South East Coast Ambulance Service NHS
NHS Foundation Trust

Time expired medications in education and training Standard Operating Procedure

Contents

Scope

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

1.2. This procedure covers the use of time expired medications for formal training and education purposes within the Trust.

1.3. Time expired medications are those which have been withdrawn from operational use due to passing the expiry date stated on the product by the manufacturer or supplier.

1.4. This procedure details the processes for obtaining, transporting, storing, utilising and disposing of time expired medications in order to ensure safe systems of work relating to these practices.

1.5. The maintenance of accurate records at each stage are intrinsic to these safe systems of work.

1.6. Part of these safe systems of work must include that time expired medications are identified as such at all stages of the procedure, from requisition until disposal. This is to act as a safeguard against the risk of expired medications inadvertently being returned to the live system.

1.7. This procedure does not include or allow any administration rights of any kind to any person.

1.8. This procedure specifically excludes the use of expired controlled drugs (or any medications which are managed as controlled drugs) for educational purposes.

1.9. This procedure does not cover the use of in date (‘live’) medications for training. Where live medications are used for educational purposes within the operational system (for example demonstrating to a new member of staff how to open a glass ampoule) the medication must be withdrawn, recorded and disposed of in line with the Trust’s existing medicines management procedures for spoiled medications.

1.10. This procedure only provides authority for SECAmb staff delivering trust authorised courses as part of their employed duty and does not apply to any sub-contractor or partner organisation.

2 Procedure

2.1. Educators within the Trust are authorised by the Trust’s Chief Medical Officer to store time expired medications for educational purposes within authorised locations (see appendix A). Educational purposes include but are not limited to:

- Identification of medication packaging and labelling.
- The range of presentations of medications (such as ampoules, pre-filled syringes, etc).

- The correct technique for opening a glass ampoule.
- The correct technique for drawing up a liquid medication into a syringe.
- Simulated patient management scenarios.

2.2. The expired medications supplied for education **must never be allowed to enter back into the operational medicines management system** where they could potentially be administered to a patient. They must be clearly and permanently marked as 'Expired medication for training use only'. Warning labels must be applied to the medication and it's packaging whilst ensuring the name and batch number of the medication is visible. Note that the exact wording of the label may vary but the key elements (not for patient use, training use only, expired, etc.) must be retained.

2.3. It is recognised that for education and training purposes the type of packaging (presentation) of the medication is more important than the medication itself. Therefore, expired medications can be broadly categorised as follows:

- Ampoules containing liquid
- Ampoules containing powder for reconstitution
- Nebules
- Pre-filled syringes
- Infusion bags and equivalent (e.g., saline, IV paracetamol).
- Inhaled substance (e.g., Penthrox)
- Sublingual sprays

2.4. These descriptions will be used for requisition, however for storage, audit, and stock check purposes then medications must be itemised by name.

2.5. All medications must be disposed of safely and in accordance with Trust guidelines for the disposal of medications once no longer required for training (see paragraph 4.4). Medications will be disposed of in a blue lidded bin.

2.6. Only authorised individuals who are registered with the Health and Care Professions Council (HCPC), Nursing and Midwifery Council (NMC), or other registered body, may withdraw time expired medications and these must only be used for educational purposes. Once withdrawn, the individual must retain responsibility for these medications until returned or destroyed and they must only be used under supervision of the individual who has withdrawn them.

3 Obtaining and storing medications for training

3.1. To ensure that time expired medications are kept separate from the live operational stock, they will only be stored at designated education centres which do not hold a stock of operational medications (see appendix A). The supplied time expired medication must only be used at these sites

and must not under any circumstances be taken to other locations for training or any other purpose.

3.1.1. In order to prevent ‘cross-contamination’, if live (in-date) medicines are to be used or demonstrated at any of the locations identified in paragraph 3.1, time-expired medications must not be used simultaneously (even within another room or location within the same venue).

