SOPs should be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each one should be clearly marked with the date of issue and review date. SOPs should be approved by the Accountable Officer or by the person to whom he has delegated this task. The AO remains finally accountable for all the systems for the safe management of CDs.

**Ordering and receipt**

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

**Ordering**

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

**Receipt**

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

- Who should sign for receipt
- How the goods should be checked (e.g. matching of the details on the delivery note to the goods) and appropriate stock control documentation completed
- Any tamper-evident seals on packs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks.
- If the tamper evident seal is broken or the contents do not match the expected amount stated on the pack, the pharmacy should contact the supplier.
- The action to be taken if the item received is incorrect
- Arrangements for storage of incorrect items for return, if appropriate
- Specifications of the entry required in the register including who should make the register entry and whether a witness is required
- It is good practice to record receipt at the first opportunity and in any event no
later than 24 hours after receipt.
  • As a matter of good practice the balance in stock should be checked and recorded as correct by the person making the entry
  • The stock must be put away into the appropriate section of the Controlled Drug cabinet promptly.

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

Issuing of CDs to wards and departments
There should be a local procedure for the issuing of CDs to wards and departments. The procedure should ensure the security of the CDs and should be auditable. It should include:
  • The procedure for checking that the requisition is valid (complete and signed by an authorised signatory)
  • The mechanism for correcting an incomplete or inaccurate requisition
  • Specifications of the details required on labels (see below)
  • Specification of entry required in the register including who should make the register entry
  • Whether a witness is required. The decision as to whether a witness is required or not should be made following a risk assessment.
  • Arrangements for transfer of the CDs to the ward or department

Labelling of CDs
There should be a standardised procedure for labelling CDs. The label should state:
  • Drug name, form and strength
  • Quantity
  • “Store in CD cupboard”
  • Department / ward name or number
  • Date of issue
  • Expiry date if dispensed from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g., methadone liquid.)
  • “Keep out of reach and sight of children”
  • Address of pharmacy
Depending on local circumstances, some pharmacies may also wish to add
  • The requisition number
  • The batch number of a product that has been dispensed from bulk
Each carton, syringe or bottle must be labelled individually. In addition, labels may also be placed on outer wrappers or containers.

Record-keeping - CD registers
The Pharmacy department is required to keep registers of receipts and supplies of Schedule 2 and certain Schedule 3 CDs.
  • Register entries must be made in consecutive, chronological order. The entry must be made on the day when the drug is received or supplied, or on the next day. Entries must be in ink or be otherwise indelible
  • If a mistake is made the entry should not be crossed out, deleted, obliterated or defaced; liquid paper must not be used. If an error is found, it must be bracketed and accompanied by a clearly recognised signature; the balance shown should be accurate and easily read. A footnote should be added to explain the alteration.
The following staff may complete the CD register:
• Any registered pharmacist under their own authority
• Any competent member of Pharmacy staff, ideally a regulated healthcare professional under the authority of the chief pharmacist, provided this is included in the SOP
• Any person who is being trained by a competent member of pharmacy staff, such as a trained technician or a pharmacist, under their supervision. The supervisor should countersign entry

Each drug form and strength should be on a different page in the register.
The drug name, form and strength must be written at the top of the page.
An index should be kept at the front of the register.
For CDs supplied, the register entry must also include:
• Date of transaction
• Name and address of person/department supplied
• Licence or authority of person/department supplied
• Amount supplied
• Form in which supplied
• Name of patient, if individually dispensed

For CDs received into stock the following details must be recorded in the CD register:
• The date on which the CD was received
• The name and address of the supplier, e.g. wholesaler, pharmacy
• The quantity received
• The name, form and strength of the CD

The stock balance in the register should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system. The frequency of such checks should be determined locally following a risk assessment. The 2001 Regulations were amended in July 2006 to make clear that the record keeping requirements of the CD Regulations are a minimum and do not prevent any person required to keep a register from including additional relevant information

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

Checks of CD stocks performed by pharmacy staff

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

This check may be undertaken by any competent person approved by the pharmacist with operational responsibility for CDs, the store supervisor, or by a trainee working under their direct supervision and this should be included in an SOP. The check should be recorded in the register by means of signature, date and an appropriate entry, for example, “Stock checked. Balance correct”.

Checks of CD stocks held in wards or departments
All stocks of CDs held in wards and departments should be checked by a pharmacist or pharmacy technician at least every six months and at other times when requested by the
ward or department manager; wards and departments not achieving a compliance standard of 100%, will deliver against a ward/ department specific action plan, and be re-audited before the next 6-monthly audit. The programme is overseen by the Chief Pharmacist and reported to the Medicines Optimisation Committee. The stock check procedure should cover the following:

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

The procedure may also include a check of patients’ own CDs held on the ward at the time A record of the stock check should be made clearly in ink in the CD register. The entry should be signed and dated by the person who carried it out.

