Australian Government
Department of Health and Aged Care

COVID-19 VACCINE

Reference Guide

Version 2.0

About this guide

The contents of this guide are current as at October 2023. Changes to COVID-19 vaccine supply in Australia and recommendations made by the Australian Technical Advisory Group on Immunisation (ATAGI) will be contained in the Australian Immunisation Handbook (the handbook) and ATAGI statements. COVID-19 vaccine registrations and product information (PI) documents are maintained on the TGA website.

Overview

Nature of the disease

COVID-19 is the name given to the infectious disease caused by the SARS-CoV-2 virus. SARS-CoV-2 is a strain of a large family of viruses called coronaviruses (CoV). Coronaviruses can cause several different respiratory diseases, including:

- MERS – Middle East Respiratory Syndrome
- SARS – Severe Acute Respiratory Syndrome (SARS-CoV-1)
- The common cold
- COVID-19 (SARS-CoV-2)

SARS-CoV-2 contains 4 main structural proteins: spike (S) glycoprotein, small envelope (E) glycoprotein, membrane (M) glycoprotein and nucleocapsid (N) protein.[1]

Most COVID-19 vaccines target the spike protein, which contains 2 subunits: S1 and S2. S1 contains the receptor binding domain, which binds to the angiotensin-converting enzyme 2 receptor on host cells. This allows the virus to enter cells.[2]

Older age is by far the strongest risk factor associated with morbidity and mortality from COVID-19.[3,4] Certain medical conditions independently increase the risk of severe disease but to a lesser extent than age.[5] A higher number of concurrent comorbidities cumulatively increases the risk of severe disease.[6,7]

Clinical features

As COVID-19 has mutated into different strains, including Delta and Omicron, the clinical symptoms profile has changed. Omicron is more transmissible than the wild type of SARS-CoV-2 and previous variants.

The incubation period after exposure to SARS-CoV-2 (Omicron) is most commonly 3 days but can be up to 14 days.[8] The most common symptoms with the Omicron variants are:

- Runny nose
- Sore throat
- Sneezing
- Headache.[9]

If you are concerned about a person who may have undiagnosed COVID-19, you can refer your community and patients to the Department of Health and Aged Care symptom checker or National Coronavirus Helpline on 1800 020 080.

The prevalence of post-COVID-19 condition is highly variable due to differing definitions. A systematic review and meta-analysis including over 750,000 participants reported that 45% of COVID-19 patients experience a range of unresolved symptoms at 4 months.[10] Risk factors for post-COVID-19 condition may include the presence of comorbidities, prior hospitalisation from COVID-19, female sex, older age, high body mass index and smoking. Vaccinated people have a significantly lower risk of post-COVID-19 condition (OR, 0.57; 95% CI, 0.43-0.76).[11]

Recommendations

ATAGI are the specialist team responsible for making recommendations on COVID-19 vaccination in Australia. International and national data are reviewed for current infection risk and vaccine efficacy, and World Health Organization (WHO) recommendations and expert advice are analysed to inform the recommendations made. Due to these factors, ATAGI recommendations are likely to change as COVID-19 evolves and we gain new data.

All current COVID-19 recommendations can be found in the COVID-19 chapter of the handbook. The handbook should be referred to for further vaccine preparation and administration information.

Vaccine recommendations – View the ATAGI recommended COVID-19 vaccine doses poster for a summary of vaccine recommendations for people with and without risk factors. The poster includes primary course and booster dose recommendations across all age groups.

Vaccines and doses – View the COVID-19 vaccines in Australia poster for a summary of the vaccines available, primary dose schedule and vaccine storage requirements.

Advice during pregnancy, breastfeeding or planning pregnancy – Vaccination recommendations do not change based on the persons current reproductive status. View the ATAGI Shared decision making guide for women who are pregnant, breastfeeding or planning pregnancy for the latest advice including preferred vaccine formulations and dose intervals.

People who are severely immunocompromised – An extra primary course dose is recommended for some people to maximise the level of immune response to as close as possible to the general population. For the latest recommendations view the ATAGI statement on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised and the handbook.

Use of sedation – ATAGI has provided some general advice for the use of sedation to administer COVID-19 vaccines and acknowledges that some health services have their own procedural guidelines for vaccination under sedation. More information can be found in the ATAGI advice on use of sedation for COVID-19 vaccination.

COVID-19 Vaccines in Australia

The following COVID-19 vaccines are available as at October 2023 and have been registered for use in Australia by the Therapeutic Goods Administration (TGA). Refer to the TGA website for further information about COVID-19 vaccine registration as well as the Product Information (PI) for each vaccine and the handbook's COVID-19 chapter.