3.2. Time expired medications will be stored in a medicines pouch, clearly labelled ‘expired medication for training use only’. Unless actively in use for training this pouch must remain ‘red tagged’ at all times – this will perform part of the fail-safe system as any red tagged pouches in the operational medications system would be directly returned to the medicines distribution centre (MDC).

3.3. Time expired medications must be stored within a locked medications cabinet in the Clinical Education equipment store. Red-tagged pouches containing time expired medications must be stored in a separate locked cabinet in the equipment store. Access to these cabinets should only be for authorised persons.

3.4. The medications cabinet must not contain anything other than time expired medications and associated packaging and documentation and must be clearly marked externally as ‘Time expired medications – authorised access for educational purposes only’.

3.5. Each expired medications store will have a maximum and a minimum stock level. When the minimum stock level is reached, a requisition request may be submitted to the MDC to return the store to the maximum stock level.

3.6. Within the live medications steam, if medications are due to expire the Medicines Governance Team will offer the time expired medications to Clinical Education through a Senior Education Manager. The Senior Education Manager should check stock and accept or decline.

3.7. Upon receiving this request, the Medicines Governance Team will collect the requested medications from expired stock prior to disposal. Once the requested quantity has been reached, the Medicines Governance Team will arrange direct delivery to the approved location to be transferred to the expired medications store at the authorised location directly (see paragraph 5.3). The person who accepted the offer (see paragraph 3.6) or submitted the request will be contacted. That person must collect the expired medications in person and transfer them to the expired medications store directly (see paragraph 5.3). This responsibility cannot be delegated to any other individual. Warning labels (see paragraph 2.2) must be applied prior to the time-expired medication leaving the MDC.

4 Recording expired medications released for training

4.1. As part of the medicines management process, it is essential that records are kept detailing how all expired drugs are disposed of. For most expired medications this record will be maintained by the Medicines Governance Team.

4.2. Expired medications which are released for educational purposes will be considered as 'disposed of' by the Medicines Governance Team and recorded as Clinical Education stock.

4.3. It is therefore essential that all medications released for educational purposes are eventually disposed of appropriately, however before this occurs, they may be used for educational purposes in line with this procedure.

4.4. If at any stage these medications are no longer required for educational purposes, the medications must be disposed of immediately in line with current Trust procedure.

4.5. Additionally, if this procedure is suspended or withdrawn for any reason then all medicines stored for educational purposes must be disposed of immediately in line with current Trust policies to ensure the Trust remains compliant with Care Quality Commission (CQC) requirements and governance.

4.6. At each authorised location where expired medications are stored, a stock record book must be maintained, detailing as a minimum:

- Any medications added.
- Current numbers of medications stored.
- Any medications removed.
- Any medications disposed of.

4.7. The stock record book must be clearly marked on the front cover 'Expired medication for training use only – stock record' and should remain locked within the expired medicines cabinet.

4.8. Where medications are disposed of this must be in-line with current Trust guidance but may include where medications are used for education and subsequently placed into a sharps bin (for example when practicing opening ampoules or drawing up medications) OR where medications are still whole but cannot be returned to the expired medications store for any reason.

4.9. Stock checks must be completed a minimum of once every 30 days by a Senior Education Manager or allocated deputy – these should be recorded in the stock record book in red ink.

4.10. Each pouch must have a pouch packing list to record the use of medications. This form should be completed in line with Trust protocol. When medications pouch is restocked, the packing list should be filed with medicines records.

4.11. A separate register exists for signing pouches in and out of the drugs pouch cabinet.

5 Withdrawing and transporting medications for training

5.1. When authorised persons withdraw medications for training purposes, they will retain responsibility for the safe storage, usage and either return or disposal of these medications.

5.2. The quantity withdrawn must be recorded in black ink in the stock record book within the expired medications store. Where possible this should be witnessed by another individual who should sign accordingly, or if no witness is available this should be clearly marked.

