South Central Ambulance Service
NHS Foundation Trust

SAFE AND SECURE HANDLING OF MEDICINES POLICY

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TABLE OF CONTENTS

DOCUMENT INFORMATION

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1. Introduction

1.1 The South-Central Ambulance Service NHS Foundation Trust is expected to comply with the current legislation and national guidance to meet the needs of the service. This policy is aimed at ensuring the safe and secure handling of medicines and medical gases.

1.2 Authorised registrants have access to drugs, including controlled drugs and have a responsibility to ensure they are stored and recorded correctly to reduce the risk of theft and misuse.

1.3 All clinical staff have a responsibility to report any concerns relating to medicines. This includes missing, damaged, and unused medicines

2. Scope

2.1 This policy applies to all staff who have access to medicines and who are employed by SCAS this includes volunteers such as community first responders and private providers working for SCAS.

2.2 The guidance within the policy must be followed. Failure to do so could result in disciplinary action.

2.3 It is the responsibility of the clinician administering the medication to ensure that it used correctly. The UK Ambulance Service Clinical Practice Guidelines (JRCALC) as well as the SCAS Medicines Protocols and Patient Group Directions can be used as a guide to support clinical decision making.

3. Equality statement

3.1 The Trust is committed to promoting positive measures that eliminate all forms of unlawful or unfair discrimination on the grounds of age, marriage and civil partnership, disability, race, gender, religion/belief, sexual orientation, gender reassignment and pregnancy/maternity or any other basis not justified by law or relevant to the requirements of the post. The Trust will therefore take every possible step to ensure that this procedure is applied fairly to all employees regardless of the afore mentioned protected characteristics, whether full or part time or employed under a permanent or a fixed term contract or any other irrelevant factor.

3.2 By committing to a policy encouraging equality of opportunity and diversity, the Trust values differences between members of the community and within its existing workforce, and actively seeks to benefit from their differing skills, knowledge, and experiences in order to provide an exemplary healthcare service. The Trust is committed to promoting equality and diversity best practice both within the workforce and in any other area where it has influence.

3.3 Where there are barriers to understanding; for example, an employee has difficulty in reading or writing, or where English is not their first language, additional support will be put in place wherever necessary to ensure that the process to be followed is understood and that the employee is not disadvantaged at any stage in the procedure. Further information on the support available can be sought from the HR Department.

4. Aim

4.1 The aim of this policy is to ensure that all staff working for SCAS fully understand the standards and procedures to ensure the safe and secure handling of medicines and medical gases.

4.2 The policy is for staff to refer to and follow to ensure the legislation in relation to the security and storage of medicines is followed and there is less opportunity of risk.

5. Roles and responsibilities

5.1 Trust Board

5.1.1 The Trust Board will be responsible for ensuring that sufficient funds and resources are available for the safe and secure management of medicines

5.2 Chief Executive

5.2.1 The Chief Executive has overall responsibility for ensuring that systems for the safe and secure management of medicines are followed and that the security of medicines handled by the Trust is maintained

5.2.2 They may delegate these duties but always the responsibility remains with the Chief Executive. They are the Controlled Drug License Holder and are responsible for ensuring that the systems and processes used to govern medicines are robust, comply fully with legislation, national guidance and regulatory requirements to ensure the secure and effective management of medicines.

5.3 Medical Director

5.1.1 Review and amend this policy to ensure it still meets the high standards for the safe handling and security of medicines and medical gases.

5.1.2 If there are any concerns found within the policy the Medical Director must report this to the Trust Board and Trust Committees for their support and consideration.

5.4 Controlled Drug Accountable Officer (CDAO)

5.4.1 The CDAO is responsible for ensuring appropriate arrangements are developed and implemented at the relevant body for the safe and secure use and management of CDs.

5.4.2 Please refer to the Controlled drugs policy, section 4.4 for additional information.

5.5 Head of Operations

5.5.1 To ensure that all registered clinical staff within the area of SCAS are aware and comply with the Controlled Drug Policy and associated SOPs.

5.5.2 Responsible for all medicines within area of SCAS and ensuring clinical staff comply with the Controlled Drugs Policy and relevant SOPs.

5.5.3 Responsible for oversight in ensuring CD safe and stock management policies are adhered to by all relevant staff.

5.5.4 Liable for the entrusting another member of their team with CD responsibilities with the appropriate level of skills and knowledge

5.6 Medicines Optimisation and Governance Group

5.6.1 The Medicines Optimisation and Governance Group are involved in developing the policy and keeping up to date with the current laws, legislation, and regulations in the management of current and new medicines.