Discrepancies
The balance recorded in the hardcopy register and/or, where relevant, the pharmacy stock control system, should be reconciled against the stock of every product in the CD cupboard. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate misuse. The discrepancy should be reported to a senior pharmacist within one working day. There should be a careful check of transactions in the register and in the stock control system to trace an error or omission. If an error is traced then a register entry should be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and the witness. If no error or omission can be traced the Chief Pharmacist and Accountable Officer should be informed. They should decide on what action to take.

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

The time periods for archiving CD documentation are:

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

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

Supply to outpatients and discharge patients
For outpatient prescriptions being given directly to the patient or their representative:

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

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From July 2006, there has been a requirement for persons asked to supply CDs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient. Where the person is the patient or their representative, the dispenser:
  • May request evidence of that person’s identity and
  • May refuse to supply the medicine if he is not satisfied as to the identity of the person
  • Where it a healthcare professional acting in his professional capacity on behalf of the patient, the dispenser:
  • Must obtain the person’s name and address
  • Must, unless he is acquainted with that person, request evidence of that person’s identity; but
  • May supply the medicine even if he is not satisfied as to the identity of the person
Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The new requirement placed on the dispenser therefore allows them:
  • Discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.
**From 1st January 2008,** it will be a requirement to record the following information in the CD register for Schedule 2 CDs supplied on prescription:
  • Whether the person who collected the drug was the patient, the patient’s representative or a health care professional acting on behalf of the patient
  • If the person who collected the drug was a health care professional acting on behalf of the patient, that person’s name and address
  • If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory). And whether evidence of identity was provided by the person collecting the drug.
  The patient’s date of birth may be used as a second check if necessary.

**Transfer of CDs**
At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties. Wherever possible, the drug must be transported in a secure, lockable container and a suitable delivery document completed to provide a full audit trail.

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

**Process for the safe Disposal/destruction**
Unwanted CDs should be denatured and disposed of in a pharmacy. CDs should be disposed of in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used again.
There should be a local policy for disposal of CDs and this policy must be in accordance with current Home Office guidance, Waste Management Regulations and Environment Agency guidance. The methods used for denaturing should be in accordance with Royal Pharmaceutical Society guidance. (See *Medicines, Ethics and Practice (MEP)* published by the Royal Pharmaceutical Society.)

**Process for the safe Destruction of stock controlled drugs**
Any pharmacy- held stock of obsolete, expired or unwanted Schedule 2 CDs not returned by patients that requires destruction can only be destroyed in the presence of an authorised person authorised by the Secretary of State for Health in England and Wales.
**Authorised witnesses in England, Scotland and Wales currently include inspectors of the General Pharmaceutical Council, and police constables. Additionally any NHS England**
Controlled Drugs Accountable Officer may designate an individual and/or class of persons as an Authorised Witness.

**The Associate Clinical Director for Mental Health, the Deputy Director and Director of Nursing are authorised to witness the destruction of controlled drugs at Trust sites.**

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

Further guidance can be found at [https://www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf](https://www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf) Until they can be destroyed, obsolete, expired and unwanted stock CD\$ requiring safe custody, according to arrangements appropriate to their schedule, must be kept segregated from other CD\$ in the CD cupboard.

Stock CD\$ awaiting destruction should be clearly marked in order to minimise the risk of errors and inadvertent supply.

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

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed
- Date of destruction
- Signature of the authorised person in whose presence the drug was destroyed It is good practice for the person carrying out the destruction to also sign against this record.

**Process for the safe Destruction of controlled drugs returned by patients**

These are CD\$ that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used by the patient or their representative to the pharmacy. Controlled Drugs that have been returned by patients do not form part of the pharmacy stock and can be destroyed without the presence of an Authorised Person.

Although recording of patient-returned CD\$ is not a current legal requirement in relation to the Misuse of Drugs Regulations 2001, as amended, The Controlled Drugs (Supervision of Management and Use) Regulations 2013 require Standard Operating Procedures to be in place for maintaining a record of the CD\$ specified in Schedule 2 that have been returned by patients A record of CD\$ returned by patients should be kept and a record of destruction should be made. As a matter of good practice, destruction should be witnessed, preferably by a pharmacist or pharmacy technician.

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

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

Controlled drugs requiring safe custody awaiting destruction should be stored in the controlled drug cabinet separately from pharmacy stock controlled drugs. Destruction of controlled drugs should occur with sufficient frequency (for example, monthly) to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment.
Methods of disposal for CDs

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

All Controlled Drugs in Schedule 2, 3 and 4 (part 1) should be destroyed by being denatured and rendered irretrievable before being placed into pharmaceutical waste containers and sent for incineration.

Wherever practicable, CD denaturing kits should be used to denature CDs. Where this is not possible or practical other methods of denaturing may be used. Details of suitable methods for destruction of CD's in different dosage forms can be found in, Medicines, Ethics and Practice (MEP) published by the Royal Pharmaceutical Society and it is strongly recommended that these methods are used. The low risk position provided by the Environment Agency is based on the use of appropriate and safe methods, which do not pose risks to the environment or human health. Small amounts of CDs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable by emptying the contents into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration”. The other option would be to use denaturing kits following a risk assessment. Where denaturing kits are used, their use should be included in an SOP.