South East Coast Ambulance Service NHS
NHS Foundation Trust

Administration of Medicines
Standard Operating Procedure

Contents

1 Scope

1.1. South East Coast Ambulance Service NHS Foundation Trust (the Trust) is committed to providing high quality patient care.

1.2. The purpose of this Standard Operating Procedure (SOP) is to improve the standards in the security, management and administration of medicines in SECAmb.

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.

2 Introduction

2.1. Definition of Medicines

2.1.1. “Any substance or combination of substances presented for treating or preventing disease in human beings or in animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product.” Council Directive 65/65/EEC.

2.2. Legal framework for the administration of medicines

2.2.1. Medicines are administered to a patient in accordance with a prescription, Patient Specific Direction (PSD), Patient Group Direction (PGD), Trust Approved Protocol or other relevant exemptions specified in the Human Medicines Regulations 2012.

2.3. Personnel authorised to administer medicines as per scope of practice

- Paramedic
- Paramedic practitioner (PP)
- Critical Care paramedic (CCP)
- Advanced Technician
- Associated Ambulance Practitioner (AAP)
- Associate practitioner
- Technicians
- Emergency Care Support Worker (ECSW)
- Community first responder (CFR)

3 Procedure

All Medicines

All medication should be administered in accordance with the SECAmb Scope of Practice and Clinical Standards policy.
For PGD and Trust Protocol medicines, staff must ensure compliance to administer these drugs (e.g. up-to-date competency assessment through Parapass via JRCALC, training etc).

Clinicians must know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indication.

Where possible, clinicians must check any other medication the patient is receiving or has taken recently for contraindication with the medicine to be administered.

If there are any risks associated with the handling or administration of a medicine, clinicians must ensure the risks are minimised where possible, and suitable equipment used.

Staff should also have completed the necessary training prior to administration of any medicines.

Clinicians must check that the patient is not allergic to the medicine before administration.

Clinicians must have considered the dosage, weight where appropriate, method of administration, route and timing

Clinicians must check the batch number and expiry date of the medicine to be administered to ensure the medicine is in date prior to administration to our patients.

Clinicians must receive the patients consent before administration where applicable.

Where possible, clinicians must always get a double check on the medication prior to administration to reduce the risk of error.

Clinicians must make a clear, accurate and immediate record of all medication administered or refused on the patient clinical record (PCR) or electronic PCR (ePCR)

Documentation must include

- Incident number (CAD number)
- Patients name address, date of birth

- Record valid, informed consent was given by the patient (where applicable)
- Record reason for refusal (where applicable)
- Contact details of GP (if registered)
- Diagnosis/working diagnosis
- Dose given/ route given by
- Batch number and expiry date of medicines given
- Time of administration
- Advice given to patient
- Signature and name of staff who administered medication
- Details of any adverse reaction and action taken

Where further clarity or information is required, clinicians are encouraged to contact the clinical operation desk, however verbal orders are not permitted within SECAmb and the clinician at scene retains full accountability for all medications administered.

Following administration, the patient should be evaluated and assessed for any adverse effects.

All adverse medications events should be reported via the yellow card scheme https://yellowcard.mhra.gov.uk and a datix (DIF1) submitted.

Controlled Drug (CD) Administration
Please refer to the Administration of Controlled Drugs SOP.

4 Definitions

Associate Ambulance Practitioner (AAP)/Technician	A non-registered healthcare worker who predonminantly forms part of a two-person crew. They are trained in technical ambulance skills, assessment techniques and emergency medical care.
Administration	To give a medicine either by introduction into the body e.g., orally, by injection or by external application e.g., impregnated dressing
Adverse Drug Reaction (ADR)	An unwanted or harmful reaction which occurs after administration of a drug or drugs and is suspected or known to be due to the drug(s)
CDs	See Controlled Drugs
CDLO	Controlled Drug Liaison Officers. CDLOs are members of the police force.
Community First Responders (CFRs)	Community First Responders (CFRs) are volunteers who respond to local emergency calls and provide lifesaving first aid before an ambulance arrives.

Controlled Drugs (CDs)	Drugs that are controlled under Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.
Controlled Drugs Accountable Officer (CDAO)	Member of staff responsible for the governance of controlled drugs within the Trust.
Disposal of Old Pharmaceuticals (DOOP)	Pharmaceutical waste containers designed specifically to render pharmaceuticals products unusable and irretrievable.
Emergency Care Support Worker (ECSW)	A non-registered healthcare worker who forms part of a two-person crew to respond to calls. This role is designed to work alongside another clinician.
Emergency Responder (ER)	A non-registered, service-trained volunteer who attend a range of emergency calls alongside ambulance crews.
General Sales List (GSL) medicines	A medicine that can be sold in general retail outlets (such as supermarkets) without the supervision of a pharmacist. These medicines must be intact in original packaging and often have restricted pack sizes e.g., Paracetamol packs containing 16 tablets
Human Medicines Regularions (HMR)	The main legislation covering the manufacture, importation, distribution, advertising, labellinh, sale and supply of medical products for human use and pharmacovigilance.
Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Clinical Guidelines	These are established clinical practice guidelines which include medicines commonly used by ambulance services.
Licensed Medicine	Medicine with a Marketing Authorisation, formerly known as a Product Licence and granted by the Medicines and Healthcare Products Regulatory Agency (MHRA).
Medicine	Medicinal Products as defined by the Medicines Act 1968 i.e. a substance administered by mouth, applied to or introduced into the body for the purpose of treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, contraception, inducing anaesthesia, or otherwise preventing or interfering with the normal operation of a physiological function.
Medicines Governance Group (MGG)	The formal group within SECAmb that makes decisions and recommendations regarding medicines and their use within SECAmb.