5.7 Medication Safety Officer

5.7.1 Support active reporting of medicine errors

5.7.2 Reflecting and learning from medication incidents and errors

5.7.3 Support and be guided by the Trust Pharmacist, Medical Director and National Medication Safety Network.

5.8 Assistant Director of Operations

5.8.1 Ensure that stock and audit checks are completed

5.8.2 If there are any issues or concerns that they are addressed.

5.8.3 Make sure operational staff are aware of this policy

5.8.4 Ensure that operational staff are following the guidance.

5.9 Human Resources

5.9.1 Acting on Disclosure and Barring Service checks that may highlight previous behaviour regarding CDs.

5.9.2 Ensuring that all the relevant policies and procedures are kept up to date, that relevant staff have been informed and all staff records are kept up to date.

5.10 Team Leaders

5.10.1 All registered clinical staff within their team a r e aware of and willing to work within this policy.

5.10.2 Complete stock and audit checks of medicines

5.10.3 If any medicine discrepancies or concerns are found or reported to follow them up and to ensure that the member of staff is aware that a Datix® needs to be completed within 24 hours.

5.11 All staff

5.11.1 All staff have a responsibility to follow this policy

5.10.4 All staff responsible for the administration, disposing and recording of medicines must ensure that:

- Any medicines administered or disposed of are recorded accurately and the balance matches what has been used/disposed of.
- Medicines are disposed of safely after use

- Any discrepancies or concerns must be reported to the appropriate manager and by complete a Datix® within 24 hours so it can be acted on without delay.

6. Controlled Drugs

SCAS handles CDs in Schedules 2-5 of the Misuse of Drugs Regulations 2001 (MDR), which are subject to secure storage as these drugs are considered to be at a higher risk of diversion.

Whilst the Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No 798) cover the safe custody of CDs in community pharmacies and care homes and not to ambulance trusts, they are considered by the Home Office to be the minimum standard for storage of CDs. As such CDs should be held with the security recommendations contained within this policy.

The law requires that there must be suitable and sufficient provision for safe and secure storage of controlled drugs on all premises. Each premises will have a designated controlled drug safe that conforms to Home Office Regulations. Each safe will have a CD Register for morphine sulphate, and additional CD Registers for other CDs as required.

6.1 Access to Controlled Drug Safes

Access to Controlled Drug Safes is restricted to the following personnel

6.1.1 Any person authorised by the Medical Director
6.1.2 Registered Paramedics
6.1.3 Registered Nurses
6.1.4 Clinical Team Leaders
6.1.5 Incident Response Officers
6.1.6 Group Station Managers
6.1.7 Logistics Support Unit personnel authorised by the Logistics Manager

6.2 CD storage in static Trust premises

6.2.1 Schedule 2 and 3 CDs must be stored in a Trust approved CD safe with a lock complying to BS 3621.
6.2.2 All CD safes should meet the Sold Secure Standard (SS) 314 – 'Specification for security cabinets' standard – silver level.
6.2.3 Electronic keys and/or electronic access cards are preferred to ensure audit trails of storage can be maintained.
6.2.4 CDs held by specialist groups, e.g., BASICS doctors must be stored in a separate Trust approved CD safe with a lock complying to BS 3621.
6.2.5 Emergency escape door sets (as with external doors) should be certificated to LPS 1175 SR2 as a minimum requirement.
6.2.6 Panic hardware (certificated to BSEN179).
6.2.7 Doors should be fitted with door contacts programmed in to a 24-hour alarm circuit which is armed at all times (audible or silent).
6.2.8 The cabinet must be affixed to a solid wall (refer to Misuse of Drugs (Safe Custody) Regulations 1973 and must allow sufficient room to store adequate stock levels safely, in addition to the CD register and order books.
6.2.9 All external doors and those along the route to the CD storage area should be certificated to LPS 1175 SR2 or similar as a minimum requirement
6.2.10 CD Rooms must be built to the standards in schedule 2, section 3 or the

Misuse of Drugs (Safe Custody) Regulations 1973.

6.2.11 All CD safes and rooms must be kept locked when not in use.

6.2.12 The lock on CD safes must not be common to any other lock in the Trust.

6.2.13 No other medicines or items should be kept in the CD cupboard. Any exception to this must be approved by the Head of Pharmacy should be detailed in local protocols/ procedures.

