Management of controlled drugs
Part 1: Legal aspects and safe handling

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Controlled drugs are medicines, available in a variety of formulations, that are subject to specific legislation to monitor their safe storage, management and administration. These drugs are generally powerful analgesics or sedatives that may be addictive or sold and used for recreational purposes. They include those commonly used in health care, such as the analgesics diamorphine, morphine, fentanyl and codeine, and the benzodiazepines such as diazepam and temazepam. Healthcare organisations and staff, such as nurses and pharmacists, must ensure that procedures are in place and followed to meet the legislative requirements for the safe storage and use of these drugs.

This procedure forms Part 1 of a two-part series on “Management of controlled drugs”. It outlines the legislation governing the safe management and handling of controlled drugs in practice and discusses the different categories of controlled drugs and their safe and appropriate use in the hospital environment. Part 1 should be read in conjunction with Part 2, which covers prescription and administration of controlled drugs, including self-administration of controlled drugs. Although the term “medicines” rather than “drugs” is commonly used, this procedure refers to “controlled drugs”, in line with the terminology used in relevant legislation.

Nursing staff working in an area where controlled drugs are stored have a professional responsibility to be aware of and understand the local policies and procedures associated with controlled drugs, and to ensure that these are adhered to. Nurses also need to be aware of Standards for Medicines Management, published by the Nursing and Midwifery Council (NMC, 2010), and the NMC Code (NMC, 2015). The standards cover controlled drugs in

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Controlled drugs are regulated in the United Kingdom (UK) under the Misuse of Drugs Act 1971 and subsequent published amendments. They appear in schedule 2 of the act, which is readily available online. The Medicines Act 1968 is also relevant: it outlines the legal sale, supply and administration of medicines.

Do not undertake or attempt any procedure unless you are, or have supervision from, a properly trained, experienced and competent person. Always first explain the procedure to the patient and obtain his/her consent, in line with the policies of your employer or educational institution.
The Misuse of Drugs Regulations 2001 divide controlled drugs into five schedules, striking a balance between the medicinal or therapeutic benefit of the drug and the harm when misused. For each level, the schedules dictate requirements such as ordering, storage, completing prescriptions and record keeping. The controls are higher for Schedule 1 controlled drugs than for schedule 5. Controlled drugs in Schedule 2 are those most commonly seen in clinical practice, and must be stored in a locked cupboard. The only requirement for Schedule 5 drugs is to retain invoices for two years.

The Government brought in new legislation following the case of Harold Shipman, the British general practitioner who had used controlled drugs to kill his patients. In response to the Shipman Inquiry Fourth Report (2004), which recommended strengthening the governance arrangements for controlled drugs, the Government introduced the Controlled Drugs (Supervision of Management and Use) Regulations 2006 (revised in 2013). The 2013 regulations apply in England and Scotland only. Wales and Northern Ireland have their own equivalent, but separate, regulations.

### Effect of the Shipman Inquiry

**Shipman killed 215 patients**

Former GP Harold Shipman killed at least 215 of his patients, an official report has concluded. The finding confirms 56-year-old Shipman as Britain’s worst serial killer.

Mr Justice Treacy, who led an inquiry into the case, by High Court Judge Dame Janet Smith, has found that a further 230 deaths were “highly suspicious” when there was a “real suspicion” he could have obtained a further 65 victims.

She said: “He betrayed their trust in a way and to an extent I believe is unparalleled in history.”

Harold Shipman was convicted in January 2000 of killing 15 of his patients with lethal heroin injections and was sentenced to life imprisonment for each of the murders.

**Su Li**

Accountable Officer

Edgar Horne Wd NHS Trust

Expiry Date: 22/7/20

ID Number: 264149467

The 2006 regulations, along with the Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007, introduced the need for an Accountable Officer to oversee the safe use, management and destruction of controlled drugs, as well as changes to record keeping. In addition, NHS England and the Medicines and Healthcare Products Regulatory Agency recommend that all large healthcare providers have an identified Medication Safety Officer, often a pharmacist (NHS England/MHRA, 2014).

In July 2015, further amendments to the Misuse of Drugs Act came into force to reflect current policy and changes in the way controlled drugs are now managed in practice. The changes included: the introduction of electronic prescribing for schedule 2 and 3 drugs; mandatory use of specific forms in the community for requisitioning schedule 2 and 3 drugs; the requirement for midwifery supply orders to be patient-specific; and rescheduling ketamine as a class B and schedule 2 drug, due to increasing concern over its misuse.

**2015 amendments to the Misuse of Drugs Act**

Controlled drugs come in a variety of formulations. Continue to become familiar with those used within your clinical area, including usual dose, strength, side-effects and how they are safely prepared. Resources such as the BNFi (in hard copy or online), and local prescribing guidelines, offer invaluable advice on the use of controlled drugs.

