



Expired Consumables in Educational Environments Procedure

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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 Trust recognises that the provision of high quality education, including simulation of patient care episodes, is an essential component of maintaining high quality care provision.
- 1.3. The Trust is also committed to ensuring financial, economic and environmental sustainability in line with the wider National Health Service Sustainability model.
- 1.4. This procedure seeks to ensure efficient and economical use of resources when using medical consumables in an educational environment, and applies to all Trust colleagues when providing, receiving or supporting programmes of education.
- 1.5. For the purposes of this procedure, a medical consumable is considered to be any item designed to be used during a patient care episode and disposed of following use. Items may or may not be designed for single-use and may or may not have a clearly displayed expiry date.
- 1.6. This procedure does not cover the use of medications in education, which are considered under a separate procedure.
- 1.7. This procedure only provides authority for SECAMB staff at Trust authorised courses and does not apply to any sub-contractor or partner organisations (which would be expected to follow their own procedures) or to colleagues delivering education external to the Trust (for example in private employment).

2 Procedure

- 2.1. Educators within the Trust are authorised by the Trust's Chief Medical Officer to store and use medical consumables which are not suitable for use in a live clinical environment for the sole purpose of using for educational purposes. Reasons why medical consumables may not be suitable for use in a live clinical environment include (but are not limited to):
 - Consumables which have exceeded their stated expiry date.
 - Consumables where packaging has been torn or damaged prior to use.
 - Consumables which have been soiled by non-hazardous waste (for example, water damage to packaging).
 - Consumables which have already been opened and used for training, or are no longer within the correct packaging.



- Consumables which are incomplete or partially damaged.
- Consumables which have been withdrawn or are subject to a manufacturer's recall (unless the nature of the withdrawal / recall is such that the item may cause harm to educators or learners).

For ease of reference, throughout this procedure such medical consumables will be referred to collectively as 'expired medical consumables'.

2.2. Educational purposes which expired medical consumables may be used for include (but are not limited to):

- Demonstration of the consumable appearance, function, or usage by educators.
- Handling and familiarisation of the consumable by the learner.
- Ensuring training bags (such as Primary Response bags) and vehicles (such as the Simbulance or Ambulance Education Room, AmbER) are fully stocked as per the Trust's Standard Load List.
- Simulated patient care scenarios where consumables are used as though providing care but to a simulated patient.
- Simulated skills practice, where isolated interventions are repeated to gain and maintain competence or confidence.

2.3. It is incumbent upon the educator to ensure that any consumables are appropriate for the educational purposes for which they are being used. For example:

2.3.1. A bag-valve-mask (BVM) which is damaged may be appropriate for demonstrating usage or how to overcome the risk of damage, but may not be appropriate for individual skills practice where this may reinforce poor technique or incorrect learning.

2.3.2. An oxygen mask may be appropriate for repeated use on a manikin, but not on a live simulated patient where there would be a potential risk of infection.

2.4. Regardless of the reason for the consumable being unsuitable for use in a live clinical environment, all other elements of appropriate use and Trust policy and procedure must be maintained. This includes correct disposal, sharps safety, etc.

2.5. It is recognised that the above authority notwithstanding, there will be circumstances where it is appropriate to use in date, intact medical consumables for educational purposes. For example:

2.5.1. Where there is insufficient availability of expired medical consumables it may be necessary to use in date, intact stock to ensure learning needs



are met. It is important that whilst expired medical consumables should be the preferred option for education provision, the lack of these should never adversely affect the quality of education.