6.2.14 It is essential that CD cupboards are well organised and tidy, to minimise the risk of selection errors.

6.3 CD security in static Trust premises

6.3.1 All premises storing CDs should have a Medicines Crime Impact Assessment and regard to any issues identified by the HSSO

6.3.2 All premises in which CDs are held should have protection to ground floor windows e.g., barred windows or similar.

6.3.3 All entrances should be well lit and prevent areas of shadowing or pooling

6.3.4 The requirement for CCTV outside any premises will be assessed through the Medicines Crime Impact Assessment. Where CCTV is used it should be detector activated, which is recorded.

6.3.5 Any vegetation at the site should be kept to a maximum height of 1000mm in respect of ground planting and any tree foliage should fall to no lower than 2m from the ground.

6.3.6 Parked vehicles must not be impeded by trees or other vegetation.

6.3.7 Foliage and trees to be cut back and maintained on a regular basis to prevent access to building.

6.3.8 Hard landscaping can inadvertently create seating or loitering spots and encourage antisocial behaviour, therefore if used it should be designed to avoid this problem.

6.3.9 A perimeter fence certificated to LPS 1175 SR1 & lockable/ access control gates (local planning regulations permitting)

6.3.10 External doors (including fire escape doors) manufactured to LPS 1175 SR4.

6.4 CD storage on vehicles

6.4.1 All vehicles (marked and unmarked) must be locked, alarmed and immobilised when not occupied or in use by the duty crew. This does not apply when the vehicle is in use for an emergency episode of clinical care.

6.4.2 Whilst on duty it is the responsibility of all staff to ensure any drugs are appropriately disposed of and securely stored in the vehicle. If a vehicle must be left unattended all doors and windows should be closed and any medicines should be out of sight.

6.4.3 The vehicle must be locked, alarmed and (if fitted) have the magnetic blue light removed so as not to draw attention to the fact that there may be CDs and other valuable trust property inside the vehicle.

6.4.4 Vehicle keys must be stored in a designated secure digital safe place on station (HART team excepted), or be on the practitioner, and NOT left on the vehicle or its ignition whilst the vehicle is not in use. Please refer to the Controlled Drug Policy, section 7.3.4 for additional information.

6.4.5 Vehicles containing CD safes should be stored overnight in a secure Trust premises

6.4.6 Vehicles must have all brackets and fixtures supplied with the CD safe fitted in accordance with the manufacturer's instructions.

6.4.7 Vehicles must have CD safes fixed to a secure vehicle mounting point (metal structure of the vehicle) with bolts which can only be accessed from

within the safe.

6.4.8 Vehicles should have auditable CD safe access.

6.4.9 Vehicles should have tinted windows which ensure that CD safes are not visible from the outside of the vehicle.

6.4.10 Some makes or models of ambulance cars may have a false floor. Extra precautions must be taken by installing a bracket (supplied and installed to the manufacturer's instructions) to a secure mounting point on the vehicle chassis. The bolts used to secure the safe to the bracket should only be accessible from within the safe

6.4.11 For vehicles off road refer to SOP MEDCD009

6.5 CD Room Security

6.5.1 Rooms must be lockable to minimum BS 3621 and have a door viewer to aid observation.

6.5.2 Be without windows, but if unavoidable, the window should be a non-opening light, with laminated glass certified to BSEN356:2000 Performance Specification P5a (minimum) or a fixed security grille installed from the inside to LPS1175 SR2 or similar.

6.5.3 Have motion activated lighting

6.5.4 Have a requirement for staff entering to remove any face coverings, with due regard to religious and cultural customs. This includes helmets, anti-pollution cycle masks and fashion eyewear (not including prescription sunglasses).

6.5.5 Have white light to BS5489:2003 or EN13201.

6.5.6 Windows certificated to BS PAS 24:2012 or similar, as minimum and opening lights should be fitted with restrictors (limited to 100mm opening). Windows should be lockable.

6.5.7 CCTV should be installed overtly, coverage to include entrances of medicines and CD holding rooms, including opening of CD cabinets, but to comply with the provisions of the Data Protection Act 1998 and the Information Commissioner's Office CCTV code of practice (2008).