Familiarise yourself with policies and procedures

It is your responsibility, if dealing with controlled drugs, to make sure you are familiar with the policies and procedures of the clinical area and organisation. These policies will align with the legislative requirements described above and you must follow them at all times. Local incidents such as thefts can contribute to stricter policies and procedures for some controlled drugs than the legislation requires, for example in relation to the storage of morphine oral solution, codeine or some benzodiazepines.

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The role of the nurse in charge

The nurse in charge of the area where controlled drugs are stored has overall responsibility for their safe storage and use, as well as for ordering the controlled drugs for that area. The controlled-drugs keys need to be held separately from other keys. Other registered nurses or operating department practitioners can hold the keys, and order controlled drugs if delegated to do so, but the legal responsibility belongs to the nurse in charge. See Section 11 in the NMC Code with regard to appropriate delegation (NMC, 2015).

Ordering controlled drugs: specific order book

Always follow local procedures for ordering and receiving controlled drugs. Each area must have only one order book in use at any one time. Schedule 2 and 3 drugs require a specific order book with duplicate pages which must be kept for two years. All relevant stationery must be stored securely in a locked cupboard to reduce the risk of theft and fraudulent misuse. Only those drugs listed in the departmental stock list may be routinely requisitioned, reflecting the patterns of usage in the department (NMC, 2010; Standard 26.14).

Receiving controlled drugs

Always follow the local procedure for receipt of controlled drugs, which will define the appropriate persons permitted to receive controlled drugs and how to identify them—normally a registered nurse, or other appropriate person, such as an operating department practitioner, with a clear identity badge. The pharmacy will send the drugs in a locked or sealed box or container. Controlled drugs will never be left unattended.

Controlled-drugs cupboard

Controlled drugs must be kept in a locked and securely attached cupboard that is used only for storing controlled drugs and associated paperwork (to avoid the potential for tampering with records). The cupboard must meet the specifications of the Misuse of Drugs (Safe Custody) Regulations 1975 and conform with BS2881 (BSI, 1989). Manufacturers will outline how they meet these requirements. The cupboard must be kept locked at all times unless in use, and keys kept with an authorised person and readily available.

Ordering controlled drugs: authorised signatories

The pharmacy will have copies of all the names and signatures of those staff authorised to order controlled drugs (NMC, 2010) and will carefully check these against the order form when processing an order. Controlled drugs are not kept within emergency drugs cupboards. If you need controlled drugs unexpectedly when the pharmacy is closed follow the local policy. It is usually possible to obtain a single dose from another ward or clinical area, with an entry made in the controlled-drug book of that area, as well as the receiving department. Stock should not be transferred between wards/clinical areas.

Checking the delivery against the order

As a matter of good practice, the receiving person should not be the same person who ordered the controlled drugs (DH, 2007). On arrival, the receiving person will open the box and check the number of individual drugs against the order in the ward controlled-drugs order book.
The controlled-drugs record book provides a log of all Schedule 2 controlled drugs received and issued in the department or ward. It will have separate pages for each preparation and each formulation. This is a continuation page for morphine sulfate (MR) capsules 30 mg, formerly recorded on page 3.

Errors must remain legible: bracketed or crossed out with a single line. Two registrants must sign and date the error and give the reason.

The index must be kept up to date. It will show the number of the current page to turn to for each drug and formulation.

Each entry relating to receiving and issuing a controlled drug, must be signed and dated, and witnessed.

Once a controlled-drugs record book is finished, it must be sealed and stored securely on the ward. Write the date of the last entry on the cover, and the date (two years later) on which it can be destroyed.

The controlled-drugs record book must be a bound book: most local policies do not permit use of loose-leaf pages.

If the number of drugs delivered is correct, then the receiving person will sign the relevant sheet in the ward controlled-drugs order book in the "received by" section (NMC, 2010). NICE (2016) highlights the requirements for information that should be shown on the form for controlled drugs.

The receiving person will then take the ward controlled-drugs record book (not the order book) and enter the new stock into it, recording the date, the serial number of the requisition, the amount and form of the drug and the new stock balance. He or she (and a witness) will sign the book, then lock the book and the new stock in the cupboard. Follow local policy, but, generally, words (not numbers) are used to record the controlled drugs received from pharmacy, to reduce the chance of subsequent fraudulent alterations (NMC, 2010).
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Stock checks of controlled drugs

Regular stock checks will take place. The frequency will vary according to local policy but may be every 24 hours. Perform these checks at a time when you will not easily be disturbed; follow local policy. Check the cupboard stock against that recorded in the book, not the other way round. You do not need to open boxes/packets that have tamper-proof seals. Liquid controlled drugs are normally checked once a week and whenever a discrepancy is noted or suspected. Generally, volume discrepancies larger than 5 mL per 100 mL are considered significant and must be reported.

