

Advice to healthcare professionals preparing doses in clinical areas

This COVID-19 advice has been produced by the NHS
Pharmaceutical QA Committee

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The first stop for professional medicines advice

Document Control

Changes since version 1a

- Addition of Controlled Drugs to the Scope.
- Addition of a decision tree to decide which process is applicable for vial sharing.
- Addition of process flow for multiple doses from one vial
- Separation / formatting of existing process flows
- Clarification that 5 withdrawals are permitted from a vial being used in one preparation exercise but 2 withdrawals if the vial has been stored.

COVID-19 Guidance: Minimising Wastage of Critical Injectable Medicines

Advice to healthcare professionals preparing doses in clinical areas

Introduction

During the emergency period relating to Covid-19, it is essential to minimise wastage of critical medicines. This guidance provides advice to health professionals on how to safely provide a supply of injectable medicines to meet the increased demand whilst minimising wastage.

Scope

- The guidance contained in these documents applies to injectable medicines used in the treatment and supportive care of COVID-19 patients when UK-wide supply of these medicines is severely constrained.
- The guidance applies only to the preparation of intravenous medicines. It does **not** apply to medicines given by epidural or spinal route.
- The principles of preparation outlined in this guidance can be applied to controlled drugs. However local governance policies and procedures relating to the safe & secure handling and storage of stock syringes and part-used vials of controlled drugs apply.
- The guidance is valid only for the duration of the current COVID-19 emergency situation.

General Principles for multiple use of vials and ampoules

Unpreserved injectable medicines are licensed for single use only. This is predominantly due to the risk of microbiological contamination once the container has been breached. The risk of contamination is higher for open ampoules than sealed vials.

During the current emergency period relating to Covid-19, vial and ampoule sharing is permitted in the following circumstances:

- Part-used vials can be stored for up to 12 hours to allow a second dose to be removed, but must then be discarded (see Appendix 1).
- Vials and ampoules can be used to make a small batch (approx. 5) of identical products in one preparation exercise. Step by step instructions for making small batches can be found in Appendix 2 (vials) and Appendix 3 (ampoules)
- Ampoules must not be stored or re-used once opened
- Vials must be pierced using a needle (do not remove the bung)
- Administration should be completed as soon as possible after preparation and always within 24 hours.
- Finished products and any part-used vials must be labelled and stored in the fridge (unless specified not to) while awaiting use.

Additional Good Practice Advice

- Use Aseptic Non Touch Technique (ANTT) at all times
- When making a batch, work on only one product at a time
- Work in an uncluttered area that is as quiet and free from distractions as possible
- Wear a clean non-sterile apron and clean gloves (sterile preferred, if available)
- Clean preparation area with a disinfectant wipe, preferably with sporicidal activity (e.g. containing hydrogen peroxide)
- Label all products once prepared
- Use standardised instructions and labels where available

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Storage and Use of Part-Used Vials

1. Storage after use

- Check that there is no leakage or damage to vial. If there is, discard.
- Label the vial with the time and date of opening. Suggested methods are:
 - Attach an adhesive label to the vial, avoiding covering any critical information on the vial label (drug name and strength)
 - Write on the label with indelible marker, avoiding covering any critical information on the vial label
- Place in the fridge