6.5.8 Medicine-holding area surveillance e.g., detector-activated CCTV which is recorded.

6.5.9 An electronic access control system with a clear audit trail e.g., swipe cards or fobs used by all staff.

6.5.10 Ensure CDs are kept off the floor and out of dust range, locked away in a CD Cabinet.

6.5.11 Any drugs containing fluid should be kept in a locked cabinet where only staff have access to.

6.6 CD Cupboard Security

6.6.1 Be manufactured to the specifications set out in the Misuse of Drugs (Safe Custody) Regulations 1973. Such CDCs would not be expected to hold stocks of CDs exceeding 250 grams.

6.6.2 Be attached to an immovable wall or floor (e.g., not a partition or wooden floor). Ideally the wall should be an internal wall to reduce the likelihood of a 'ram-raid'.

6.6.3 Possess a locking mechanism which should be unique to the safe and be as robust as possible to maximise security (e.g., a multiple point).

6.6.4 Be electronically access controlled and auditable, ideally avoiding numeric keypads as a sole means of access to the CDC.

6.6.5 Be alarmed to BSEN 50131:2008 grade 2 – triggered by forced entry and if a door is left unsecured (SOP for response). Police response for activated alarms in un-staffed ambulance trust buildings where CDs are stored. Alarm receiving certificated to BS5979.

6.6.6 Any key safes forming part of the access controls to CD cabinets should be formed from steel sheet that is at least 3mm thick, has a combination lock without a separate key override and is secured by internal bolts to a solid wall.

6.6.7 Only store CDs and associated CD records; no other item or medicine should be stored in the safe.

6.6.8 Be certificated to the SOLD SECURE standard silver rating.

6.7 CDs on person

6.7.1 CDs should be kept out of sight as much as possible when being stored on the person

6.7.2 Under no circumstances should staff place themselves or others in danger by attempting to stop someone if threatened to hand over medicines, or when witnessing a person stealing medicines

6.7.3 CDs should only be held on person by authorised registered healthcare professionals

6.8 Patients own CDs

6.8.1 CDs transported with a patient on admission into hospital and on discharge are individually dispensed for a named patient and therefore are considered to be in the patients' possession.

6.8.2 On admission to hospital crew should communicate the presence of patients own CDs to the receiving site.

6.8.3 Patients own CDs must not be

6.8.3.1 Stored in the ambulance CD safe

6.8.3.2 Recorded in the CD Record Book

6.8.3.3 Accepted for disposal

6.9 Controlled Drug Keys

6.9.1 CD keys may only be held by authorized staff

6.9.2 If CD keys are found to be missing:

6.9.2.1 Immediately report this to the line manager

6.9.2.2 Complete a Datix report

6.9.2.3 Check the contents of the CD safe against the CD record book

6.9.2.4 Inform the Head of Pharmacy and the CDAO

6.9.3 If an authorized key holding member of staff is under investigation or facing disciplinary action:

6.9.3.1 Keys obtained from the staff member

6.9.3.2 Authorization lists updated immediately

6.9.3.3 Line managers to ensure the return of keys and ID is documented

6.10 Management of CDs

6.10.1 Refer to the Controlled Drug Policy for the following:

6.10.1.1 Destruction and Disposal of CDs

6.10.1.2 Broken or damaged CDs

6.10.1.3 Unused and out of date CDs

6.10.1.4 Order, record, receipt and transport of CDs
6.10.1.5 Storage of CDs in vehicles off road
6.10.1.6 Security of CD stationery
6.10.1.7 Managing CD losses
6.10.1.8 Stock checks and auditing
6.10.1.9 Reporting CD concerns

7. Medical Gases

7.1 Staff Responsibilities

7.1.1 All staff, clinical and non-clinical have responsibility to handle medical gases with care
7.1.2 Staff must not use or operate any medical gases that they have not been trained to use
7.1.3 Any damage or deficits found on the medical gases must be reported as per section 9.3 below.
7.1.4 Records for replacement of empty cylinders are completed accurately

7.2 Handling Cylinders

7.2.1 Cylinders must always be handled with care and never violently knocked or allowed to fall over
7.2.2 The valve to the cylinder should be closed when not in use
7.2.3 Do not roll the cylinder as this can cause the valve to open
7.2.4 Before using the cylinder, it should be checked for the following

i. That the cylinder is in date
ii. If there is any sign of damage to the cylinder e.g., damage to the casing
iii. The valve isn't contaminated or dirty with oil or grease, as this could be highly flammable
iv. The correct size and type of cylinder is selected for its required use (Refer to the Health and Safety Minimal Lifting Policy, sections 5.6 and 7)
v. There is no indication of leaking gas e.g., hissing sound. If there is an indication of a leak close the valve immediately.
vi. Only non-interchangeable fittings are present
vii. That the manufacturers safety sticker is present on the cylinder.