5.3. During authorised transit the medications must be kept within their marked pouch which is red tagged and locked within a suitable designated container used only for the purposes of storing and transporting time expired medications, and clearly marked as such.

5.3.1. Authorised transit is defined as the movement of the time expired medications between the MDC and the expired medications store at the authorised location, and the movement from the expired medications store to the specific area of use at the authorised location only.

5.4. The container used for the authorised transit of expired medications must be locked shut and labelled ‘Expired Medications for use in training only’.

5.5. A person signing out medications has responsibility for returning them to the store or disposing of them appropriately. Withdrawn expired medications cannot be transferred from one person to another without first being returned to the expired medications store from which they were withdrawn.

5.6. Once no longer required any remaining medications must be returned as soon as possible to the expired medications store and the stock record book must be updated in black ink with the number of medications returned, and the number disposed of.

5.7. Any discrepancies must be reported using the Datix, DIF1 reporting system.

6 Auditing and safeguards

6.1. The following safeguards are in place to ensure the security of time expired medications used for educational purposes, along with how these methods will be audited:

6.2. All time expired medications used for educational purposes will have stickers attached prior to leaving the MDC (see paragraph 2.2) – if any

time expired medication is found unmarked this must be reported via a DIF1 report.

6.3. All time expired medications used for educational purposes will be stored in designated and marked storage cabinets and only at authorised sites which do not have storage for 'live' operational medications (see section 3). The stock control of these storage locations will be audited through completion of a stock record book and any discrepancies will be reported using the Datix, DIF1 reporting system.

6.4. Designated storage sites must have three points of security access:

- External building access using ID card 'swipe' system
- Locked room containing expired medicines cabinet
- Locked medicines cabinet

6.5. Where key codes are used the codes must be kept secure; must only distributed to authorised personnel; and must be changed in line with current Trust policy. The code used must be unique and not used elsewhere in the trust for medicines management.

6.6. All time expired medications used for educational purposes will be kept within a medications pouch, clearly marked 'expired medication for training use only' and secured with a red tag before, after and between uses (see paragraph 3.2).

6.7. Records of requests for expired medication (see paragraph 3.6 and 3.7) must be retained by the Medicines Governance Team.

7 Definitions

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

7.2. DIF1 is the report used to notify of an incident.

7.3. Educators are defined as any Trust employee or volunteer who is authorised to deliver education or support the development of others as part of their role. This includes, but is not limited to, Clinical Education staff, specialist paramedics, Practice Educators, Key Skills Facilitators, Resilience Department trainers, Community First Responder (CFR) trainers.

8 Responsibilities

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

8.2. 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.

8.3. 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.

8.4. 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.

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

8.6. 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.**

8.7. 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.

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

8.9. **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.

8.10. 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).

8.11. 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.

8.12. 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.

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

8.14. 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.

8.15. 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.

8.16. 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.

9 Education and Training

9.1. Familiarisation with this procedure should form part of the induction process for all colleagues taking on an Educator role (or relevant education support role) within the Trust.

9.2. All individuals who undertake any element of the process described in this procedure (including not but limited to the Medicines Governance Team, colleagues at the Medicines Distribution Centre, the Senior Education Managers, and the educators using time-expired medications) must ensure they are familiar with this procedure prior to applying it.

10 Audit and Review (evaluating effectiveness)

10.1. 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.

10.2. 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).

10.3. 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.

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

10.5. The current stock levels of stored expired medications will be checked and recorded at each authorised location before and after each withdrawal / return of expired medications. Each check should be completed and signed for by the authorised individual and must be witness checked. Any discrepancies must be escalated immediately via the Datix, DIF1 system.

10.6. An independent stock check of all stored expired medications will be made at each authorised location at least once every 30 days by a Senior Education Manager or allocated deputy. The results must be recorded in the stock record book in red ink. Additionally, the completion of the stock check should be recorded on the outside of the medication's cabinet. Any discrepancies must be escalated immediately via the Datix, DIF1 system.