"Off-label" use of Medicine	Medicine with a Marketing Authorisation but being used outside the terms of the Summary of Product Characteristics (Data Sheet).
Non-medical Prescriber	Nurses, pharmacists, physiotherapists, podiatrists and community practitioners who have undertaken further professional training in prescribing.
Non-registered staff	SECAmb staff who are employed to deliver patient care but are not formally registered with a professional body (e.g. CFRs, ECSWs, TAAPs etc).
Operational Team Leaders (OTLs)	OTLs are registered paramedics with responsibilities for the safe and secure storage, handling and management of medicines including controlled drugs within operational locations (e.g., ambulance stations).
OTLs	See Operational Team Leaders
Parenteral medicines	Medicines which are administered by injecting directly into the body, bypassing the skin and mucous membranes. The common parenteral routes are intramuscular (IM), subcutaneous (SC) and intravenous (IV).
Patient Group Direction (PGD)	A written instruction to enable certain healthcare professionals to supply or administer a medicine to groups of patients that may not be individually identified before presentation for treatment.
Patient Specific Direction (PSD)	A written instruction from an appropriate prescriber for medicines to be supplied or administered to a named patient. This includes instructions on patients' prescription charts.
Pharmacy (P) Medicines	Any medicinal product other than those designated as GSL or POM products. Pharmacy medicines can be sold or supplied from registered pharmacy by or under the supervision of a pharmacist, subject to certain exceptions.
Preparation of medicines for administration	The activities associated with the preparation of the medicine for use. These include the calculation and selection of doses, the withdrawal of volumes from containers, the preparation of injections from vials/ampoules of dry powder and the preparation of complex admixtures.
Prescription-Only-Medicine (POM)	A medicinal product which may only be sold or supplied against the signed prescription of an appropriate prescriber (e.g., doctor, dentist, independent or supplementary prescriber) and some nurses specified in the Prescriptions Only Medicines (Human Use) Order 1997.

	The exceptions to this are for emergency medicines used for the purpose of saving a life and exemptions to Medicines Act for podiatrists.
PSD	See Patient Specific Direction.
Registered Doctor	A person whose name appears on the List of Registered Medical Practitioners maintained by the General Medical Council.
Registered Nurse	A person whose name appears on the Register maintained by the Nursing and Midwifery Council as a registered nurse.
Registered Paramedic	A person whose name appears on the Paramedic Register maintained by the Health and Care Professions Council.
Registered Pharmacist	A person whose name appears on the pharmacist register maintained by the General Pharmaceutical Council.
Standard Operating Procedures (SOP)	A document that describes in detail, step-by-step, how a task should be carried out. It also describes the responsibilities, including audits, necessary to safely manage and accountably manage any set processes. It is a working document detailing current agreed working practices
Trainee Associate Ambulance Practitioner (TAAP)	An individual undertaking training to become a associate ambulance practitioner (see associate ambulance practitioner for further details).

5 Responsibilities

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

5.1. The **Executive Medical Director** 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.

5.2. 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 Executive Medical Director and Executive Director of Operations providing pharmaceutical professional advice with regards to all medicines related policies, procedures and practices.

5.3. 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.

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

5.5. 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.**

5.6. 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.

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

5.8. **Controlled Drug Accountable Officer** is also the **Executive Medical Director** 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.

5.9. 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).

5.10. 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.

5.11. 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.

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

5.13. 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.

5.14. 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.

5.15. **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.

6 Education and Training

The individual is required to have successfully completed the required education and training for their role/grade and must be up to date with Trust statutory and mandatory requirements and authorised for administration of medicines by completion of the appropriate PGD quizzes.

7 Audit and Review for CD SOPs

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

7.2. Deviations from this SOP must be investigated immediately.

7.3. Any deviations for controlled drugs that cannot immediately be resolved must be immediately escalated to the Chief Pharmacist and CDAO and a Datix (DIF1) report submitted immediately.

7.4. The CDAO with support from the Director of Operations and Chief Pharmacist must report outstanding controlled drugs concerns to the Medicines Governance Group and the local liaison officer (CDLO)

7.5. The CDAO with support from the Chief Pharmacist must report outstanding concerns to the CD LIN (local intelligence network) on a quarterly basis.

7.6. Patient Group Directions (PGD) administration will be audited in line with annual audit plan and NICE framework for auditing of PGDs.

7.7. 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.

7.8. 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).

7.9. 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.

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

8 References

8.1. Human Medicines Regulations 2012. http://www.legislation.gov.uk/uksi/2012/1916/contents/made

8.2. Nursing and Midwifery Council, Standards for Medicines Management https://www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-for-medicines-management.

8.3. NICE guidance, Patient Group Directions, Medicines practice guideline (MPG2GD) March2017

https://www.nice.org.uk/guidance/mpg2/chapter/recommendations

8.4. Security standards and guidance for the management and control of controlled drugs in the ambulance sector. National Ambulance Service Medical Directors March 2017

8.5. Controlled Dugs (Supervision of Management and Use) Regulations 2013 (SI (2013/373))

8.6. Misuse of Drugs Act 1971, 2001 Regulations

8.7. Harold Shipman Inquiry Fourth Report - The Regulation of Controlled Drugs in the Community 2004

8.8. Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs DOH 2007

8.9. Safer Management of Controlled Drugs – Annual Report CQC 2020

8.10. Controlled Drugs (supervision and management and use) Regulations 2013 Department of Health

9 Equality Analysis

9.1. 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.

9.2. 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.

10 Financial Checkpoint

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