

Section 20 - Controlled Drugs In Operating Departments

1 General Information

Controlled drugs are drugs which are liable to abuse and misuse and are controlled by the Misuse of Drugs Act 1971 and misuse of drugs regulations.

Medicines classified as controlled drugs are listed in the current issue of the BNF.

2 Responsibilities

The Registered Nurse/ODP in Charge of the theatre/department is responsible for ensuring: -

- 2.1 The safe custody of the keys of the controlled drug cupboard. Key-holding may be delegated to other suitably trained, registered healthcare professionals but the legal responsibility rests with the registered nurse/ODP in charge.
- 2.2 Controlled drug cupboard keys should be kept separate from other keys, and only be given to other approved staff when access to controlled drugs is required.
- 2.3 Any duplicate key to the controlled drug cupboard must be kept secure at all times and access to this key restricted. Records of access to the duplicate key must be maintained.
- 2.4 The safe custody of the stocks of controlled drugs. Controlled drug cupboards must be kept locked when unattended.
- 2.5 Entering the new stock in the Controlled Drug Register, confirming, by signing that the drugs ordered were received, and that the total in the register agrees with the physical stock count.
- 2.6 That the regular controlled drug stock check is carried out by staff in the department and that this is recorded, at least once every 24 hours.
- 2.7 Carrying out regular checks to ensure the procedures laid down for dealing with controlled drugs are complied with.

3 Single Dose Ampoules

It is recommended that single dose ampoules be used when parenteral controlled drugs are used in operating departments. The use of communal ampoules is not good anaesthetic or aseptic practice.

SECTION 20 - CONTROLLED DRUGS IN OPERATING DEPARTMENTS

4 Requisitioning Stock From Pharmacy

- 4.1 The registered nurse or ODP in charge of the operating theatre is responsible for the requisitioning of CDs for use in that area. The task of requisitioning CDs can be delegated to authorised staff such as a registered nurse or ODP, however the legal responsibility for the CDs remains with the registered nurse or ODP in charge.
- 4.2 All registered nurses and ODPs who are authorised to order controlled drugs must supply a specimen of their signature to pharmacy before attempting to order controlled drugs for ward stock. This specimen signature must be authorised by the ward/department/theatre manager.
- 4.3 Controlled drugs for ward stock must be ordered in a Controlled Drug Order Book (HMSO Code No. 90-500), which are obtained from pharmacy.
- 4.4 Before an order is written, carbon paper must be correctly inserted between the white top copy and the pink copy, to ensure a carbon copy of the order is obtained.
- 4.5 All orders must be written in ink or indelible ball point pen. Block capitals must be used when writing an order and the ward/department, drug name, form, strength, ampoule size if more than one available and quantity required must be stated.
- 4.6 A separate page with carbon copy is used for each preparation ordered. Each order must be signed in full by an authorised nurse/ODP. Initials are not acceptable.
- 4.7 Any alterations made to an order must be initialled by the nurse signing the order.
- 4.8 When the order is completed the whole order book should be sent to the Pharmacy Department without removing any pages.
- 4.9 The Pharmacy department **will not make a supply** against an incorrectly completed order.
- 4.10 Any order which is to be cancelled before a supply is made must be crossed with two lines, marked "CANCELLED" and signed and dated by the person cancelling the order. Staff must ensure carbon paper is in place before cancelling the order.

The white copy of a cancelled order must not be removed from the order book by ward staff.

SECTION 20 - CONTROLLED DRUGS IN OPERATING DEPARTMENTS

5 Supply Of Theatre Stocks

- 5.1 Pharmacy will maintain a set of SOPs for processing requests for controlled drugs.
- 5.2 Pharmacy will maintain a CD collection log which will provide a full audit trail of all staff involved in the supply and collection of CDs from pharmacy.
- 5.3 Controlled drugs are delivered to wards and departments in sealed tamper evident security envelopes.

6 Delivery Of Theatre Stocks

- 6.1 For delivery of controlled drugs via porter, the controlled drugs will be sealed in a security envelope. The porter or driver will sign the "accepted for delivery" section or the pharmacy CD collection log before the transit bag is handed over by pharmacy.
- 6.2 If a member of ward or pharmacy staff delivers the controlled drugs they must sign the "accepted for delivery" section or CD collection log before leaving pharmacy with the controlled drugs.

