South East Coast Ambulance Service NHS
NHS Foundation Trust

Changing Security Codes for Medicines Storage Standard Operating Procedure

Contents

1 Scope

1.1. The security of medicines is the responsibility of every healthcare professional and Trust employee employed by South East Coast Ambulance Service NHS Foundation Trust (SECAmb).

1.2. South East Coas t Ambulance Service NHS Foundation Trust (the Trust) is committed to providing high quality patient care.

1.3. This procedure is applicable to all clinicians in the Trust and sets out the scope of clinical practice to which clinicians must adhere.

1.4. This procedure is designed to provide the framework required to ensure all medicine door codes are routinely changed and, that this process is appropriately recorded for the purpose of audit.

1.5. Staff must adhere to this procedure so that medicines are stored securely.

1.6. All medicine access doors and key safes must be kept shut and secure at all times and access is only available for staff in line with their role and responsibilities.

1.7. In line with the Medicines Policy, all medicines security codes should be changed every **three months** by the **Operating Unit Managers (OUMs)** or nominated deputy and when staff have left Trust employment and may have access to the code.

1.8. Should a breach in security be suspected or confirmed, all medicines security codes must be changed immediately.

1.9. In medicines storage areas, senior members of the Logistics or Medicines Distribution Centre (MDC) teams will be responsible for the medicines security codes changes.

2 Procedure

2.1. All codes for key safes, doors or cupboards that allow access to medicines, including Community First Responder (CFR) cupboards, must be changed at a minimum of **3 monthly** intervals (or earlier if required).

2.2. The mechanism for how the code is changed will vary from type to type and manufacturer's guidance should be available at each location for each type of coded lock.

2.3. The code(s) should be changed by the OUM or delegated to the Operational Manager (OM) or Operational Team Leader (OTL) with

assurance this has been completed on the Manager Weekly / Monthly Medicines Security and Storage Audit.

2.4. For medicines stores, senior members of the Logistics or MDC teams will be responsible for the medicines security code changes.

2.5. CFR cupboards will also be changed on a 3 monthly basis via the OTLs.

2.6. The code should only be known to staff with the authority to access the area protected by the code and must **not** be divulged to unauthorised staff. Drugs codes must only be verbally communicated, they must not be put in writing, emails or social media, even when there is a closed group.

2.7. A definitive list should be kept up to date and held on a secure network with limited access by the local OTL team or the **Emergency Operations Centre Manager (EOCM)** within the Emergency Operations Centre (EOC).

2.8. Should any member of staff working outside of their normal area require access, the codes can be obtained via the duty OTL at the station in question or the EOCM.

2.9. Where codes have been changed, these must be communicated **verbally** to the EOC via an EOCM who will amend the secure electronic list. Under no circumstance must they be sent using any form of written communication.

2.10. For all requests made for a code, the duty manager must be satisfied that the requestor has a legal right to access the medicines requested prior to releasing the code. Confirming the identity of the requestor via GRS can be used to verify the rights to access the key codes.

2.11. Any codes changes, due to a breach or suspected breach of security, should be initiated as soon as possible by the Duty OM, Incident Command Hub or delegated to the Duty OTL. The senior member of staff investigating the incident should be advised when the code list is updated on the secure network, with a confirmation of the change .

2.12. Any authorised staff member is responsible for maintaining the security of any codes and can only store them on devices with suitable encryption (such as password or biometric access). There must be no unsecured hand written lists made in note books and under no circumstances be covertly displayed on stations or near access points to drug stores i.e. door frames.

2.13. The security of medicines on Ambulance stations and Make Ready Centres or any other Trust site holding medicines is the responsibility of all staff within these areas on a day to day basis.

2.14. If there are areas that have a door code in addition to swipe card restricted access, the Security team will be responsible for changing this every 3 months and informing the OM/OUM.

3 Responsibilities

3.1. The **Chief Executive Officer (CEO)** is accountable for Medicines use and governance in the Trust.

3.2. The **Chief Medical Officer** through delegation by the CEO, has overall responsibility for medicines governance system design and overall assurance. The Executive Medical Director has responsibility for the implementation, review, and thus revision where required, of this procedure.

3.3. The **Chief Pharmacist** is the professional medicines governance lead for the Trust and is responsible for producing robust systems and processes which comply fully with legislation, national guidance, and regulatory requirements to ensure the safe and effective management and use of medicines throughout the Trust. The Chief Pharmacist supports the Chief Medical Officer and Executive Director of Operations providing pharmaceutical professional advice with regards to all medicines related policies, procedures and practices.

3.4. The **Executive Director of Operations**, through delegation by the CEO, has overall responsibility for the implementation, operation and local assurance of this policy. The Executive Director of Operations has overall responsibility for holding his/her staff to account for any deviations from this policy and is responsible for the operational compliance of this procedure.

3.5. The **Executive Director of Operations**, **Chief Medical Officer** and **Chief Pharmacist** are responsible for escalating unresolved concerns to the Medicines Governance Group (MGG).

3.6. The Executive Director of Operations delegates local responsibilities and accountability for this procedure to the **Associate Directors of Operations**, **Operational Unit Managers, Operational Managers, Specialist Managers** and where relevant the **Head of Fleet and Logistics.**

3.7. The **Associate Directors of Operations, Operational Units Managers**, **Operational Managers, Specialist Managers** and where relevant the **Head of Fleet and Logistics** delegate their local responsibility and accountability for this policy to their staff including the **Operational Team Leaders (OTLs), Logistics Manager**, and others.

