

Document Control

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Storage of Medicines Standard Operating Procedure			
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2.0	April 2021	Draft	Inclusion of reference to skilled not registered staff. Addition of requirement to change pin codes when staff member leaves or breach of security incidence has occurred. Addition of requirement to ensure pin codes are not visible. Addition of the cleanliness of all medicine storage areas is the responsibility of the local team.
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1. Purpose

Ordering the correct medication in a timely manner, avoiding omitted doses and storing medication appropriately is fundamental to the patients care within a safe environment. This Standard Operating Procedure (SOP) has been written to inform healthcare professionals about the appropriate storage of medicines within hospitals, units and clinics.

2. Responsibilities

2.1 Registered professional

2.1.1 The Registrant in charge is responsible for the custody of medicines within their ward/clinic/unit or service in accordance with the Northern Devon Healthcare NHS Trust Medicines policy.

2.1.2 The Registrant in charge is responsible for ensuring that this procedure is followed and that the correct storage and security of medicines on the ward is maintained.

2.1.3 The Registrant in charge is responsible for controlling access to the storage areas, medicines cupboards and trollies. The responsibility remains with the Registered Nurse in charge even if he/she decides to delegate the duty.

2.1.4 The Registrant in charge is responsible for any delegation of medicine related tasks to skilled not registered staff in line with the 'Skilled not registered staff policy' and specific service related standard operating procedures.

2.2 Pharmacy team

2.2.1 The pharmacy team are responsible for provision of day to day advice to registered professionals regarding the safe storage of medication.

2.2.2 The pharmacy team are responsible for undertaking the yearly audit on Safe and Secure Medication.

2.2.3 The pharmacy team are responsible for reporting and assisting in the investigation of any incidences which breach this SOP.

2.3 The Divisional Associate Directors of Nursing/registered professional

2.3.1 The Divisional Associate Directors of Nursing or lead registered professional is responsible for the implementation of this SOP within their clinical area.

2.3.2 The divisional Associate Director of nursing or lead registered professional is responsible for reporting and assisting in the investigation of any incidences which breach this SOP.

3. Scope

This SOP relates to the following staff groups who may be involved in organising the storage of medicines:

Registered practitioners

Medical staff and all registered professionals

Medicines Management Pharmacy Team

Staff undertaking this procedure must be able to demonstrate continued competence as per the organisation's policy on assessing and maintaining competencies.

4. Location

The Storage of Medicines SOP can be implemented in all clinical areas where medicines are required, stored and where competent staff are involved in managing medicines according to this SOP.

5. Equipment

- Lockable cupboards suitable for the storage of medicines including Controlled Drugs and Drugs of Diversion.
- Lockable medicines trolley
- Lockable storage cupboards for patient own drugs – key lock or electronic lock
- Lockable fridge with a minimum/maximum temperature thermometer and monitoring chart.

6. Procedure

6.1 Areas of Storage for Medicines

6.1.1 All medicines must be stored safely and all storage areas must be kept locked with access restricted to authorised staff only. The keys/access code must only be in the possession of a Registered Healthcare Professional. For the purpose of the SOP 'keys' refers to all keys or pincodes used for medication storage i.e. medication cupboards, medication lockers, medication trolleys, controlled drug cupboard and refrigerators.

6.1.2 It may not be practical to store large volumes of fluids in the medicine cupboards. If this is the case, store them in a locked and secure designated area with restricted access to staff only.

6.1.3 All items issued by the pharmacy must be stored securely and locked in one of the following:

- Controlled drugs cupboard
- Internal medicine cupboard
- External medicine cupboard
- Drug refrigerator and/or freezer
- Diagnostic reagent cupboard
- Medicine trolley/medicine cupboard for medications in current use
- Individual lockable bedside medicine cupboards
- Infusion and sterile fluid area

6.1.4 Drug cupboards to be used for internal and external medicines must comply with current British Standard BS2881:1989 Specification for Cupboards for the storage of medicines in healthcare premises.

6.1.5 All medicines cupboards must be secured to permanent fixtures. Medicines trolleys must be locked and secured to the wall to immobilise them when not in use. Patient's own medicine cupboards must be fixed to patient's lockers/bedside cabinets.

6.1.6 Medicine trolleys and cupboards must not be left unlocked or unattended at any time, including during the medicine round.

6.1.6 Medicines must not be stored on the shelf underneath the medicines trolley.

6.1.8 Locked cupboards, refrigerators, trolleys or any other secure receptacles used for the storage of internal or external medicines must be kept exclusively for the storage of medicines.

