

the use of a single container for more than one injection dose – guidelines for wards, theatres and other clinical areas

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A report of a fatality which was caused by the contamination of a vial of sodium chloride led a group of Edinburgh pharmacists to formulate a policy for the multiple use of injection containers

A medication error reported in *Pharmacy in Practice* described an incident in which a patient with falciparum malaria was given two intravenous flushes withdrawn from a 100ml glass vial of sodium chloride injection.¹ The same syringe was used to withdraw both flushes and the solution in the vial was contaminated during the second withdrawal.

The vial was subsequently used to provide flushes for three other patients. Each of the three patients was cross-infected with falciparum malaria and one of the three died.

In commenting on the report, the editors of the medication errors series proposed that re-education and training of the members of

staff involved in an incident such as this were essential but insufficient to prevent recurrence. They proposed that removal of the source of the error was the most effective method of preventing recurrence. To achieve this, they recommended that hospital pharmacies should identify wards and departments in which glass vials of sodium chloride injection and water for injections were used and, where appropriate, substitute ampoules.

POLICY FORMULATION

During our discussions in the pharmacy on the formulation of a policy for the multiple use of injection containers, we recognised that the risk is not confined to the drawing up of intravenous flushes. Also, many members of staff in the hospital might not appreciate that an injection supplied in a container with a rubber stopper is not necessarily intended for use as a multi-dose container. This is perhaps most true for infu-

sion bags which are widely available in the hospital and from which flushes can be withdrawn through the additive port. Therefore, while agreeing with the proposal to withdraw vials of sodium chloride injection and water for injections where possible, we were aware that this would not remove the potential risk associated with other injection containers.

The easiest way to eliminate the risk would have been to introduce a policy of taking only one dose from a container and then discarding it. However, this would not have been feasible due to the practical and financial implications of introducing such a policy. We therefore decided to prepare guidelines to define the circumstances in which it is acceptable to use a single container for more than one injection dose. These guidelines have undergone widespread consultation among pharmaceutical, medical and nursing colleagues to ensure that all aspects of the administration of injections are covered and that none of the

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Guidelines for wards, theatres and other clinical areas on the use of a single container for more than one injection dose

Reports of serious infections and fatalities due to the inappropriate use of single containers to prepare more than one dose of an injection have recently been published.¹

These guidelines have been prepared in order to minimise the risk to patients.

Multi-dose injections

Multi-dose injections are those that contain antimicrobial preservatives, as stated on the label. The most commonly used preservatives are m-cresol, methyl parahydroxybenzoate, phenol, benzyl alcohol.

Multi-dose injections may be used to prepare one or more doses. They have a limited storage time (in-use storage time) after withdrawal of the first dose, depending on the particular medicine and preservative.² N.B. this in-use storage time is not the same as the expiry date printed on the label. The in-use storage time is stated elsewhere on the label, in the product information leaflet, or in the product data sheet or summary of product characteristics. If no in-use storage time is stated, the container must be treated as if it does not contain a preservative (go to "Single-use injections" section).

Single-use injections

Original containers of injections that do not contain a preservative must be discarded immediately after use. However, if the injection is stable when refrigerated, then it may be stored in a fridge and used for the in-use storage time stated by the manufacturer or a maximum of 24 hours after the first dose is withdrawn if no in-use storage time is stated.³ This also applies to solutions used as diluents, and for flushes. Any container that has been physically opened e.g. an ampoule, rather than a dose withdrawn through the access port or rubber bung, must be discarded immediately after use.

General good practice

1. All containers that are not discarded immediately after use must be clearly labelled with the date and time that the first dose was withdrawn, and stored appropriately. If a container that has been used is not labelled with this information, or if there is doubt about how it has been stored, it must be discarded.
2. All containers may be used to prepare more than one dose at the same time, as long as good practice procedures are followed.
 - a. A new, sterile syringe and needle must be used to withdraw each dose, in order to prevent cross-infection between patients.
 - b. The contents of each withdrawn dose must be clearly identifiable at all times.
 - c. Injections must be withdrawn from the original container immediately prior to administration as far as possible. There is a limited time for which a dose withdrawn into a syringe is stable, both chemically and microbiologically. The lowest risk is with injections that are used immediately.
3. These guidelines are based on the published evidence currently available. A risk assessment must be undertaken for any practice that deviates from the recommendations given.