7 Receipt Of Theatre Stocks

- 7.1 Each theatre must have its own Controlled Drug Record Book. These books are obtained from pharmacy.
- 7.2 Pharmacy will undertake to check new Record Books within 72 hours of issue.
- 7.3 Controlled drugs delivered to the theatre must be received by a designated person who must check them against the details in the order book. The registered nurse/ODP receiving the controlled drugs should be a different registered nurse/ODP from the person who requisitioned them.
- 7.4 Any discrepancies must be reported to pharmacy immediately.
- 7.5 If there are no discrepancies, the registered nurse/OPD must sign the pink copy of the order in the Ward Controlled Drug Order Book. The pink copy remains in the order book.
- 7.6 Details of the controlled drugs received must be entered in the Controlled Drug Record Book in red ink or red indelible ball point pen. The right hand column must be completed detailing quantity, order number and date. The new balance must agree with the physical stock count. Two registered staff are required for

SECTION 20 - CONTROLLED DRUGS IN OPERATING DEPARTMENTS

this checking procedure, one of the signatures must be that of the registered nurse/ODP who received the controlled drugs.

8 Storage

- 8.1 Controlled Drugs must be kept in a locked cupboard separated from other drugs. The Pharmacy Manger must approve controlled drug storage areas. The cupboards must not be marked in any way to distinguish it from other cupboards. Colour coding of locks and keys is the preferred method for ease of identification by department staff if required.
- 8.2 The key of the Controlled Drugs cupboard is kept separately and carried by the registered nurse/ODP in charge of the department at all times.
- 8.3 Controlled Drug Record Books and Order Books should be kept in a secure place.
- 8.4 The controlled drug cupboard must not be used to store any other items.

9 Supply Of Controlled Drugs For Administration To Individual Patients In Operating Departments.

- 9.1 The registered nurse/ODP in charge of the operating department may supply Controlled Drugs to an anaesthetist for administration to a patient in the operating department.
- 9.2 It is recommended that single dose ampoules be used when parenteral drugs are used in operating departments. The use of communal ampoules is not regarded as either good anaesthetic or aseptic practice.
- 9.3 The registered nurse/ODP must
 - Enter the date and time of the transaction in the Controlled Drug Record Book
 - Enter the patient's name and the dose supplied.
- 9.4 The registered nurse/ODP and the anaesthetist both sign the entry. It is acknowledged that in the operating theatre the registered nurse/ODP signing the, "witnessed by" column is witnessing the dispensing of the controlled drugs to the anaesthetist, and NOT the actual administration of that drug to the patient.
- 9.5 The registered nurse/ODP is responsible for ensuring that each entry in the Controlled Drugs Record Book is complete and that the balance is correct.
- 9.6 The anaesthetist is then responsible for the control of the drugs obtained in the manner described above.

SECTION 20 - CONTROLLED DRUGS IN OPERATING DEPARTMENTS

9.7 The anaesthetist must ensure that each dose administered to a patient is entered in a permanent record, such as the anaesthetic record, patient's drug cardex.

9.8 The key to the controlled drug cupboard must be returned to the registered nurse/ODP in charge of the operating department immediately. The anaesthetist and the registered nurse/ODP in charge of the operating department must, before finishing the shift, check the stock and sign and date the register to confirm that the stock balance is correct.

10 Return/Destruction Of Unused Controlled Drugs

10.1 The anaesthetist is responsible for destroying any unused portion of opened ampoules, or partly used vials of controlled drugs. The amount destroyed must be recorded in the Controlled Drug Record Book and on the anaesthetic sheet.

10.2 A second suitably qualified person, e.g. a registered nurse, medical practitioner or registered ODP or a Pharmacist, must witness the entry indicating the quantity of controlled drug destroyed.

10.3 Un-opened issued ampoules/vials must be returned to stock. They are entered in the Controlled Drug Record Book as being returned to stock by the registered nurse/ODP who signs and dates the entry. The name of the patient from whom the controlled drug was returned is also entered. The anaesthetist also signs this entry.

11. Stock Checks

11.1 The Controlled Drug Order Books and Record Books must be available at all times for inspection by authorised staff.

11.2 The balance of each controlled drug stocked in an operating department should be reconciled at least once every 24 hours. However, it is advised that stocks be checked at the beginning and the end of each operating session.

11.3 The registered nurse/ODP in charge is responsible for ensuring that the Controlled Drug stock checks are carried out.

11.4 Two registered nurses or ODP's, should perform this check (a student nurse or ODP may be the second checker provided they have the necessary knowledge to carry this out).