6.1.9 Internal medicines, injectable medication and external medication must be stored in separate locations within the medicine cupboards.

6.1.10 All doors leading to security sensitive areas where medicines are stored are access controlled. Where PIN codes are used as part of the access control system, the codes should be changed at sufficient frequency to ensure discrepancies can be identified in a timely manner. The trust defines this as every 6 months. In addition, pin codes should be changed when a member of staff leaves or a breach of security incidence has occurred.

6.1.11 Pin codes should be kept secure and there should not be written or on visible display within any clinical area.

6.2 Monitoring Medicines and Storage

6.2.1 Medicines must be stored in conditions according to the manufacturer's guidance such as to prevent deterioration by temperature, humidity, compression and exposure to light or radiation.

6.2.2 Most medicines require storage in a cool dry place at room temperatures not exceeding 25°C. Check the product's information for specific instructions. The pharmacy department should be contacted for advice should the ambient storage conditions temperature rise above 30°C.

6.2.3 Items requiring cold storage must be locked in a refrigerator or freezer in accordance with the manufacturer storage instructions. The refrigerator and/or freezer must be kept solely for medicines and equipped with a maximum/minimum thermometer to monitor and record the temperatures daily.

6.2.4 Controlled Drugs and Drugs of Diversion must have a three monthly audit check by a Medicines Management Pharmacy Technician/Pharmacist and Registered Professional. The audit checks the actual and recorded balances as well as the expiry dates. A written record is made in the relevant books and signed by the authorised aforementioned persons.

6.2.5 Medicines with the nearest expiry date should be used first. All expiry dates must be checked monthly to avoid wastage or inappropriate administration.

6.2.6 Medicines must be stored in the packaging in which they were supplied/ dispensed. They are not to be removed from their packaging except when being prepared for immediate administration.

6.2.7 Medicines must not be transferred from one container to another nor the contents of packages combined.

6.2.8 Medicine labels must never be altered once they are applied to the packaging and issued to the patient or ward.

6.2.9 An apparent loss of medicines, a medicine cupboard that has been tampered with, loss of keys or suspected misuse of medicines must be reported to the Registered Professional in charge at once. All such incidents must be reported as per the Northern Devon Healthcare NHS Trust's Incident Reporting procedure which will alert the pharmacy staff.

6.2.10 Flammable, caustic or toxic products (including certain drugs) which are hazardous to health must be handled in accordance with Control of Substances Hazardous to Health (COSHH) Regulations. Special care must be taken to prevent or control contact with these products. Stock levels are kept to a minimum and advice on handling and storage obtained from the supplying pharmacy.

6.2.11 The cleanliness of all medicine storage areas is the responsibility of the local team.

6.3 Emergency Medicines

6.3.1 For clinical emergencies e.g. cardiac arrest, all wards should stock the agreed emergency medicines.

6.3.2 Medicines for clinical emergencies must be stored in a tamper-evident receptacle/container and not stored in a locked cupboard but at an agreed strategic and accessible location away from public areas.

6.3.3 Once emergency packs have been used, expired or the seals broken, a replacement emergency pack is ordered from pharmacy, as soon as possible, and the opened pack returned to pharmacy once a replacement has been received. Ensure all the necessary needles and syringes are easily accessible.

6.4 Medicines Keys for areas with 24 hour registered professional on site

6.4.1 All medicine storage keys must be in the personal possession of a Registered professional on the ward/unit/clinic.

6.4.2 Holding the key may be delegated to other Registered professionals and authorised pharmacy staff when needed for legitimate purposes.

6.4.3 Keys controlling access to stored medicines must not be labelled with written identification. Colour coding or numbering is appropriate.

6.4.4 A spare set of keys must be kept in a locked cupboard or safe within the main pharmacy department

6.4.5 Keys must not be given to non-registered staff or other unauthorised healthcare staff e.g. Audit Personnel.

6.4.6 During a shift-change, it is the responsibility of the registered professional holding the keys to hand them to the registered professional in charge of the next shift.

6.4.7 All areas with cupboards, refrigerators and trolleys containing medicines must remain locked at all times unless in current use, except medicines for emergency use (see section 6.3).

6.4.8 Any apparent loss of keys or medication must be reported immediately to the nurse in charge and logged using the Trust Incident Reporting system.

6.5 Medicine Keys for areas that do not have 24 hour registered professional on site

6.4.1 All medicine storage keys must be in the personal possession of a Registered professional on the ward/unit/clinic.

6.4.2 Holding the key may be delegated to other registered professionals and authorised pharmacy staff when needed for legitimate purposes.