3.8. The **Executive Director of Quality and Nursing** has responsibility for matters relating to regulatory compliance, risk management, health and safety relating to this procedure.

3.9. **Controlled Drug Accountable Officer** is a Trust medical doctor who is responsible for the safe management and use of Controlled Drugs within the Trust along with co-operating and sharing information relating to concerns about the Trust's use and management under the Controlled Drug (Supervision of Management and Use) Regulations 2013. These responsibilities include keeping records of the investigation of concerns and acting where appropriate.

3.10. The **Medicines Safety Officer (MSO)** is also the **Chief Pharmacist**. The MSO supports local medication error reporting and learning. The MSO acts as the main contact for NHS England and Medicines and Healthcare Products Regulatory Agency (MHRA).

3.11. The **Medicines Governance Group (MGG)** is responsible, for providing strategic direction for the implementation of medicines management and practice within the Trust The primary objective of MGG is to ensure appropriate clinical and cost effective use of medicines, promoting the highest standards of medicines management and safe practice throughout the Trust, by ensuring that senior managers are aware of issues relating to the use of medicines within the organisation as part of the overall clinical and corporate governance structure.

3.12. The **Medical Gas Subgroup** provides assurance to MGG that medical gases are effectively monitored and managed within the Trust.

3.13. The **Patient Group Direction (PGD) Approval and Working Group** provides assurance to MGG and ensures the development, review, updates and implementation of PGDs are in line with legislation and national good practice.

3.14. The **Medicines Governance Team (MGT)** are responsible for ensuring the safe and efficient procurement of medicines, including controlled drugs to ensure the quality of the product, safe dispensing/packing into medicines pouches through to safe disposal of pharmaceutical waste. The MGT will support the Chief Pharmacists with drug shortages, drug

alerts and relevant information relating to medicines is communicated in a timely manner.

3.15. **All staff** are responsible for their own professional practice. All staff involved in the prescribing, supply, dispensing, handling, storage, administration and disposal of medicines, including controlled drugs, must receive appropriate training and assessment of competence before commencing their roles. All staff who handle medicines are personally accountable for complying with this policy and relevant standard operation procedures, for reporting any concerns and for the safe handling of all medicines.

4 Audit and Review (evaluating effectiveness)

4.1. OTLs, OMs, and OUMs (or other delegated registered clinicians) must complete Weekly, Monthly Medicines Security and Storage Audits on the central database to ensure compliance with this SOP.

4.2. Deviations from this SOP must be investigated within 24 hours and corrective action taken to obtain full compliance by the next audit.

4.3. Concerns arising from any audit that cannot be locally resolved and full compliance assured by next audit must be escalated to the Medicines Team via a DIF1 (Datix) report.

4.4. Any unexplained loss of medicines or deviation from SOP must also be reported via a DIF1.

4.5. The Medicines Governance Team will review the Daily, Weekly and Monthly Medicines Security and Storage Audits to ensure compliance with this SOP.

4.6. The Chief Pharmacist and staff will complete 6 monthly Medicines Security and Storage Audit and report any repeated deviations or other concerns to the Medicines Governance Group.

4.7. Ad hoc inspection of medicines security and storage will take place as part of Crime Reduction Surveys and Trust Quality Assurance Visits.

4.8. Deviations arising from these inspections must be escalated to the Medicines Team via a DIF1 (Datix) report.

4.9. The CDAO (Executive Medical Director) with support from the Executive Director of Operations and Chief Pharmacist must report outstanding concerns to the Medicines Governance Group and the Controlled Drugs Liaison Officer (CDLO).

4.10. The CDAO with support from the Chief Pharmacist must report outstanding concerns to the Controlled Drugs Local Intelligence Network (CD LIN) on a quarterly basis.

4.11. All procedures must have their effectiveness audited by the responsible Management Group at regular intervals, and initially six months after a new policy is approved and disseminated.

4.12. Effectiveness will be reviewed using the tools set out in the Trust's Policy and Procedure for the Development and Management of Trust Policies and Procedures (also known as the Policy on Policies).

4.13. All policies have their effectiveness audited by the responsible Management Group at regular intervals, and initially six months after a new policy is approved and disseminated.

4.14. Effectiveness will be reviewed using the tools set out in the Trust's Policy and Procedure for the Development and Management of Trust Policies and Procedures (also known as the Policy on Policies).

4.15. This document will be reviewed in its entirety every three years or sooner if new legislation, codes of practice or national standards are introduced, or if feedback from employees indicates that the policy is not working effectively.

4.16. All changes made to this procedure will go through the governance route for development and approval as set out in the Policy on Policies.

5 Associated Trust Documentation

5.1. Controlled Drugs Policy

5.2. Record Keeping and Controlled Drug Register Entries SOP

5.3. Medicines Policy

5.4. Administration of Controlled Drugs SOP

5.5. Changing Security Codes for Medicines Storage SOP

5.6. Controlled Drug Stock Checks and Reconciliation SOP

5.7. Handling of Drug Alerts and Recalls SOP

5.8. Medicine Temperature Recording SOP

5.9. Disposal of Controlled Drugs SOP

5.10. Security Management Policy

5.11. Expiry Date Checking and Rotation of Medicines SOP

6 Equality Analysis

6.1. The Trust believes in fairness and equality, and values diversity in its role as both a provider of services and as an employer. The Trust aims to provide accessible services that respect the needs of each individual and exclude no-one. It is committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.

6.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature then for the duration of the contract, the contractor or supplier would itself be considered a public authority and have the duty to comply with the equalities duties when carrying out those functions.