South East Coast Ambulance Service NHS
NHS Foundation Trust

Administration of Controlled Drugs Standard Operating Procedure

Contents

1 Scope

1.1. South East Coast Ambulance (SECAmb) NHS Foundation Trust is committed to providing high quality patient care and the safe and secure management of medicines.

1.2. Only SECAmb authorised Registered Healthcare Professionals (HCP) can be in possession of stock-controlled drugs (CDs) in the course of their duties. Non-registered staff cannot possess stock CDs unless this is authorised by SECAmb as part of their duties in line with the Trust CD policy (e.g. Logistics staff transporting stock CDs).

1.3. A CD can only be administered to a patient by a competent registered HCP, who is authorised by the Trust and meets the necessary compliance requirements (Patient Group Directions (PGD) drugs must be previously authorised via JRCALC plus).

1.4. This Standard Operating Procedure (SOP) describes:

1.4.1. The process of withdrawing controlled drugs (CDs) at the start of shift.

1.4.2. The governance around administering CDs to patients and documentation requirements.

1.4.3. How CDs are accounted for and returned at the end of a shift.

1.4.4. The action to be taken if CDs are retained whilst staff are off duty.

1.4.5. Accountability of all staff who handle CDs.

1.5. The requirements for record keeping.

2 Procedure

2.1. CDs are withdrawn at the start of each shift where the quantity, batch number, signature of the member of staff withdrawing the stock and the witness is documented either in a paper CD register or on an electronic CD register (Omnicell).

2.2. If no witness is available (under exceptional circumstances e.g., Solo Response Vehicles (SRVs)) the following action will need to be taken:

- ‘NWA’ (No Witness Available) must be documented in the paper CD Register entry.
- The ‘Emergency Barcode’ to be used against the electronic entry (Omnicell, see ‘Use of the Omnicell Emergency Access Barcode’).

2.3. Use of this exceptional circumstance will be regularly monitored.

2.4. Only two ampoules of Morphine Sulphate injection and two ampoules of Diazepam injection should be carried at any one time. Critical Care Paramedics (CCPs) at SECAmb are authorised to carry Ketamine and Midazolam injections in addition to this and Paramedic Practitioners (PPs) are authorised to take out Midazolam injections and Codeine tablets.

2.5. A balance check of the CD must be carried out by the authorised healthcare professional (HCP) prior to withdrawal of CDs. Any discrepancy should be reported immediately to the duty Operational Team Leader (OTL) for further investigation and a DIF-1 raised on the Trust Datix Incident Reporting system.

2.6. The HCP making a CD withdrawal and the witness are equally responsible and accountable for the balance check.

2.7. The required CD MUST be withdrawn from CD storage in line with the SOP on Record Keeping and Controlled Drug Register Entries.

2.8. The CD MUST then be stored in the personal issue, controlled drug pouch or an authorised secure container.

2.9. Non-registered staff can only possess rectal Diazepam in the specialist pouch but cannot possess other CDs. Paramedics must not entrust their CD pouch to non-registered colleagues or delegate any other aspect of the use of CDs in practice (i.e. preparation or administration).

2.10. The SECAmb formulary includes CDs with multiple administration routes. The indication, formulation and administration route must be carefully checked before use. All attempts must be made to ensure a second check is performed by a witness where possible. Please refer to the CD policy for more details.

2.11. Prior to patient administration of a CD, the following details must be recorded on the Patient Care Record (PCR) or electronic Patient Care Record (ePCR):

- Incident number (CAD number)
- Name of the patient
- Date and time of administration
- Drug name, form and dose administered
- Batch number & expiry date
- Route of administration
- Personnel number relating to the clinician who administered the drug
- Witness name and ID where possible

2.12. Waste disposal is also witnessed and recorded on the ePCR (see Disposal of Controlled Drugs SOP).

2.13. If a dose is prepared and it (or part thereof) is not required, the remaining dose should be discharged into a 'Disposal of old Pharmaceuticals' container (DOOP pot). The amount disposed of in the DOOP pot must be recorded on PCR or ePCR and witnessed.

2.14. Partially used syringes of CDs must not be handed to another crew member or HCP taking over patient care as accountability for the CD remains with the original practitioner.

2.15. All administrations of CDs must be entered into a CD register ensuring the CAD number and dose administered is documented (see SOP Record Keeping and Controlled Drug Register Entries). This must be witnessed by a second member of staff authorised to act as a witness.

2.16. During this process, a balance check must be performed. Any discrepancies in CD balances need to be reported immediately to the duty OTL for further investigation.

2.17. If an ampoule containing a CD is broken, the ampoule and any remaining particles should be placed in a DOOP container. A DIF1 should be completed with the incident number recorded in the CD register (see SOP for Record Keeping and Controlled Drug Register Entries).

2.18. All CD wastage must also be recorded in the CD register (see SOP Record Keeping and Controlled Drug Register Entries).

2.19. If CDs are retained whilst staff are off duty, a DIF1 form MUST be completed. CDs MUST be returned to station and the CD register reconciled within 24 hours.

3 Definitions

3.1. Datix is the Trust's incident management system.

3.2. DIF1 is the report form process used by Datix.

3.3. CAD is the automated dispatch system used by the emergency operations centre (EOC).

4 Responsibilities

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

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

4.3. 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.

4.4. 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.

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

4.6. 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.**

4.7. 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.

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

4.9. **Controlled Drug Accountable Officer** is also the **Chief Medical Officer** and 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.

4.10. 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).

4.11. 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.

4.12. The role of The **Non-Medical Prescribing (NMP) Group** is to provide overarching multidisciplinary leadership for non-medical prescribing (NMP) within the Trust. In doing so, it manages the process of Trust approval to train as a non-medical prescriber and to prescribe, taking account of service redesigns and improved patient access to medicines. The NMP Group aims to strengthen and monitor the governance issues associated with non-medical prescribing, to determine potential and support existing non-medical prescribers, advise the MGG on matters relating to non-medical prescribing and will report exceptions relating to non-medical prescribing to the MGG.

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

4.14. 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.

4.15. 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.

4.16. **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.

5 Audit and Review for CD SOPs

5.1. OTLs (or other registered clinicians delegated by local managers) must complete weekly and monthly Medicines Security and Storage Audits on the central database to ensure compliance with this SOP.

5.2. Deviations from this SOP must be investigated immediately.

5.3. Any deviations that cannot immediately be resolved must be immediately escalated to the controlled drugs accountable officer (CDAO) via a DIF1 report.

5.4. The CDAO with support from the Executive Director of Operations and Chief Pharmacist must report outstanding concerns to the Medicines Governance Group and the Police controlled drugs liaison officers (CDLOs).

5.5. 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.

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

5.7. 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).

5.8. 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.

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

6 Associated Trust Documentation

6.1. Controlled Drugs Policy

6.2. Controlled Drugs Possession Using Body Worn Pouches

6.3. Changing Security Codes for Medicines Storage

6.4. Controlled Drug Stock Checks and Reconciliation

6.5. Disposal of Controlled Drugs

6.6. Security Management Policy

6.7. Expiry Date Checking and Rotation of Medicines

6.8. Ordering and Distribution of Medicines

6.9. Receipt of Medicines from External Suppliers

6.10. Record Keeping and Controlled Drug Register Entries

6.11. Use of the Omnicell Emergency Access Barcode

7 Financial Checkpoint

7.1. **This document has been confirmed by Finance to have no unbudgeted financial implications.**

8 Equality Analysis

8.1. 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.

8.2. 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.