- 2.5.1.1. In these cases, where consumables are requested specifically for education purposes, the Logistics team should endeavour to supply consumables which have the shortest possible shelf-life to ensure that longer shelf-life products are retained for live clinical use.
- 2.5.2. Where high-fidelity simulation is taking place, it is recognised that the ability to identify equipment within packaging and open packaging immediately prior to use in a high-pressure situation is an important element of the 'human factors' aspects of clinical training. Although this may be able to be simulated in other ways, this is not always the case.
- 2.5.3. Some awarding bodies or education providers may place specific requirements on the provision of equipment for assessment activity, and these must be complied with.
- 2.6. Expired medical consumables **must never be allowed to enter back into the operational stock management system** where they could potentially be used to stock an operational vehicle or used within a patient care episode. The following safe systems of work have been introduced (or in some cases, already exists) to ensure this risk is mitigated:
 - 2.6.1. Storage of expired medical consumables must be within an entirely separate area from any in date, intact consumables intended for operational use. The storage area must be clearly labelled as education equipment and include a clear warning that the stored consumables are not for patient use. [A recommended example is included at Appendix C].
 - 2.6.2. The storage area for expired medical consumables must remain locked with access restricted. Generally, colleagues who have a specific role responsibility for restocking vehicles (i.e. Make Ready Operatives) should not have access to this area to prevent inadvertent access.
 - 2.6.3. Wherever expired medical consumables are used for educational purposes, a safety poster must be displayed to show that simulation / educational activity is taking place and that equipment and consumables used are not for patient use. [A recommended example is included at Appendix D]. Ideally, this will be confined to specific education environments (such as a Clinical Education Centre or Simulation Suite within a Make Ready Centre), however it is recognised that this will not always be the case.
 - 2.6.4. Any expired medical consumable must be clearly and permanently marked as 'not for patient use'. Warning labels displaying this information must be applied to the packaging (both large multi-item boxes and



individual item packaging) ensuring that the batch number and expiry date (where applicable) remain visible.

- 2.6.4.1. Responsibility for applying these labels will sit with the individual who identifies the equipment has passed (or is nearing) the expiry date and labelling must occur prior to the expired consumables being transported to another location (either within the same site or to another site).
- 2.6.4.2. In practice, within most Operating Units this will be completed by the Make Ready / Vehicle Preparation team who will identify the expired consumables, apply the labels, and then pass to a designated person within the OU leadership team for appropriate and safe storage.
- 2.6.4.3. Centrally held consumables will be labelled by the logistics team, and then passed to the Clinical Education department for use.
- 2.6.5. Standard practice in the clinical environment is that consumable packaging should be checked to ensure it is in date and intact before use, and this should continue to be promoted as best practice. Whilst it is recognised that this is not infallible, it does provide a further level of assurance. Similarly, consumables which are not contained within their packaging for any reason should not generally be used for patient care.
- 2.6.6. All courses should continue to promote best practice by encouraging learners to check and confirm the expiry date on consumables packaging prior to use. Where the consumable used within simulation has expired, the correct (expired) date should be read out and the person confirming the check should verbally note the consumable has expired prior to using it within the educational environment – this minimises the introduction of a ‘human factors’ error where learners become used to ignoring expiry dates.
- 2.7. Expired medical consumables which are no longer required for educational purposes (for example following use, where surplus to requirements, or where unsuitable due to damage) must be disposed of in line with Trust procedure.
- 2.8. It is the responsibility of the Educator to ensure that any expired medical consumables used within a specific educational programme / session are either returned to the correct storage location in line with this procedure, or are disposed of appropriately at the end of the session. No expired medical consumables should be left unaccounted for.

3 Definitions

- 3.1. 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.

- 3.2. Medical Consumables are defined as any item designed to be used during a patient care episode and disposed of following use.
- 3.2.1. Expired Medical Consumables are those medical consumables which are not suitable for use in a live clinical environment for a range of reasons (see paragraph 2.1 for further details).

4 Responsibilities

- 4.1. The **Chief Executive Officer (CEO)** has overall accountability for all practice and governance in the Trust.
- 4.2. The **Chief Medical Officer** through delegation by the CEO, has overall responsibility for clinical 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 **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.
- 4.4. The **Head of Logistics** is responsible for identifying and supplying expired medical consumables to be used for educational purposes, as part of a stock control and rotation system. Consideration should also be given to supplying consumables which are not yet expired, however which are most likely to expire prior to being used operationally.
- 4.5. The **Clinical Equipment and Consumables Working Group (CECWG)** is the organisational focus for advice and best practice relating to the acquisition, use and management of medical consumables.
- 4.6. The **Clinical Education Sub Group** is the gatekeeper of educational quality and assurance for clinical teaching with the Trust.
- 4.7. **Make Ready Centre Managers** and the **Clinical Education Equipment Coordinator** are responsible for ensuring that expired medical consumable are ordered and stored in compliance with this procedure.



- 4.8. All **Educators** (and those in roles which support education provision) are responsible for ensuring that expired medical consumables utilised for educational purposes are used safely and appropriately, in line with the requirements of this procedure. All expired medical consumables should be disposed of appropriate when they are no longer required or are unsuitable for use in education.
- 4.9. **All employees** are responsible for adhering to this procedure.

