Australian Technical Advisory Group on Immunisation (ATAGI)

Guidance on the use of multi-dose vials for COVID-19 vaccination

Version 5.1

Updated: 11 January 2024

What has changed:

- Removal of vaccine formulations that are no longer available and addition of new formulations.
- To see ATAGI's latest recommendations, visit the Australian Immunisation Handbook.

These guidelines provide advice on the correct use of multi-dose vials and are provided in the context of the COVID-19 pandemic to minimise the risks of vial contamination, administration errors and vaccine wastage.

There are multiple formulations of COVID-19 vaccines. For detailed information refer to https://www.health.gov.au/resources/publications/covid-19-vaccines-in-australia-a3-poster?language=en.

PLEASE NOTE: MOST COVID-19 VACCINE VIALS CONTAIN MULTIPLE DOSES. DO NOT ADMINISTER THE ENTIRE CONTENTS OF A VIAL TO A SINGLE PATIENT.

Equipment required

Sites must have the equipment listed in the ATAGI Checklist of minimum equipment requirements to administer COVID-19 vaccines, including:

- access to a clean preparation area for drawing up vaccine dose(s), away from direct patient contact and distraction
- multi-dose vial(s) of COVID-19 vaccine.

Note: vaccine presentation and instructions for handling and vaccine administration vary by the brand and manufacturer.

For dose preparation:

- A separate sterile single use syringe of an appropriate volume for each dose to be given
  - a 1mL syringe for doses < 0.5mL
  - a 2-3mL syringe for doses ≥0.5mL
  - a low dead space syringe is recommended for the paediatric formulations
- sterile bevelled drawing up needle, 19-21 gauge preferred (not required if using the same needle to draw up and administer the vaccine, for example with the paediatric formulation of the Pfizer vaccine).
- separate sterile single use injecting needle (22-25 gauge, 25mm long for a child or adult, 38mm long for a very large or obese person) for each dose that will be given. A low dead space needle is recommended for paediatric formulations; where this is not available, a standard sterile single use injecting needle is acceptable.
- sterile 0.9% sodium chloride (NaCl) without preservative for dilution of Pfizer.
  - adolescent/adult formulation of Pfizer: 1.8mL for dilution
  - paediatric formulation of Pfizer: 1.3mL for dilution
- procedure tray of suitable size to hold the prepared dose(s)
- 70% isopropyl alcohol wipes
- approved suitable sharps disposal container.

Note: fixed dose integrated needle/syringe devices, such as the SoloShot Mini™ 0.5mL, measure a fixed dose of 0.5mL. They can be used for vaccine doses which require 0.5mL. They are not suitable for use with Pfizer vaccines because they cannot be used to accurately measure the doses under 0.5mL.

If drawing up several doses for use during an immunisation session, have a suitably sized, clean container and labelled clearly with the:

- date and time doses were drawn
- name of the person who prepared the doses
- vaccine name
- vial batch number
- vial identifier (if available)
- expiry time of drawn doses.

Prepared doses should be stored in line with current recommendations. ATAGI recommends that, when possible, pre-drawn doses in syringes should be used within one hour if kept at room temperature, and within 6 hours if kept at 2–8°C. This is to minimise any risk of infection. However, data on stability of pre-drawn doses of the Novavax vaccine in syringes are not available and storing pre-drawn doses of this vaccine in syringes is not preferred.

The age-appropriate formulation of any COVID-19 vaccine should be used to ensure the correct dosage is administered.

To reduce the risk of administration error, the paediatric and adolescent/adult formulations of COVID-19 vaccine vials (including both vaccine and saline solution) and any prepared doses should be stored separately from each other in clearly marked areas, ideally in dedicated containers in separate spaces (e.g., in different shelves in a vaccine fridge or separate vaccine fridges where possible). Prepared syringes should be labelled using colour coded labels to differentiate between paediatric and adolescent/adult doses.

For more information refer to the latest version of the Product Information of the respective vaccine and formation published on the TGA website: https://www.tga.gov.au/product-information-0.

