

Policy for the use of multiple dose vials of injectable medication

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

February 2025:

Removal & amendment of Point 1.4 as no guidance from Health and Safety Executive found on multi dose vials and NHS Commissioning Board became part of NHS England in 2013.

Addition of statement from NHS England National Infection Prevention & Control Manual within Point 1.4

Addition of NHS England National Infection Prevention & Control Manual within Section 9

Removal of NHS Pharmaceutical Quality Assurance Committee reference from Section 9

October 2021 – minor wording changes.

KEY WORDS

Multi-dose vials

1 INTRODUCTION

- 1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy for the use of multiple dose vials of injectable medication to ensure patient safety.
- 1.2 The majority of vials supplied by the Pharmacy Department are vials which are intended for the administration of a single dose with any remainder discarded immediately. There are however, a few vials which do contain a preservative and are intended to allow multiple doses to be withdrawn from the same vial.
- 1.3 In a reported incident a patient died following the cross-contamination of a multi-dose vial which had been used for another patient who had malaria¹. Preservatives used within the vials will not protect against contamination with blood borne infections.
- 1.4 The NHS England National Infection Prevention Control Manual recommends that medications from a single-dose vial or intravenous (IV) bags are never administered to multiple patients².

2 POLICY SCOPE

- 2.1 This policy applies to all healthcare staff employed by UHL involved in the dispensing, preparation and administration of injectable medicines.

3 DEFINITIONS

3.1 Multi-dose vials of injectable medicines

Multi-dose vials are those that contain antimicrobial preservatives as stated on the label or product information and are licensed for multiple use. The most commonly used preservatives are benzyl alcohol, phenol, methyl parahydroxybenzoate and cresol.

3.2 Expiry dates

- Product expiry date is the date found on the manufacturer's package and is the date which the medicine must be used before.
- 'In-use' storage expiry is the expiry date once the product has been opened and used. The most common example is insulin which has a 28 day expiry after the first dose has been removed.

4 ROLES AND RESPONSIBILITIES

- 4.1 The executive lead responsible for this policy is the Medical Director

4.2 **Clinical Management Group (CMGs) Clinical Directors and Heads of Nursing are responsible for:**

- a) Ensuring that all relevant staff are aware of this policy.
- b) Completing the risk assessment and putting into place appropriate processes for using multi –dose vials on more than one patient within their CMG.
- c) Investigating where practice has not followed this policy, ensuring these are reported on Datix.

4.3 **Medicines Optimisation Committee** is responsible for :

- a) Overall monitoring of compliance of this policy through regular reporting of incidents and the annual Medicines code audit.
- b) Approval of all completed risk assessments from CMGs for the use of multi-vials to be used on more than one named patient.

4.4 **Employees**

- a) All staff involved in the administration of injectable medicines have a duty to follow this policy and report any concerns which may impact the safety of patients.

5 **POLICY STATEMENTS**

- 5.1 Where possible and where practice allows vials, syringes or ampoules intended to be used as a single dose must be used in preference to multi-dose vials.
- 5.2 This applies to all preparations i.e. ampoules, vials, infusion bags etc and also includes occasions where a product is given non parenterally such as for flushing nasogastric tubes or diluting nebuliser solutions.
- 5.3. Sterile fluids intended for injection, including sodium chloride 0.9%, water or medicines which do not contain a preservative must be for **single use only**. If only part of the container is used the remainder must be discarded immediately.
- 5.4. Multi-dose vials may be used to prepare more than one dose. The storage time will be limited once the first dose is withdrawn from the vial. Multi-dose vials once opened must be kept refrigerated during the in-use storage time unless stated otherwise in the product information and labelled with the time and date opened. The in-use storage time may be found on the label or in the product information sheet, but if unclear advice must be sought from Pharmacy or Medicines Information. **This storage time is not the same as the expiry date stated on the label.**
- 5.5 Multiple dose vials where used, must be restricted for the use of a **single named patient**. Each vial must be labelled with the patient's name and expiry date and time, using the in-use storage time found on the label or product information.
- 5.6. If no in-use storage time is stated, the container must be treated as if it does not contain a preservative and used for a single dose only.
- 5.7 If it is unclear to a practitioner as to whether the injectable container they are using contains a preservative or not, advice must be sought from pharmacy or Medicines Information extn 16491. Out of normal pharmacy department hours the on call pharmacist may be called to provide advice. If clarification cannot be provided then the practitioner must only use once and discard any remainder, treating as if a single dose.
- 5.8 A new sterile syringe and needle must be used for each withdrawal from a vial, even if a single dose requires more than one withdrawal.
- 5.9 Whatever preparation is selected, preparation and administration must be in accordance with the Trust's Injectable medicines policy. (B25/2010)

Authorised exceptions:

- 5.10 This policy acknowledges that multi-dose preparation for one or more patients from a vial intended for single use (without a preservative) carries greater risk when undertaken in clinical areas than when undertaken in a pharmacy aseptic unit.
- 5.11 Within Clinical Management Groups (CMGs), any decision to use a multi dose or a vial with no preservative for more than one patient must be agreed with the CMG Lead Pharmacist, Quality and Safety Lead, Head of Service/Clinical Director and Head of Nursing. This must be supported by a full risk assessment and the risks of multi-use of vials in the clinical area concerned documented on the Trust's risk register to be reviewed annually. (see Risk management Policy A12/2002.) The exception to this is radiopharmaceutical products which have an exemption from the Medicines and Healthcare product Regulatory Agency (MHRA).
- 5.12 The identified risks can be reduced/minimised with detailed procedures and training of named staff, together with audit and incident report reviews. The procedures must be approved within the CMG /Trust Policy and Guideline approval committee as appropriate.
- 5.13 A copy of the completed risk assessment must be sent to the Medication Safety Pharmacist for final approval at the Medicines Optimisation Committee and entry onto a Trust wide central database of exemptions to medication related policies.