10.7. The Medicines Governance Team will also undertake an inspection check every 6-months as part of their normal processes.

10.8. It is acknowledged that any incident of a time expired medication entering the live operational system is a significant error which should be considered a 'never event'. Any such instance must be investigated with a full root cause analysis.

10.9. Any reporting of such an incident would take place via the Datix, DIF1 reporting system and should prompt an immediate review of this procedure.

10.10. The procedure will be reviewed if an incident report prompts an earlier review (see paragraph 10.8); or if the procedure is no longer valid or required.

11 Associated Trust Documentation

11.1. SECAmb Waste Management policy

11.2. SECAmb Medicines Policy, v6

11.3. SECAmb Pouch Tagging Process SOP

12 Financial Checkpoint

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

Appendix A: Authorised storage sites for time expired medications

Haywards heath College Clinical Education Centre is the only site authorised for the storage of time expired medications for training purposes only.

Pouch	Drug	Pack Size	Packing level	Minimum level to leave distribution centre
Arrest	Adrenaline 1:1000 pre-filled syringe	1	4	4
	Amiodarone 300mg pre-filled injection	11	1	1
Cardiac	Aspirin 300mg Tablets	32	16	2
	Atropine 600mcg ampoule for injection	10	6	2
	Furosemide 20mg in 2ml for injection	10	2	2
	GTN Spray 400micrograms per spray	1	1	1
	Ondansetron 2mg in ml amp for Injection	5	2	2
	Ticagrelor 90mg Tablets	56	14	2
Fluids	Activated Charcoal 50g suspension in 250ml of water	1	1	1
	Penthrox (Methoxyflurane) 99.9%, 3 mL inhalation vapour, liquid	1	1	1
	3-way tap	100	2	1
	50ml syringe	60	1	1
	IV Paracetamol 1gram in 100ml infusion	10	4	1
	IV Giving set	50	4	1
	Sodium Chloride 0.9% 10ml ampoule for injection	50	5	2
	Sodium Chloride 0.9% infusion bags 500ml	**10**	1	1
Hypo	Glucagon 1mg Injection	1	1	1
	Glucose 40% gel 40g tube	3	2	2
	Glucose 10% Intravenous infusion	20	1	1
	50ml syringe	100	1	1
	3-way tap	100	1	1
	IV Giving set	50	1	1
Specialist	Benzylpenicillin 600mg powder for injection	25	2	2
	Calpol melts 6+ 250mg per meltlet	24	6	2
	Co-Amoxiclav powder for solution 1000mg in 200 mg	10	1	1
	Diazepam 2.5mg in 1.25ml rectal solution	5	1	1
	Diazepam 5mg in 1.25ml rectal solution	5	2	2
	Diazepam 10mg in 1.25ml rectal solution	5	1	1
	Ibuprofen 200mg tablets	84	12	4
	Ibuprofen 100mg in 5ml oral suspension sachets	12	2	2
	Misoprostol 200 microgram tablets	60	10	2
	Paracetamol 500mg tablets	100	10	4
	Paracetamol 120mg in 5ml suspension sachets	20	3	2
	Tranexamic acid 500mg solution for injection	5	2	2
	Water For Injection 10ml ampoule for injection	50	4	2
Respiratory	10ml Oral syringe	100	2	1
	Adrenaline 1:1000 ampoule for injection	10	4	2
	Chlorphenamine 10mg ampoule for injection	5	2	1
	Dexamethasone 2mg soluble Tablets	50	10	2
	Hydrocortisone 100mg Solution for injection	10	2	2
	Ipratropium 250mcg in 1ml Nebuliser solution	20	10	4
	Naloxone 400mcg in 1ml ampoule for injection	10	7	5
	Salbutamol 2.5mg in 2.5ml nebuliser solution	20	15	5