5 Education and Training

- 5.1. 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.

6 Audit and Review (evaluating effectiveness)

- 6.1. 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.
- 6.2. 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).
- 6.3. 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.
- 6.4. All changes made to this procedure will go through the governance route for development and approval as set out in the Policy on Policies.
- 6.5. It is acknowledged that any incident of an expired medical consumable entering the live operational system is a significant error. Any such instance must be investigated with a full root cause analysis undertaken to identify any learning and procedure development required.
- 6.6. Any reporting of such an incident would take place via the Datix, DIF1 reporting system and should prompt an immediate review of this procedure.

7 References



- 7.1. It is recognised that the risk of using expired consumables in a patient care episode is low, and that expiring products (as defined by their 'expiry date' label) do not becoming immediately unsafe following this expiry date. The labelled date is usually much shorter than the true shelf life, which is often unknown and therefore estimated conservatively (Pomerantz, 2004).
- 7.2. Evidence that expiry dates could be safely and effectively extended has been identified by the Shelf Life Extension Program (SLEP) which identified the majority (88%) of tested products could be extended for at least one year beyond their stated expiry date, with an average extension of 66 months (Lyon et al., 2006).
- 7.3. It is further noted that the risk associated with the use of expired consumables and equipment varies by the type of equipment and it's intended usage (for example, parenteral medications indicate a higher risk profile than non-parenteral medications; devices intended for invasive use represent a higher risk than devices which are externally applied).
- 7.4. Finally, it is important to note that this procedure is predicated on the fact that expired consumables will not enter the live operational system and that systems have been put in place to minimise this risk of this occurring. This information is provided purely to add detail around the potential consequences should this hazard be realised.
- 7.5. **Reference list:**
- 7.5.1. Lyon, R. C., Taylor, J. S., Porter, D. A., Prasanna, H. R., and Hussain, A. S. (2006). Stability profiles of drug products extended beyond labelled expiration dates. *Journal of Pharmaceutical Sciences*, 95(7), pp1549-1560.
- 7.5.2. Pomerantz, J. M. (2004). Recycling expensive medication: Why not? *Medscape General Medicine*, 6(2), pp1431–1442.

8 Financial Checkpoint

- 8.1. To ensure that any financial implications of changes in policy or procedure are considered in advance of document approval, document authors are required to seek approval from the Finance Team before submitting their document for final approval.
- 8.2. This document has been confirmed by Finance to have no unbudgeted financial implications.



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.



Appendix A: Risk Assessment

Assessment No.

Risk Assessment Form

Completed by and role: Danny Dixon, Senior Education Manager	Initial assessment date: 18/Jul/23
Location of the risk: Trust-wide	
Task / Hazard being Assessed: Use of expired medical consumables in educational environments.	

REF NO.	STEP 1		STEP 2	STEP 3	STEP 4		
	ACTIVITY	HAZARD	PERSON(S) AFFECTED AND HOW	CURRENT CONTROL MEASURES	RISK RATING		
					L x C = R		
01	Storage of expired consumables	Expired consumables could enter live system.	Patient – expired consumables used in clinical care.	1 – Expired consumables to be marked as ‘not for patient use’ 2 – Expired consumables to be stored in specific, marked areas. 3 – Storage area to remain locked. 4 – Make Ready Operatives have no access to expired consumables storage. 5 – Clinicians in practice continue to check expiry dates before use.	1	1	1
02	Use of expired consumables in training	Expired consumables could enter live system.	Patient – expired consumables used in clinical care.	1 – Expired consumables to be marked as ‘not for patient use’ 2 – Expired consumables to be used in specific, restricted area for limited time. 3 – Signage to be available identifying that expired consumables are in use.	1	1	1