2. Removal from storage for use

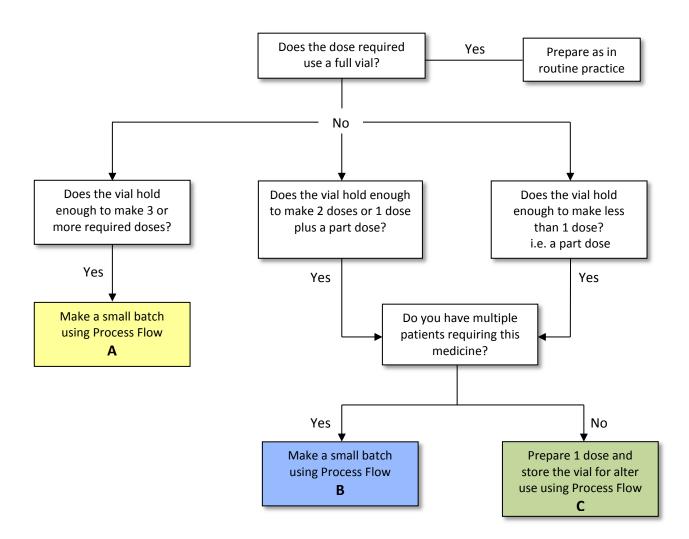
- Check that there is no leakage or damage to vial. If there is, discard.
- Check the time and date on the label
- If no more than 12 hours have passed since opening, the vial may be used
- If more than 12 hours have passed, discard the vial
- After second use, discard immediately

3. Housekeeping and stock control

Check the fridge regularly to remove and discard any expired vials

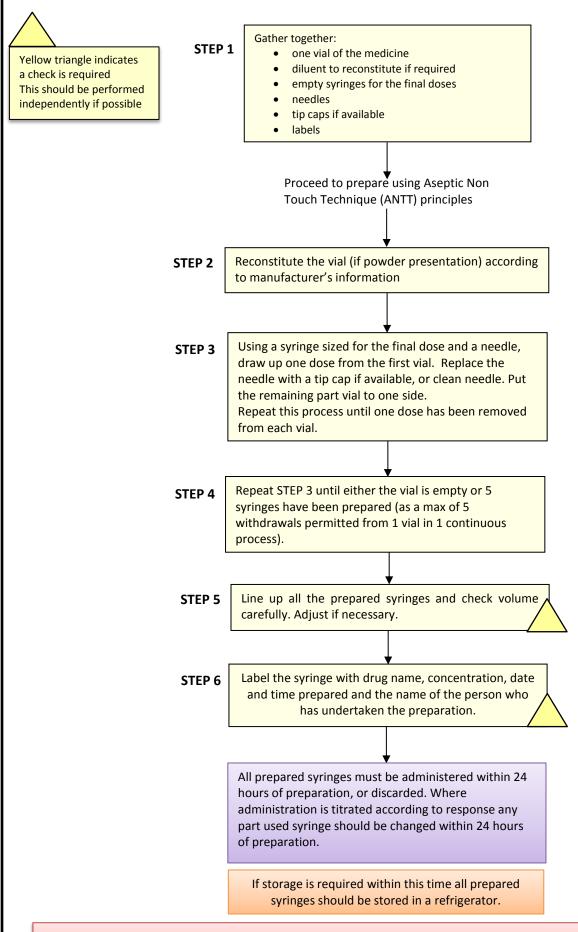
Process for Sharing **Vials** in Clinical Areas

Use the decision tree below to decide which Process Flow to follow A, B or C



Process Flow A for Sharing a VIAL in a Clinical Area

This method should be followed where multiple doses can be obtained from one vial e.g. 500 mg / 10 ml vial where a 100 mg dose is required.



If the final prepared syringe requires further dilution e.g. needs to be added to any infusion bag, this should occur prior to administration.