6.4.3 Keys controlling access to stored medicines must not be labelled with written identification. Colour coding or numbering is appropriate.

6.4.4 A spare set of keys must be kept in a locked cupboard or safe within the main pharmacy department.

6.4.5 It is the responsibility of the clinic, unit or departmental manager to ensure that adequate provision is in place for the safe and secure storage of the medicine keys during the period of time when the clinic or department is not staffed by a registered professional. Keys should be stored in safe lockable area that cannot be accessed by non-registered staff.

6.4.6 All registered professional must ensure the medicine keys are safely and securely stored according to the arrangements in place at the end of the clinic, unit or departments opening hours. This responsibility must not be delegated to non-registered staff.

6.4.7 Keys must not be given to non-registered staff or other unauthorised healthcare staff e.g. Audit Personnel.

6.4.8 During a shift-change, it is the responsibility of the registered professional holding the keys to hand them to the registered professional in charge of the next shift.

6.4.9 All areas with cupboards, refrigerators and trolleys containing medicines must remain locked at all times unless in current use, except medicines for emergency use (see section 6.3).

6.4.10 Any apparent loss of keys or medication must be reported immediately to the nurse in charge and logged using the Trust Incident Reporting system.

6.6 Expiry Date Checks

6.6.1 The expiry dates of all ward medicines must be checked on a monthly basis, this is the responsibility of the Registered professional on the ward/unit. Any out-of-date medicines must be disposed of in accordance with the Management of Pharmaceutical Waste SOP.

6.6.2 Records of when Controlled Drugs and Drugs of Diversion expiry date checks are carried out and by whom are written in the appropriate record books and are retained on the ward. See 6.2.4 for Controlled Drugs and Drugs of Diversion three monthly pharmacy check.

6.6.3 Some medicines have a limited shelf life once opened, e.g. insulin, internal liquids, eye drops or ointments and foil wrapped tablets. The date of opening and calculated expiry date must be written on these products and the medicine disposed of in accordance with local policy and procedures, as soon as the shelf life has expired.

6.7 Refrigerators

6.7.1 A locked refrigerator must be available for the sole use of storing medicines. Food, blood and/or specimens must not be stored in the medicines refrigerator.

6.7.2 The refrigerator temperature should be maintained at 2°C - 8°C (Celsius).

6.7.3 Refrigerator temperatures are to be monitored and recorded at the same time daily; using a maximum/minimum thermometer or other approved monitoring devices. The maximum and minimum temperature must be recorded on a Medicines Refrigerator Temperature Monitoring Sheet (refer to the Cold Storage of Medicines and Vaccines Procedure) and then the thermometer must be reset.

6.7.4 Fridge monitoring records must be kept for two years.

6.7.5 If internal fridge temperatures rise above 8°C or fall below +2°C, ascertain how long the temperature has been outside this range and seek advice from the Medicines Management Team or Medicines Information. They will ascertain whether the medicines can still be used. If no incidental cause of temperature change (e.g. fridge left open too long), adjust the refrigerator's temperature control as required and monitor frequently until a satisfactory temperature control has been achieved.

6.7.6 Medicines are to be stored in the main body of the refrigerator away from the door or any ice compartment (if present). Ensure sufficient space between stored products to allow the circulation of air throughout the chamber.

6.7.7 Refrigerators must be defrosted and cleaned once a month. The date of which should be recorded on the Medicines Refrigerator Temperature Monitoring Sheet (See Cold Storage SOP) with the date, time and action. During defrosting, medicines may be transferred to a container and placed on a separate shelf in ward domestic refrigerator. Medicines are returned to the medicines refrigerator, when the temperature reaches the required range.

6.8 Medical Gas Cylinders and Flammable Materials

6.8.1 Medical gases are licenced medicinal products and as such must be prescribed.

6.8.2 Medical gas cylinders should be stored securely and safely. Empty and full cylinders must be separated and restrained securely to avoid them falling.

6.8.2 Procedures must be in place for ordering, storing and controlling movement of medical gas cylinders.

6.8.3 Hospital Technical Memorandum 2022 applies to sites with piped medical gases. These sites must also have backup cylinders.

6.8.4 Stock of flammable materials and medical gases are to be kept to a minimal level and stored in a secure area approved by the fire officer.