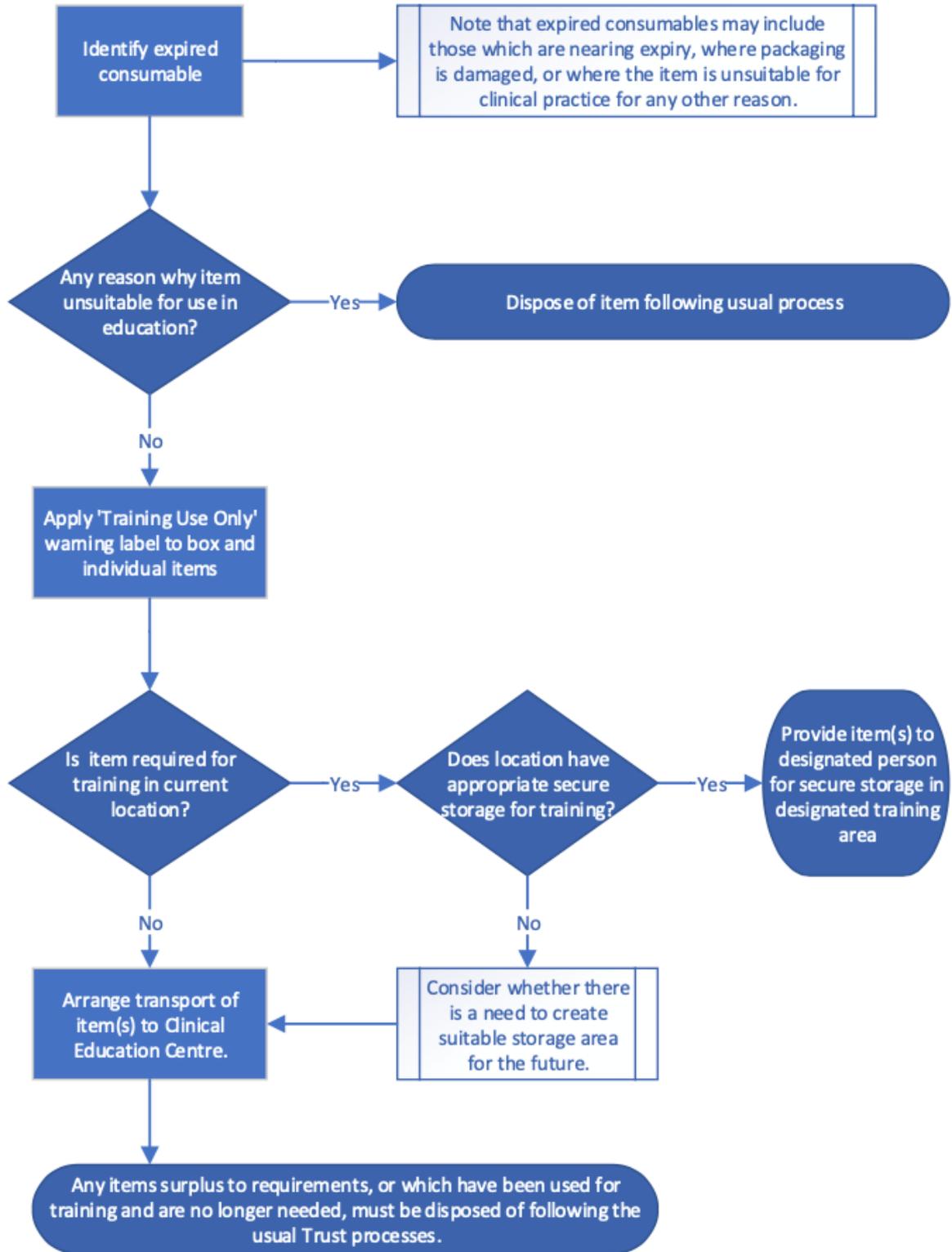


				<p>4 – Educators to retain responsibility for ensuring expired consumables remain secure.</p> <p>5 – Use of expired consumables (and management of such) to be highlighted during any briefing / course introduction.</p>			
03	Training quality	Expired consumables denatured over time.	Learner – reduction in quality of education	<p>1 – Educator to review materials prior to use and remove any which are unsuitable.</p> <p>2 – Consumables which are damaged or otherwise unusable to be disposed of.</p> <p>3 – Learners to identify materials which are unsuitable for use and dispose of.</p>	1	1	1

Date 18/Jul/23 Signature D. Dixon	1 st Review date Signature	2 nd Review date Signature	3 rd Review date Signature	4 th Review date Signature	5 th Review date Signature	6 th Review date Signature
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Appendix B: Flow chart





Appendix C: Storage of out of date consumables signage



EXPIRED CONSUMABLES STORAGE LOCATION

Expired and non-sterile equipment is being stored at this location for training use only. This equipment is clearly marked, and must not be used for clinical purposes or returned to operational stock for any reason.

The nearest clinically ready equipment can be accessed at:

IN AN EMERGENCY ALWAYS CALL 999



Appendix D: Training in progress signage