SECTION 20 - CONTROLLED DRUGS IN OPERATING DEPARTMENTS

- 11.5 The stock checks may be recorded in the Theatre's Controlled Drug Record Book or a separate register may be used. Whichever method is used must be applied consistently and there cannot be more than one system in place.
- 11.6 Each time a controlled drug check is done the date, time and signature of the two registered nurses/ODPs should be recorded for each individual item.
- 11.7 The NHS Lanarkshire Controlled Drug Governance Team will be responsible for a 3 monthly controlled drugs check which will be recorded in the Controlled Drug Record Book against each individual preparation. The registered nurse /ODP in charge must verify the identification of the visiting Controlled Drug Governance Team staff. When the check is completed and no discrepancies are found, the member of the Controlled Drug Governance Team and the nurse/ODP sign the Controlled Drug Record Book accordingly.
- 12. Transfer of Patients to Other Clinical Areas With Controlled Drugs Attached.**
- 12.1 When a patient is transferred to another clinical area with controlled drugs such as infusions, syringe drivers or patches attached to them, the current administration and monitoring chart must be transferred with him/her.
- 12.2 The registered nurse/ODP in the clinical area the patient leaves must check the administration system and volume/quantity remaining and sign, date and time the administration and monitoring chart to ensure that the record is accurate when the patient is handed over, and that the quantity remaining is correct.
- 12.3 The registered nurse in the clinical area to which the patient is transferred to must check the administration system and volume/quantity remaining and sign, date and time the administration and monitoring chart to confirm that the record is accurate
- 13. Patient Controlled Analgesia**
- 13.1 Controlled drugs for administration via a PCA device should be prescribed stating the drug concentration, bolus dose, lock out time and rate of background infusion, if appropriate.
- 13.2 Two registered practitioners that have been trained and assessed as competent must be present during the set up and start of the device. One must prepare the controlled drug to be administered and attach the device to the patient; the other must check each step. They must both verify the programme against the written prescription and must sign the administration record chart, as a record of this check. Both practitioners are equally accountable for the process.

SECTION 20 - CONTROLLED DRUGS IN OPERATING DEPARTMENTS

- 13.3 The following details should be recorded in the Controlled Drug Record Book:
- Date and time when PCA commenced
 - Name of patient
 - Quantity in syringe
 - Form (name, formulation and strength) in which administered
 - Name/signature of practitioners who set up the PCA
 - Name of the prescriber
 - Balance in stock
- 13.4 When the PCA is discontinued, the time, date and the residual amount of drug in milligrams should be recorded on the PCA chart together with the signatures of the two practitioners involved. The residual controlled drug must be disposed of in accordance with Pharmaceutical Waste guidance; small residual amounts are disposed of in a clinical waste bin as long as this volume is less than 1% of the total original content.
- 13.5 The local procedure for PCA must be followed at all times

14. Breakages

All breakages must be reported to the person in charge. Breakages must be entered in the Controlled Drug Record Book explaining the reason for the discrepancy between the physical stock and the amount shown in the Controlled Drug Record Book, and this signed by a two registered practitioners (nurse, midwife or ODP).

e.g.: 30.03.18 1x 50 mg ampoule Pethidine broken by A Nurse (signature), witnessed by B. Nurse (signature)

One of the signatures must be that of the nurse/ODP in charge of the ward/department at that time.

15. Discrepancies

- 15.1 Any discrepancy between the physical stock and the amount shown in the Controlled Drug Record Book must be reported immediately to the registered nurse/ODP in charge as soon as possible and investigated immediately as follows:-
- Check arithmetic since last balance

SECTION 20 - CONTROLLED DRUGS IN OPERATING DEPARTMENTS

- Check **all** controlled drug stock held with a second person.
- Check other register sections of same drug class for erroneous entries.
- Sense-check the Record Book, e.g. check correct pack sizes have been entered, patterns of entry for potential missing entries, unusual quantities etc.
- Check that orders have all been entered by checking ward requisition book, delivery notes etc.
- Check diary and contact all members of staff in the clinical area during the relevant period to verify any supplies made that have not been entered.

If the discrepancy can be resolved at any of the above steps, a bracket should be placed around the wrong entry, initialled and dated.

Any discrepancy which cannot be resolved must be reported to the registered nurse/midwife in charge or department manager, the relevant pharmacy manager and to the Accountable Officer.

- 15.2 Difficulties with measuring quantities of liquid medicines accurately will lead to **minor** discrepancies. The Controlled Drug Record Book volume may, in these circumstances, be adjusted as necessary and signed by two registered nurses/ODP or one registered nurse/ODP and a pharmacist.