6.9 Storage of Patient's Own Drugs

6.9.1 Patient's own drugs are medicines brought into hospital by patients and remain the property of that patient.

6.9.2 Patient's own medicines are used on the ward according to the Patient's Own Drugs (PODs) for inpatient setting – Standard Operating Procedure. The medication is kept in the patient's locker for use when:

- The Registered professional is administering medication.
- A self-administration scheme is in operation, or
- A Medicine Management scheme for using patients' own drugs is in operation, or
- Patients who wish to continue treatment with their own non-prescribed medicines e.g. herbal or homeopathic preparations. These must be recorded on the drug chart as also being taken to avoid potential interaction or side effects and annotated as the patient's own.

6.9.3 Patient consent is always sought before using the patient's own medicines.

6.9.4 Patient's own medicines used for self-administration or medicine management schemes must be stored in a fixed locked cupboard or a bedside locker with a key or electronic lock.

6.9.5 Patient's Own Controlled Drugs (CD) or Drugs of Diversion (DOD) must be entered in the Patient's Own CD or DOD books which are separate registers from CD and DOD ward stock record books. A record must be kept of the quantity brought into the hospital.

6.9.6 Patients must sign the 'Patient's Own Controlled Drugs and Drugs of Diversion Consent Form'. The Registered Nurse will fill in the form on admission of the patient to the ward and complete it on return or destruction of the patient's CD or DOD. Refer to Self- Administration of Medication for Adults Standard Operating Procedure and CD SOP.

6.9.7 Where a patient's medication is to be continued after leaving the hospital, but not utilised in any of the schemes mentioned above while in hospital, the patient's own medication is prepared for discharge. It is placed in a green bag, labelled with the patient's name, hospital number and locked in a secure cupboard to be returned to the patient on discharge from the hospital.

6.9.8 Following the death of a patient, any patient's own drugs held in safe custody is considered as part of the deceased patient's estate and is returned to the patient's relatives. Advice is given to the relatives to retain all medicines for seven days for legal reasons before returning the medicines to the dispensing community pharmacy for safe disposal. This is recorded in the patient's notes and on the consent form.

6.9.9 Any medicines belonging to the deceased patient that are retained for disposal at the request of the relatives must be disposed of in accordance with the Management of Pharmaceutical Waste SOP.

6.9.10 Any medication, which might be relevant to the cause of death in Coroners' cases, must be retained and handed to the police.

6.10 Storage of Medicines in Transit

6.10.1 Medicines should be transported in sealed boxes/packages with a clear audit trail for supply and delivery. Cool boxes should be used to transport/store vaccines to clinic sessions.

6.10.2 All cold storage items must be labelled clearly as such, on the item and on the outside of the packaging/box. These items must be unpacked immediately by the staff on receipt of the products onto the ward/clinic.

6.10.3 Pharmaceuticals can only be stored on non-Northern Devon Healthcare NHS Trust premises for sessional clinics with a prior risk assessment.

6.10.4 Items must be signed for on release to a driver and on receipt from a driver.

Contracted drivers should be used to transport and deliver medicines. Where medicines are required outside normal delivery times an approved taxi courier service may be utilised.

6.11 Breaches of safe storage of medication

Any breaches of security in relation to safe storage of medication should be reported via the trust DATIX system. The trust Controlled Drug Accountable officer and the trust Local Security Management Specialist must be informed if the breach in safe storage involves a controlled drug.

7. Monitoring Compliance with and the Effectiveness of the Policy

7.1 Standards/ Key Performance Indicators

- Yearly pharmacy 'Safe and Secure Audit'

- Related DATIX reports

7.2 Process for Implementation and Monitoring Compliance and Effectiveness

Ward managers/Lead registered professional to disseminate updated SOP to all staff within their clinical area.

Ward managers/Lead registered professional to review SOP and ensure medication storage within their clinical area complies with the updates SOP

8. References

- Control of Substances Hazardous to Health Regulation (COSHH)
- Misuse of Drugs Act 1971 and regulations
- Medicines Act 1968
- Duthie Report 2005
- British Standard BS2881:1989
- Medicine security ward/department checklist (NHS protect)

9. Associated Documentation

9.1. Northern Devon Healthcare NHS Trust Policies for:

- Management of Pharmaceutical Waste SOP
- Patient's Own Drugs SOP
- Controlled Drugs SOP
- Drugs of Diversion SOP
- Cold Storage SOP
- Self-administration of Medicines SOP
- Medicines Policy for Skilled Not Registered Staff
- Safe and Secure Medicine Audit (NHS protect)
- SACT policy