7.3 Faulty Cylinders

7.3.1 Faulty cylinders can be harmful, especially if not handled with care or if stored incorrectly.
7.3.2 Cylinders containing medical gases are stored under pressure and so can be flammable or support combustion. If the cylinder is faulty, whether due to accidental or malicious damage, it could cause serious harm.
7.3.3 Any damaged or faulty cylinder must be:

i. Reported immediately to the line manager
ii. An incident report should be completed
iii. The manager should contact the medical gas cylinder supplier to remove the defective cylinder
iv. The cylinder should be placed with the empty/used cylinders and marked as faulty/damaged

7.4 Security of Medical Gases in Stations

7.4.1 The door to access the medical gases room should be locked
7.4.2 The room should be kept secure at all times either by either physical key or card access. Access should be able to be gained with staff identity card, or otherwise a secure physical key which must be kept in a key safe.
7.4.3 If an identity card is used for access, there must be a key safe as a back-up option. Only staff should know the code to this, which should be changed on a monthly basis.
7.4.4 Only authorised staff may enter the storage area at any time

7.5 Security of Medical Gases on Vehicles

7.5.1 If a cylinder is accidentally left at the scene of an incident or in a hospital this should be reported to the line manager and arrangements made for the retrieval of the cylinder
7.5.2 Medical gas cylinders must not be swapped with other ambulance trusts

7.6 Storage of Medical Gases on Stations

7.6.1 Ordering, receipt and distribution of medical gases should be monitored through Trust approved electronic medicines tracking systems where available
7.6.2 With the exception of the Hazardous Area Response Team (HART) there should only be 1 storage area per station.
7.6.3 The storage room should be cool and dry with good ventilation and be well lit
7.6.4 There must be visible signage to locate the storage room in case of a fire
7.6.5 Visible signage showing safety warnings and requirements should be displayed where there are medical gases stored.
7.6.6 Visible hazard warning signs should be in place prohibiting smoking, welding and naked lights
7.6.7 The storage room must be free from clutter of combustible materials
7.6.8 The medical gas supplier should be involved in the set-up of the medical gas storage room to ensure the cylinders are stored correctly.
7.6.9 There should be space for both full and empty cylinders. These should be stored separately.
7.6.10 There should be space for different gases, and these should be stored separately.
7.6.11 There should not be excessive amounts of cylinders stored.
7.6.12 Cylinders should be kept on trolleys or storage racks, where they will not fall over.
7.6.13 Cylinders size F, HX, G and J should be stored in an upright position on concrete floored pens and secured firmly to prevent falling or being knocked over.
7.6.14 Cylinders size C, CD, D and E should be stored horizontally on secured racking
7.6.15 Where cylinders are stored upright, they should be secured with a chain, and where possible the chain should run through the collars of the cylinder
7.6.16 Cylinder storage should be designed so that appropriate stock rotation takes place and that medical gases closest to their expiry date should be used first
7.6.17 Additional information on individual medical gases can be found in the relevant BOC Material Safety Data Sheet (http://www.boconline.co.uk/en/sheq/safety-data-sheets/index.html)

7.7 Storage of Medical Gases on Vehicles

7.7.1 If medical gases are being administered during transportation, then they must be secured to the racks of the body work of the vehicle, inside the cupboard or in a response bag.

7.7.2 Loose cylinders should not be kept on the ambulance stretcher, floor or shelves as they pose a missile risk during hard braking.

7.7.3 The smaller cylinders which are in use at the scene of an incident can be stored in individual carry bags but should be secured with straps to prevent them from coming loose.

7.7.4 When carry bags are not in use they should be kept out of the way and not on the floor as could be a trip hazard.

7.7.5 The pipeline system in the ambulance should be checked annually by an approved technician.

7.7.6 The purpose-built system to secure medical gases inside the ambulance must be approved by SCAS Fleet services.

7.7.7 Operational staff must not try to repair the storage system in place for medical cases and should report any concerns to the duty bronze manager.