16. Action In The Event Of Missing Controlled Drug Cupboard Keys

If a controlled drug cupboard key goes missing, it must be reported immediately to the registered nurse/ODP in charge, who is responsible for ensuring that the following action is taken:-

- Ask all staff on duty to check if they have the keys on their person.
 - If the key is still missing, contact staff who have left the premises. If one of them has the key they must return it immediately.
 - If the key is still missing, conduct a thorough search of the ward/department.
 - If the key remains missing (either assumed lost or with a member of staff unable to return it) then the duplicate key may be issued for use.
 - Carry out a full inventory check
- 16.2 If the lock has to be replaced, contact pharmacy for advice.
- 16.3 Complete a DATIX form recording all relevant details and actions taken and submit to the relevant manager. Inform the Accountable Officer. If there is evidence or suspicion of criminal activity, the police must be informed.

SECTION 20 - CONTROLLED DRUGS IN OPERATING DEPARTMENTS

17. Action In The Event Of A Breach Of Security Involving Controlled Drugs

- 17.1 A breach of security includes any deviation from the procedures that causes actual or potential loss or theft of medicines. Examples of such incidents include:-
- Controlled drugs are found to be missing from department
 - Controlled stationery is found to be missing
 - A key for controlled drug cupboards areas is found to be missing
 - Patients own controlled drugs are found to be missing
 - An unauthorised person has access to controlled drugs or controlled drug stationery
- 17.2 Theft of controlled drugs is a serious criminal offence under the Medicines Act 1968, the Misuse of Drugs Act 1971 and other legislation and will be dealt with accordingly by the NHS Board Accountable Officer, professional and regulatory bodies and the police.
- 17.3 Any person who discovers a breach of security is responsible for reporting it immediately to the charge nurse or line manager. All concerns will be treated in the strictest confidence regardless of whether the subsequent review substantiates these concerns. The registered nurse/midwife/ODP in charge must take reasonable steps to determine that controlled drugs are in fact missing, see para. 15 above.
- 17.4 All breaches of security that cause actual or potential loss or theft of controlled drugs must be investigated and the appropriate corrective and preventive action taken. If medicines have been misappropriated police charges may be brought.
- 17.5 If they are unable to satisfy him/herself that all medicines can be accounted for, they must report suspicions to the relevant manager immediately. Where a non-clinical manager has been informed of suspected or actual theft of medicines, he/she must inform relevant professional leads including the appropriate pharmacy manager.
- 17.6 The NHS Lanarkshire incident policy should be followed in all cases of suspected or actual theft of medicines. Staff should be familiar with and refer to the local Fraud Policy in all cases of suspected or actual theft of medicines.
- 17.7 Should the result of the preliminary review identify any evidence of actual theft, the Accountable Officer and police should be contacted immediately. Any evidence should be retained pending police investigation.

SECTION 20 - CONTROLLED DRUGS IN OPERATING DEPARTMENTS

18. Expired Stock

- 18.1 When department/theatre controlled drugs reach their expiry date the Controlled Drug Governance Team should be informed. A member of the Controlled Drug Governance Team will visit and destroy the expired controlled drugs in situ, witnessed by a member of theatre staff. The theatre staff must verify the identification of the visiting member of staff. The member of the Controlled Drug Governance Team and the nurse/ODP in charge must both sign the Controlled Drug Record Book and indicate the date on which the drugs were destroyed, the quantity and the reason for destroying them. Such entries should be made in red ink/indelible ball point pen.

e.g. 30.03.18 Destroyed by Pharmacy 4 x 10 mg tablets expired.

A Pharmacist (signature), A Registered Nurse/Midwife/ODP (signature).

The CD's will be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used.

- 18.2 Expired stock must not be returned to Pharmacy in the ward box or brought to Pharmacy by a nurse/ODP.

19. Stock No Longer Required

- 19.1 When a theatre/department has controlled drugs which they will not use before their expiry date, they should contact pharmacy. A member of pharmacy staff will visit the ward/department and assess the stock involved. Ward/Theatre staff must verify the identification of the member of pharmacy staff. If it is agreed that the stock should be returned to pharmacy, the member of pharmacy staff and the nurse/ODP in charge must sign the Controlled Drug Record Book and indicate the date on which the drugs were removed and the quantity removed. Such entries should be made in red ink/ball point pen.

e.g. 30.03.18 Returned to Pharmacy - 10 x 50 mg ampoules

A Pharmacist (signature), A Registered Nurse/Midwife/ODP (signature).

- 19.2 Stock considered to be excess must not be returned to Pharmacy in the ward box or be brought to Pharmacy by a member of ward/department/theatre staff.