6 EDUCATION AND TRAINING REQUIREMENTS

- 6.1 All relevant staff must have read and understood this policy and the procedures therein. If additional training is felt to be required by an area the Pharmacy Team can be contacted.

7 PROCESS FOR MONITORING COMPLIANCE

The following table lists the monitoring arrangements for this policy:

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Datix Incidents relating to inappropriate use of multi dose vials	Medication safety pharmacist	Datix incident reporting system	Regular review of incidents	Chief pharmacist / Medicines Optimisation Committee
Review of completed Risk assessments	Medication safety pharmacist	Risk register	Annual	Medicines Optimisation Committee

8 EQUALITY IMPACT ASSESSMENT

- 8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
- 8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

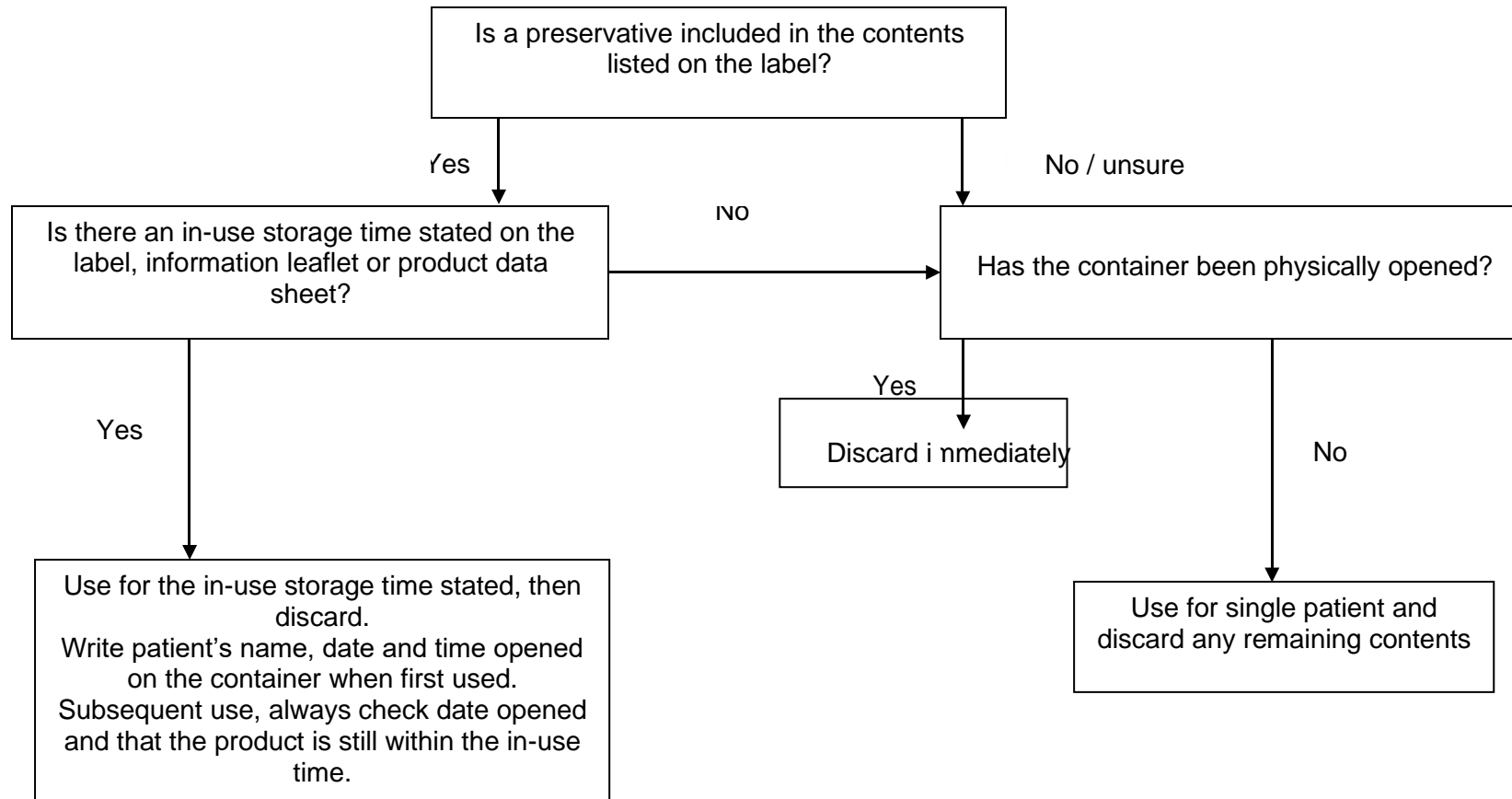
9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

1. Medication Errors - parenteral vial errors must stop. Pharm in Pract 1999;9:220
2. The NHS England National Infection Prevention Control Manual – Version 2.10 May 2024
3. Leicestershire Medicines Code

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

- 10.1 This document will be uploaded onto SharePoint and available for access by Staff through INsite. It will be stored and archived through this system.
- 10.2 This Policy will be reviewed every three years or sooner in response to clinical or risk issues.

**Decision aid about using a vial on more than one occasion.
(to be used in conjunction with the detailed information given in
the policy)**



Based on the Drug and Therapeutics committee Bulletin – Lothian
University Hospital NHS Trust Hospital Pharmacist 2001:8:22-24