7.7.8 In non-DCA vehicles medical gas cylinders should be secured during transport to avoid movement

7.7.9 The cylinder valve must be closed whilst re-fueling the vehicle

7.7.10 Vehicles must be locked when not in use to ensure the security of medical gases, and other drugs, on board

8. General Medicines

8.1 Medicines must be stored according to the following requirements in static medicines storage areas:

8.1.1 Medicines must not be stored on the floor

8.1.2 Medicines must not store on the top of cupboards

8.1.3 Any heavy boxes of medication must be stored at waist height or below. Please refer to the Minimal Handling Health and Safety Policy section 7.

8.1.4 All medicines in static medicines storage areas must be stored lockable medicine cupboards compliant to British Standard BS2881:1989

8.1.5 Medicine modules bags must be sealed with serial numbered tags and stored in a locked medicines cupboard compliant to British Standard BS2881:1989

8.1.6 Specialist staff groups, for example specialist paramedics, must have separate lockable medicines cabinets compliant to British Standard BS2881:1989 for storage of specialist medicines.

8.1.7 All medicines room should have lighting of sufficient brightness to allow clear visibility such as to be able to read medicine labels with ease. This includes emergency lighting, in case of a power failure.

8.1.8 Medicines rooms should conform to infection control requirements for clinical areas

8.1.9 Medicines rooms must be cleaned regularly and free from dust.

8.1.10 Wall surfaces and ceilings must be clean and have a non-shedding, non-permeable finish.

8.1.11 There should be a method of communicating to update stock levels and stock required in the medicines room e.g., whiteboard

8.1.12 There must be no external windows, but if this is unavoidable the window glass must be opaque with bars (or similar) fitted to prevent theft.

8.1.13 Hands free pedal bins must be in place to dispose of rubbish with infection control in mind.

8.2 Medicines stored on vehicles:

- 8.2.1 When the vehicle is operational, the drug bag' should be kept locked away when not in use.
- 8.2.2 When not operational, vehicles should be kept locked.
- 8.2.3 Drugs bags should be secured at the end of every shift
- 8.2.4 Drugs must always be kept in designated places on Trust vehicles; this will depend upon the type of vehicle operated.
- 8.2.5 Drugs should not be transported in private cars except when staff are authorised to do so by the Head of Pharmacy

8.3 The Trust and all staff have a responsibility to follow the COSHH regulations to ensure the safety of staff and patients. There are some medicines which are hazardous and have the potential to be harmful if not handled or stored correctly. Please refer to the COSHH Policy for further information.

9. Temperature Monitoring of Medicines

9.1 Medicines specify the required storage temperature on their packaging or labelling. For ambient (room) storage it is usually stated a maximum of 25°C or 30°C.

9.2 Storage above the licensed temperature range may reduce the shelf life of the product, but the medicine is still likely to be fit for use. Medicines with ambient temperature storage are relatively robust and usually allocated a long shelf life, typically 2 years.

9.3 There is limited if any evidence of direct harm due to medicines stored above the licensed temperature in hospitals, but harm cannot be excluded.

9.4 Medicines which are susceptible to degradation by high ambient temperatures over a shorter period have more stringent requirements e.g., shorter shelf lives.

9.5 The recommended storage temperature for fridge items will be between 2°C and 8°C.

9.6 Medication should be stored in line with manufacturer recommendations to ensure the quality of the product up until administration to the patient.

9.7 Static medication storage facilities should therefore be maintained at appropriate temperatures to prevent degradation of the medicinal products and ensure the medication received by the patient is as intended by the manufacturer

9.8 It is recognised that monitoring and control of agile areas is more complex.

9.9 It is essential that the temperature of ambient static storage areas is monitored, and action taken if temperatures are out of range. The impact of temperatures above the specified range is dependent on the temperature the medicine has been stored at and the length of time the temperature has been out of range. Short excursions out of range are unlikely to impact on expiry date

9.10 Area Managers are responsible for

9.10.1 Ensuring all new and existing staff are made aware of this policy through local induction and other communication methods.
9.10.2 Ensuring compliance with this policy.
9.10.3 Ensuring that air cooling is considered in any new building or refurbishment of areas where medicines are stored.