Process Flow B for Sharing a VIAL in a Clinical Area

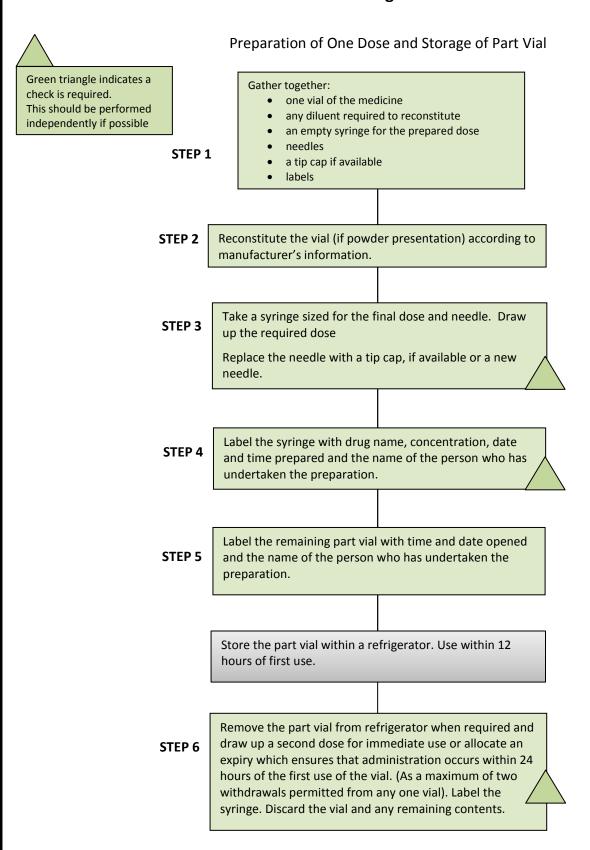
Preparation of Small Batch (to make proximately 5 products)

STEP 1 Calculate the number of vials required to enable preparation of multiple doses with no / minimal wastage. Blue triangle indicates a check is required. This should be performed Gather together: independently if possible required vials of the medicine any diluent required to reconstitute STEP 2 empty syringes for final doses tip caps if available labels Reconstitute each vial (if powder presentation) according STEP 3 to manufacturer's information. Using a syringe sized for the final dose and a needle, draw up one dose from the first vial. Replace the needle with a STEP 4 tip cap if available, or clean needle. Put the remaining part vial to one side. Repeat this process until one dose has been removed from each vial. Immediately using a new syringe and needle, enter the first part vial and withdraw a dose or part of the dose into STEP 5 that syringe. Take the next part vial and use this to either complete the dose or to create another dose. Repeat until all parts vials are used. Replace the needle with a tip cap if available, or clean needle. (A maximum of 5 withdrawals can be made from any one vial during this process) STEP 6 Line up all the prepared syringes and check volume carefully. Adjust if necessary. Label the syringe with drug name, concentration, date and STEP 7 time prepared and the name of the person who has undertaken the preparation. All prepared syringes must be administered within 24 hours of preparation, or discarded. Where administration is titrated according to response any part used syringe should be changed within 24 hours of preparation.

If the final prepared syringe requires further dilution e.g. needs to be added to any infusion bag, this should occur prior to administration.

If storage is required within this time all prepared syringes should be stored in a refrigerator.

Process Flow C for Sharing a VIAL in a Clinical Area



If the final prepared syringe requires further dilution e.g. needs to be added to any infusion bag, this should occur prior to administration.

Prepare as in

routine practice

Process for Sharing AMPOULES in Clinical Areas

Red triangle indicates a check is required.
This should be performed independently if possible

Yes Does the dose required use a full ampoule? No Calculate the number of ampoules required to enable preparation of multiple doses using ampoules with no wastage. Assemble these ampoules. Calculate the total volume required to make multiple doses with no wastage. Assemble the number of 50ml syringes (or smaller if suitable) required to hold that volume. These will be the stock syringes. Gather together: required ampoules of the medicine any diluent required to reconstitute empty syringes for final doses needles tip caps syringe to syringe connector if available filter straws or filter needles for glass ampoules Labels Proceed to prepare a stock syringe (s) using Aseptic Non Touch Technique (ANTT) STEP 1 Open one ampoule. Reconstitute if required. Create a stock solution by withdrawing the entire contents of the ampoule into the stock STEP 2 syringe. (If glass, use a filter needle or straw, if available. Repeat Steps 1 and 2 until assembled ampoules have all been individually drawn up into the stock solution syringe. The filter STEP 3 needle or straw may be used for up to 5 ampoules then should be replaced. A second stock syringe may be used if required. Remove the filter needle or straw from the STEP 4 stock solution syringe (s) and replace with a tip cap or capped needle. Mix the stock solution well and label the syringe with drug name, concentration, date STEP 5 and time prepared and the name of the person who has undertaken the preparation.

Using ANTT Principles proceed to using the ...