Procedure

1. Maintain appropriate cold chain processes and ensure that the temperature of the refrigerator has not deviated from between +2°C and +8°. If the cold chain has not been maintained, DO NOT USE the multi-dose vial.
2. Perform hand hygiene with either soap and water or an alcohol-based hand rub (ABHR) that contains a minimum of 70% alcohol before gathering supplies or handling vials.
3. Establish a separate area for the preparation of vaccine doses, away from any clinical zones.
4. Clean and disinfect the preparation area and procedure tray and allow it to dry. Ensure the area is clear of other medications and equipment, including used vials and ampoules.
5. Collect the required equipment for the procedure, including the required number of syringes, injection needles and drawing up needles.
6. Remove a multi-dose vial from the fridge. Only one multi-dose vial should be accessed at a time. Check the expiry date. Always check the vial before removing the cap to make sure you have the correct vaccine. If the vial has previously been accessed (i.e. a dose withdrawn), check the time and date of first access recorded on the vial. DO NOT USE beyond the storage time specifications in the product information or if there is not date/time of first access recorded. If unopened, record on the side of the vial the date and time that the vial is first being accessed.
7. Examine the vial for any particulate matter or discoloration. If present, DO NOT USE.
8. Perform hand hygiene again, prior to accessing the vial.
9. Remove the protective plastic cap from the top of the vial.
10. Inspect the bung (also known as septum, stopper or diaphragm). If there is any doubt about the integrity of the bung, e.g. vial leaks when turned upside down, DO NOT USE.
11. Disinfect the bung of the multi-dose vial with a 70% isopropyl alcohol swab. Allow to dry for 30 seconds.
12. Some COVID-19 vaccines may require reconstitution or dilution with a diluent. For further information, refer to the relevant vaccine's product information.
13. Table 1 outlines vaccine preparation (following reconstitution or dilution, if required) for three scenarios.

Table 1: Methods for dose extraction

Step	1. **Method for extraction of a single dose of an adolescent/adult formulation at a time****	2. **Method for extraction of multiple doses of an adolescent/adult formulation using different needles for drawing up and administration****	3. **Method for extraction of multiple doses using the same needle for drawing up and administration*****
	This method is recommended whenever one or more doses will be extracted from a vial and the remaining contents of the vial will be stored, except for the Pfizer paediatric formulations. Use an aseptic technique throughout this procedure.	This method is only appropriate where multiple doses from a vial are to be drawn up in immediate succession for administration within a single vaccination session. Use an aseptic technique throughout this procedure. Vials should never be stored with a drawing up needle attached.	This method uses the same needle to draw up and administer a vaccine dose. This method can be used at mass vaccination clinics or high-volume primary care clinics. Use an aseptic technique throughout this procedure. This is the preferred extraction method for single or multiple doses of the Pfizer paediatric formulations***
A	Attach a sterile drawing up needle to a sterile syringe and insert the needle through the bung into the vial.	Attach a sterile drawing up needle to a sterile syringe and insert the needle through the bung into the vial.	Attach a sterile injection needle of appropriate gauge and length for the vaccine recipient* to a sterile syringe and insert the needle through the bung into the vial.
B	Draw up the required volume for a single dose. Do not touch the shaft of the needle and avoid moving the needle in and out of the vial.	Draw up the required volume for a single dose. Do not touch the shaft of the needle and avoid moving the needle in and out of the vial.	Draw up the required volume for a single dose. Do not touch the shaft of the needle and avoid moving the needle in and out of the vial.
C	Remove the filled syringe with the drawing up needle attached. Do not leave the drawing up needle in the vial. Avoid touching the top of the vial.	Remove the filled syringe from the drawing up needle, leaving the drawing up needle in the bung.	Remove the filled syringe with the needle attached. Avoid touching the top of the vial.
D	Detach the filled syringe and attach a new sterile injection needle*.	Attach a new sterile injection needle* to the filled syringe, ready for administration to the patient. Without delay or distraction, attach a new sterile syringe to the drawing up needle to draw up each dose. Attach a new sterile injection needle to each filled syringe.	If doses are not going to be administered immediately, the needle must be resheathed (using safe aseptic technique). Repeat the procedure for all required doses.
E	Administer the dose as soon as possible after drawing up.	The prepared dose can be administered immediately or must be used as soon as practical for the next recipient. Doses drawn up into a syringe must ideally be used within 1h if kept at room temperature, or 6h if stored at 2-8°C. However, regarding the Novavax vaccine, data on stability of pre-drawn doses in syringes are absent, and storing pre-drawn doses of this vaccine in syringes is not preferred. Until ready to be administered, store any prepared syringes at the appropriate temperature as per product information. This includes storing in a suitably sized, clean container. Label the container clearly with the date and time doses were drawn, the name of the person who prepared the doses, vaccine name, age range, vial batch number, vial identifier (if available) and expiry time of drawn doses. Discard any filled syringe where there is suspicion that contamination or a sterility breach has occurred. Any unused doses that have been withdrawn into a syringe must be discarded after 6 hours, even if stored at 2-8°C, due to potential infection control concerns.	The prepared dose can be administered immediately or must be used as soon as practical for the next recipient. Doses drawn up into a syringe must ideally be used within 1h if kept at room temperature, or 6h if stored at 2-8°C. However, regarding the Novavax vaccine, data on stability of pre-drawn doses in syringes are absent, and storing pre-drawn doses of this vaccine in syringes is not preferred. Until ready to be administered, store any prepared syringes at the appropriate temperature as per product information. This includes storing in a suitably sized, clean container. Label the container clearly with the date and time doses were drawn, the name of the person who prepared the doses, vaccine name, age range, vial batch number, vial identifier (if available) and expiry time of drawn doses. Discard any filled syringe where there is suspicion that contamination or a sterility breach has occurred. Any unused doses that have been withdrawn into a syringe must be discarded after 6 hours, even if stored at 2-8°C, due to potential infection control concerns.