9.11 Station Managers are responsible for
9.11.1 Ensuring the dataloggers are located appropriately e.g., in treatment rooms near medication storage areas but out of direct sunlight. A digital thermometer is required for recording ambient temperatures
9.11.2 Ensuring all station staff are aware of their responsibility to monitor room and fridge temperatures and explain the process of escalation
9.11.3 Ensuring daily checks are conducted by staff and the appropriate log is completed, including resetting of the fridge temperature. The check does not have to be a registered member of staff and can be undertaken if they have been given adequate training and understand the need to escalate
9.11.4 Ensuring out of range temperatures are escalated as appropriate according to the criteria set out in the Policy and all possible actions are taken to reduce the ambient temperature where high
9.11.5 Ensuring datalogger and associated temperature monitoring equipment are in good working order and that any defective equipment is escalated

9.12 Individual staff are responsible for
9.12.1 To be aware of this policy and ensure medicines are received and stored appropriately in line with the manufacturers packaging and labelling conditions
9.12.2 Highlighting issues of faulty equipment to station managers
9.12.3 Responsible for escalating temperatures which fall outside the usual range as detailed in this policy

9.13 The process for monitoring and reporting temperature deviations is documented in SOP MED208.

10. Clinical Trials and Research Medicines

10.1 The National Pharmacy Clinical Trials Advisory Group Professional Guidance on Pharmacy Services for Clinical Trials (2013) states that 'where clinical trials take place in a hospital, all IMPs should be stored and dispensed by the hospital pharmacy and managed to the same standards as licensed medicines, in accordance with local medicines management policy. Whenever possible, IMPs should be stored in the pharmacy. However, it may be necessary to store a clinical trial investigational medicinal products (CT-IMP) on wards or in other departments (for example, if IMPs are to be used in emergency situations or for inpatients). The area should be assessed, and a study-specific SOP or suitable documentation should be produced to ensure all requirements are met to ensure the IMP is stored appropriately. The same standards should be applied to the storage of IMPs in the ambulance sector.

10.1.1 The proposed area for CT-IMP storage outside of the pharmacy medicine's unit should be risk assessed by a trial-trained pharmacy professional to determine whether it is suitable for the requirements of the trial.

10.1.2 The selected area and it's suitability must be discussed and agreed upon with a representative of both the Sponsor and SCAS research teams. Confirmation of

the suitability should be documented, and the documentation should be stored within the trial-specific site file(s).

10.2 A CT-IMP stored within or outside the pharmacy medicine unit should be supplied, ordered, handled, stored, dispensed, transported, quarantined, destroyed and made anyway accounted for in the same way as described in this document, unless the trial Sponsor requests an altered procedure that is specific to the trial delivery. A study-specific SOP should record such requirements including actions/steps where deviations from these requirements occur, which should be counter-referenced in the Study protocol and/or related study documentations provided by the study Sponsor. Documentations and communications relating to CT-IMP must be retained for the duration described in the study protocol.

10.3 The proposed area for IMP storage outside of the medicine's unit should be risk assessed by a pharmacy professional to determine whether it is suitable for the requirements of the trial.

10.4 The suitability of the area must be discussed and agreed with a member of the research team. Confirmation of the suitability should be documented, and the documentation stored within the trial specific site file(s).

10.5 IMPs should be temperature monitored in the same way as described in section 9 of this document. Additional temperature monitoring requirements may be required.

10.6 The study-specific SOP should state where the IMP is being stored and the area and frequency of the temperature monitoring required.

10.7 The study-specific SOP will detail as to what actions are required should a storage breach or temperature excursion occur.

11. Medicines Management

Please refer to the Medicines Management Policy for the following:

- Administration of Medicines
- Management of incidents involving medication
- Reporting Defects
- Adverse Drug Reaction Reporting
- Medication Recalls and Safety Alerts
- Medicines Procurement

11. Training

11.1Training must be completed by all clinical staff who have access to medication

11.2Training in the management and security of medications, including CDs should be given on induction

11.3Following this, refresher training should be given annually whether this is done by e-learning or as part of face-to-face training to ensure staff are up to date.

11.4All staff responsible for using medical gases should receive initial and annual training. The Trust therefore will provide training in:

11.4.1 How to identify medical gases from their labelling
11.4.2 What are medical gases, their properties and clinical uses
11.4.3 Administration
11.4.4 Safe and secure handling and storage of cylinders
11.4.5 How to report faulty cylinders and managing this safely
11.4.6 Fire and explosion risk
11.4.7 Service checks

10. Equality and diversity

10.1 An initial screen equality and diversity impact assessment has been carried out on this policy and, as per appendix 3, is available on request.

