

Australian Technical Advisory Group on Immunisation (ATAGI)

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

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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.

PLEASE NOTE: 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 [Australian Technical Advisory Group on Immunisation \(ATAGI\) 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:
 - separate sterile single use syringe of an appropriate volume for each dose that will be given. The recommendation is to use a 1mL syringe for doses < 0.5mL; a 2-3mL syringe may be used for doses $\geq 0.5\text{mL}$
 - sterile bevelled 19-21 gauge drawing up needle (not required if using the same needle to draw up and administer the vaccine);
 - separate sterile single use injecting needle (22-25 gauge) for each dose that will be given;
 - procedure tray of suitable size to hold the prepared dose(s);
 - 70% isopropyl alcohol wipes; and
 - approved suitable sharps disposal container.
 - Note: fixed dose integrated needle/syringe devices such as the SoloShot Mini™ 0.5mL are **not suitable** for use with Comirnaty (Pfizer). This is because they cannot be used to accurately measure the 0.3mL vaccine dose.
- If drawing up several doses for use during an immunisation session, have a suitably sized, clean, opaque container which is protected from light and labelled clearly with:
 - the date and time doses were drawn;
 - the 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 1 hour if kept at room temperature, and within 6 hours if kept at 2-8°C. This is to minimise any risk of infection.

For more information see:

- PI for [COVID-19 Vaccine AstraZeneca](#)
- PI for [Comirnaty \(Pfizer\)](#)

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, discoloration or turbidity. 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 instructions, 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: Method for dose extraction

	Standard methods		Acceptable alternative method
Step	1. Method for single or multiple dose extraction in a setting where doses are infrequently administered (i.e. to a single patient at a time) (e.g. low volume general practice clinics)**	2. Method for multiple dose extraction in dedicated immunisation clinics where doses are administered one after another (e.g. dedicated clinics being run in general practice) **	3. Alternative method for dose extraction in a dedicated mass immunisation clinic where doses are administered one after another <i>Preferred method for Pfizer hubs only.</i>
	ATAGI prefers this method whenever one or more doses will be extracted from a vial, and the remaining contents of the vial will be stored. 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 is an acceptable alternative method where the same needle is used to draw up and administer a vaccine dose. Use an aseptic technique throughout this procedure. There are some potential disadvantages to this method. This includes increased risk of coring (compared with Method 2) and potential greater frequency of injection site reactions.
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. 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 which is protected from light. Label the container clearly with the date and time doses were drawn, the name of the person who prepared the doses, vaccine name, 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. 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 which is protected from light. Label the container clearly with the date and time doses were drawn, the name of the person who prepared the doses, vaccine name, 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](#). ** **Methods 1 and 2** are preferred as they reduce the risk of local reactions by avoiding vaccine on the exterior of the needle. The potential for minor under dosing using these methods is not of concern as the patient will still receive most of the dose.

For more information read

- Individual vaccine product information
- [COVID-19 Vaccination Training Program](#)
- [National Health and Medical Research Council Australian Guidelines for the Prevention and Control of Infection in Healthcare](#)
- [ATAGI Checklist for immunisation service provider sites](#)
- Office-based practices (including general practices) must adhere to the [RACGP Infection Control Standards for Office-based Practices, 5th Edition](#)
- Australian Immunisation Handbook section '[Vaccination Procedures](#)'
- [ATAGI Clinical guidance on COVID-19 vaccine in Australia in 2021](#)
- Services Australia website using the search term 'Australian Immunisation Register' [Information on mandatory recording of COVID-19 vaccinations in the Australian Immunisation Register \(AIR\)](#)