* For guidance on the appropriate needle gauge and length, refer to the Australian Immunisation Handbook at: immunisationhandbook.health.gov.au/resources/handbook-tables/table-recommended-needle-size-length-and-angle-for-administering-vaccines

** **Methods 1 and 2** reduce the **risk of local reactions** by **avoiding vaccine on the exterior of the needle**. The potential for minor under dosing (due to vaccine volume loss in the administration needle dead space) using these methods is not of **concern** for dose volumes of ≥0.3mL as the patient will still receive most of the dose.

*** **Method 3** reduces the potential for minor volume loss (due to dead space) by using the same needle for drawing up and administering, but with an increased risk of coring (compared to method 2) and potential greater frequency of injection site reactions. Method 3 is preferred for extracting single or multiple doses of the Pfizer paediatric formulation as the proportional loss of volume is greater for the lower volume paediatric dose compared to the adolescent/adult dose.

More information

- Individual vaccine product information - refer to the latest version of the Product Information of the respective vaccine and formation published on the TGA website: www.tga.gov.au/product-information-0
- Australian Immunisation Handbook COVID-19 Chapter: https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/covid-19
- Australian Immunisation Handbook section 'Vaccination Procedures': immunisationhandbook.health.gov.au/vaccination-procedures
- National Health and Medical Research Council and Australian Commission on Safety and Quality in Healthcare *Australian Guidelines for the Prevention and Control of Infection in Healthcare*: https://www.safetyandquality.gov.au/publications-and-resources/resource-library/australian-guidelines-prevention-and-control-infection-healthcare
- ATAGI Checklist for immunisation service provider sites: www.health.gov.au/resources/publications/covid-19-vaccination-site-requirements-for-covid-19-vaccination-clinics
- Office-based practices (including general practices) must adhere to the RACGP Infection Control Standards for Office-based Practices, 5th Edition: www.racgp.org.au/running-a-practice/practice-standards/standards-for-other-health-care-settings/view-all-health-care-standards/infection-prevention-and-control
- Services Australia website using the search term 'Australian Immunisation Register' – Information on mandatory recording of COVID-19 vaccinations in the Australian Immunisation Register (AIR): www.servicesaustralia.gov.au/australian-immunisation-register-for-health-professionals