11. Monitoring

11.1 The effectiveness of this policy will be monitored through the monthly Safe and Secure Handling of Medicines audits. These will be reported to the Medicines Optimisation and Governance Group.

12. Consultation and review

12.1 A consultation exercise on the policy will be carried out with the stakeholders every 3 years, or less if there are any relevant changes to legislation or best practice.

13. Implementation (including raising awareness)

13.1 The policy will be implemented and communicated to managers and staff within the Trust via the weekly newsletter, Staff Matters. Emails will also be sent to senior managers and area managers asking them to bring the existence of the policy to their staff.

14. References

- UK Public General Acts Health Act 2006. [online]
- GOV.UK.Misuse Of Drugs And Misuse Of Drugs (Safe Custody) (Amendment) Regulations 2007. [online]
- Legislation.gov.uk. The Misuse of Drugs (Amendment) (No. 2) (England, Wales And Scotland) Regulations 2015.Statutory Instrument No. 973. [online]
- UK Statutory Instruments Misuse of Drugs Regulations 2001
- CQC The Safer Management of Controlled Drugs: Annual Update 2020 [online]
- Legislation.gov.uk. The Controlled Drugs (Supervision of Management And Use) Regulations 2013. [online]
- BOC Fire Procedure 2020
- BOC Storage and Handling of Cylinders 2020.
- Lincolnshire Community Health Services Medical Gas Policy 2017. [online]
- Solent NHS Trust Medical Gas Policy 2016.
- NASMeD & APN Security standards and guidance for the management and control of controlled drugs in the ambulance sector Version 2 April 2013
- Royal Pharmaceutical Society Professional Guidance On The Safe And Secure Handling Of Medicines. 2018
- South East Cost Ambulance Service “Standard specification for medicines rooms”

2020Legislative references

15. Associated documentation

15.1 There are also the following documents associated with this policy:

- SCAS Controlled Drugs Policy CSPP18 April 2020
- SCAS Medicines Management Policy CSPP5 April 2020
- SCAS Health and Safety Policy (Appendix A) - Minimal Lifting Policy Sept 20201 v8
- SCAS Health and Safety Policy (Appendix O) - COSHH Policy April 2020 v6

16. Appendix 1: Review Table

16.1 This policy is regularly reviewed and updated with information in line with relevant national guidance and legislation. A full 'Review Table of Contents' is available on request.

17. Appendix 2: Responsibility

17.1 The responsibility for this policy is shared between various Policy Groups, Lead Director/Officers, Working Groups and Committee members.

17.2 A full list of all responsible parties can be made available upon request.

18. Appendix 3: Equality impact assessment - Screening

18.1 An initial screening equality impact assessment has been carried out and has identified that the policy does not have an adverse or detrimental impact on any of the proscribed equality groups as the policy is designed to protect all staff who carry out work for or on behalf of the Trust.

18.2 The screening element of the initial 'Equality Impact Assessment' is available on request.

19. Appendix 4: Equality impact assessment form – Section Two – Full assessment

19.1 Due to the outcome of the initial screening equality impact assessment, it has not been necessary to carry out a full equality impact assessment.

20. Appendix 5: Ratification

Policy Title: Safe and Secure Handling of Medicines Policy

Author's Name and Job Title: Victoria Bray, Consultant Pharmacist

Review Deadline: 31st March 2022

Consultation From – To (dates): 10th March 2022 – 31st March 2022

Comments Received? (Y/N): Y

All Comments Incorporated? (Y/N): N

If No, please list comments not included along with reasons:

- Request to include alternative modules for officers/managers – outside the scope of this policy
- Request to remove requirement for barred/mesh external windows at ground floor for rooms containing medicines – a requirement for which we are inspected and therefore cannot be removed
- Request to include medicines processes within document – reference made to Medicines Management Policy, which contains reference to medicines processes, however full processes are not contained within this document as it is a policy document and not a procedure or process.

Equality Impact Assessment completed (date): 14.12.21
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Name of Accountable Group: Patient Safety Group

Date of Submission for Ratification: 13th January 2022

Template Policy Used (Y/N): Y

All Sections Completed (Y/N): Y

Monitoring Section Completed (Y/N): Y

Date of Ratification: 13th January 2022

Date Policy is Active: 14/05/2022

Date Next Review Due: 14/05/2024

Signature of Accountable Group Chair (or Deputy):

Name of Accountable Group Chair (or Deputy): Jane Campbell