Figure 1: The Lothian University Hospitals NHS Trust Drug and Therapeutics Committee Bulletin number 56

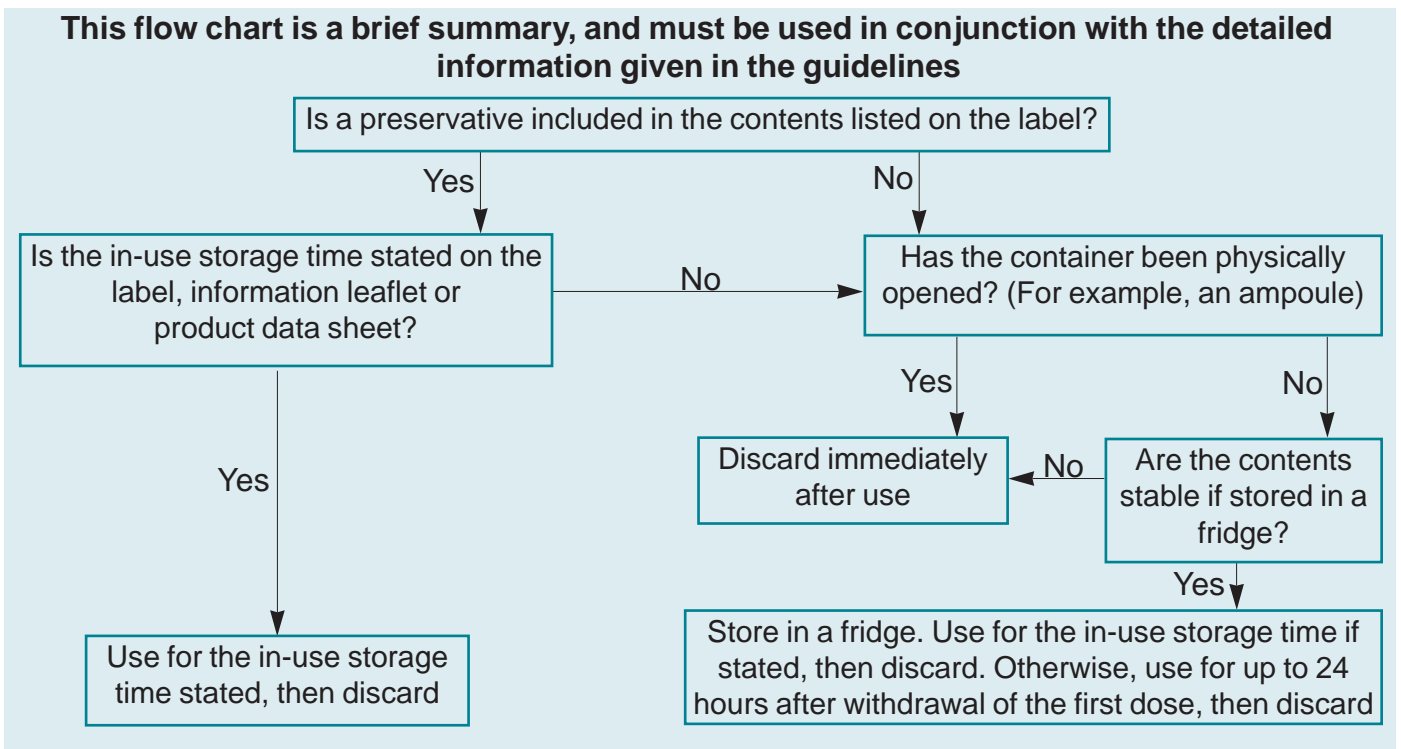


Figure 2: The flow chart which is used in conjunction with the guidelines

recommendations might compromise the treatment of patients. The guidelines have now been issued throughout the hospital in the form of a Drug and Therapeutics Committee Bulletin which is reproduced in Figure 1.

In the first section of the bulletin, we have defined multi-dose and single-use injections. Although contradictory, in the definition of single-use injections we have recognised that, under certain circumstances, it is acceptable to use a container on more than one occasion. This recognises the fact that a container of a medicine that is chemically stable can reasonably be used for up to 24 hours. Examples of this situation

are the use of epoprostenol sodium in the renal dialysis unit, methylprednisolone acetate in the rheumatology clinic and vecuronium bromide in anaesthesia.

The second section of the bulletin contains points of good practice to be observed when preparing injections. The third section is a brief summary in the form of a flow-chart that describes how injection containers are to be treated (Figure 2).

In addition to the issue of the bulletin, those responsible for training nurses and doctors in the preparation and administration of injections have included the principles of the guidelines in their training material.

REFERENCES

1. Medication errors — Parenteral vial errors must stop. *Pharm in Pract* 1999;9:220.
2. Note for guidance on the maximum shelf-life for sterile products for human use after first opening. Committee for Proprietary Medicinal Products. EMEA 1998, London.
3. The quality assurance of aseptic preparation services. Supplement on products for short-term use. Guidelines on the aseptic preparation of sterile parenteral and non-parenteral products with a maximum shelf-life of 24 hours. NHS QC Committee 1998.