Security audits

5. Are appropriate security measures applied to the storage of the medicines below? (for each medicine, please tick the appropriate response)
   - CDs
   - Internal medicines
   - External medicines
   - Refrigerator/freezer medicines
   - Intravenous fluids and sterile topical fluids
   - Flammable liquids and medical gasses
   - TID/TIAE
   - Emergency medicines (crash trolleys/anaphylaxis kits)

6. Are all cupboards, closed storage units (i.e. with doors) and refrigerators in which medicines are stored lockable?

7. Are keys providing access to medicine cupboards in the possession of an authorised person or securely stored at all times and easily traceable?

8. Are doors leading to security sensitive areas where medicines are stored access controlled?

Be aware that pharmacy also carry out regular audits and will ask for the keys to do this. The information collected will help to inform whether the governance arrangements in relation to controlled drugs are sufficient and identify any areas for improvement (see also: CQC, 2016a; NHS Protect, 2015).

Return of controlled drugs is witnessed

If it becomes necessary to return controlled drugs to the pharmacy, this will be recorded in the controlled-drugs book, and the entry witnessed. The record will include the date, the reason for return and a correction to the stock balance, together with the two signatures.

Stock checks are witnessed

Note where stock checks are recorded. For example, this may be on a page at the back of the bound record book or in a separate bound book (not on loose sheets). Stock check records can also be made on individual pages of the record book. The person conducting the stock check will sign, together with the witness, stating that a stock check has been undertaken, with the date. If there is a discrepancy, check again for an error; follow local policy, including completing an incident form, and informing pharmacy, the ward manager and the ward pharmacist (where available).

Return and disposal of controlled drugs

Follow the local policy carefully for managing expired or unused controlled drugs (see DH, 2007). These will be returned to pharmacy, usually with the pharmacist as one of the signatories, who will sign them back in at the pharmacy. The local policy for secure return will be similar to that for delivery of controlled drugs. Regular pharmacy audits will identify any surplus stocks of controlled drugs that need to be returned.

Immediate disposal of controlled drugs

Disposal of controlled drugs can occur in the clinical area following local policy. This may be necessary if less medication is administered than was prepared, for example, or if a patient requires a lower dose than that available in an ampoule.
If the keys cannot be accounted for, follow local policy. You will normally need to inform security (who may need to contact the police), the pharmacy or the on-call pharmacist, the Accountable Officer and the Director of Nursing. You will be issued with a duplicate set of keys for access but the lock on the cupboard needs to be changed urgently. Monitor the cupboard closely until the lock is changed, or move the stock and paperwork to another secure place in the interim. Complete an incident form, following local policy.

Discharge medicines of controlled drugs

When the patient is being discharged with controlled drugs to take home, these will be ordered and transferred from the pharmacy as for ward stock. If necessary, store the controlled drugs to take home in the locked controlled-drugs cupboard. (These should not be recorded as ward stock.) Do not leave controlled drugs unattended at the bedside.

Illicit substances

If you suspect that a patient is using prohibited drugs for non-medical use on the premises, follow local policy and inform the nurse in charge in a professional manner. You may need to inform the Accountable Officer, the Director of Nursing and security, as well as the medical team and the patient’s consultant. It may be necessary to involve the police.

Lost controlled-drugs keys: (a)

The keys for the controlled-drugs cupboard must be accounted for at all times. If the keys appear to be missing, inform the nurse in charge immediately. Contact all staff who have had the keys since the team was last aware of their location. If necessary, contact staff who are now off duty. If someone has taken the keys off the premises, he or she will need to return them immediately. If this is not possible, the person must return them as soon as practicable and a duplicate set will be obtained from pharmacy.

Disposal of controlled drugs in the clinical area must be witnessed and recorded in the controlled-drugs record book, stating the amount given to the patient and the amount wasted (NICE, 2016). The person disposing of the drug must sign the book, together with any witness. Record the new stock balance.

**Immediate disposal of controlled drugs is witnessed**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Patient’s Name</th>
<th>Amount given</th>
<th>Witnessed by (Signature)</th>
<th>Balance of stock</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/10/16</td>
<td>10:00</td>
<td>Ella Akhmatova</td>
<td>2.5 mg</td>
<td>NAT II</td>
<td>0 ampoules</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.5 mg of 5mg</td>
<td>NAT II</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>amoule disposed</td>
<td>NAT II</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>in sharps bin</td>
<td>NAT II</td>
<td></td>
</tr>
</tbody>
</table>

**Lost controlled-drugs stationery**

If controlled-drugs paperwork is missing, follow the same procedure as for lost keys. If the controlled-drugs record book cannot be located, start a new book and check and record the stock. Be aware that a missing book may be an attempt to cover for missing stock and the police may need to be involved.