Paediatric formulations

- Comirnaty Original (Pfizer) 6 months to 4 years formulation (maroon cap)
- Comirnaty Original (Pfizer) 5 to 11 years formulation (orange cap)

Adolescent & adult formulations

- Comirnaty bivalent Original/Omicron BA.4/5 (Pfizer) (grey cap)
- Spikevax bivalent Original/Omicron BA.4/5 (Moderna) (pre-filled syringe)
- Nuvaxovid (Novavax) (blue cap)
- Comirnaty bivalent Original/Omicron BA.1 (Pfizer) (grey cap)

Comirnaty Original (Pfizer) 12 years and older formulation (purple cap), Spikevax Original (Moderna) 6 years and over formulation (red cap), Spikevax Original (Moderna) 6 months to 5 years formulation (blue cap, purple label), Spikevax bivalent Original/Omicron BA.1 (Moderna) (blue cap, green label) and Vaxzevria (AstraZeneca) are no longer available in Australia.

Original vaccines are monovalent and are directed at, or contain, the ancestral spike protein only. Available bivalent mRNA vaccines are formulated against both ancestral and Omicron strains (either the BA.1 or BA.4/5 Omicron sub-variants). Currently, only original/ancestral vaccines are being used in people less than 12 years of age.

Immunogenicity and effectiveness

Vaccine efficacy indicates the level of protection a vaccine has demonstrated in clinical trials. Vaccine effectiveness refers to the protection the vaccine has provided during 'real world' use in the population. For a detailed review of vaccine efficacy, effectiveness and immunogenicity and ongoing studies review the PI for each vaccine on the TGA website. Consumer medicines information (CMI) resources are also available if required.

Please note that the PIs may not be inside all vaccine packaging from September 2023 as this is no longer a requirement of the TGA. All PIs are available on the TGA website.

Omicron-based bivalent COVID-19 vaccines

There are no direct data on the immunogenicity or efficacy of bivalent COVID-19 vaccines for primary course vaccination. Their preferential use for the primary course is based on superior immunogenicity and vaccine effectiveness against Omicron sub-variants, when evaluated as booster doses. Early vaccine effectiveness studies demonstrate that both BA.4/5- and BA.1-based bivalent vaccines offer excellent protection against hospitalisation and death from COVID-19 for several months.[12] Bivalent vaccines also offer some protection against symptomatic infection.[13]

A clinical trial reported 5.1-6.3 times greater neutralising antibody levels against the BA.4/5 Omicron subvariants at 1 month after a booster dose of Spikevax bivalent Original/Omicron BA.4/5 compared with Spikevax Original in adults aged 18 years and older.[14]

Original COVID-19 vaccines

Comirnaty Original

In children aged 5 to 11 years without evidence of previous SARS-CoV-2 infection, the paediatric Comirnaty dose was 90.7% effective (95% CI: 67.7–98.3) at preventing laboratory-confirmed symptomatic COVID-19 in the pre-Omicron era.[15]

Vaccine efficacy estimates are not available for booster doses in children aged <16 years. A clinical trial showed an increase in neutralising antibodies against the ancestral and early Omicron variants of SARS-CoV-2 after a first booster dose in children aged 5 to 11 years who had no evidence of past infection.[16]

Nuvaxovid (Novavax)

The clinical trial evaluating Nuvaxovid for primary vaccination was conducted prior to the emergence of the Omicron variant of SARS-CoV-2. Nuvaxovid has been shown to have high efficacy in two clinical trials conducted in the United States, Mexico and the United Kingdom during periods when the Alpha variant was predominant.[17]

Vaccine preparation

Medication safety principles must always be followed when administering any medicinal product including vaccines. Ensure you and your colleagues are following the National Safety and Quality Health Service (NSQHS) standards for consumer safety by minimising errors and unsafe processes. Standard 4 is medication safety. Review this medication safety standard as required.

The vaccination procedures section within the handbook should be referred to for general aspects and expectations of vaccine administration including pre-, during and post-vaccination. Personal protective equipment (PPE) is not specifically recommended when preparing or administering vaccines unless an additional infection risk exists.[12]

Each vaccine formulation may have a different preparation and dilution requirement, number of doses per vial and dose volume. ALWAYS check the handbook, ATAGI statements and the vaccine PI before preparing a COVID-19 vaccine if you are unsure.

Equipment required for a vaccination encounter

ATAGI state that the following equipment lists are required for each vaccination encounter:[18]

For dilution of a multi-dose vial (MDV):

- ✓ Latex free sterile 2mL or 3mL syringes for dilution
- ✓ Sterile, bevelled 19 or 21 gauge drawing up needle[19]
- ✓ 70% isopropyl alcohol wipe to clean the vial before accessing it
- ✓ Sharps container
- ✓ Sterile 0.9% sodium chloride (saline) for injection

For extracting the vaccine dose:

- ✓ Sterile low dead-volume* 1mL single use syringe for doses less than 0.5mL and a 2mL to 3mL syringe for doses greater than or equal to 0.5mL[19]
- ✓ Sterile low dead-volume* 22 to 25 gauge administration needle (25mm, or 38mm in very large or obese people)[19]
- ✓ 70% isopropyl alcohol wipe to clean the vial before accessing it
- ✓ Procedure tray (e.g. Kidney dish) for the drawn-up vaccine

*low dead-volume syringe and needle combinations (less than 35 microlitres) are recommended for Comirnaty Original vaccines. However, standard needles and 1mL syringes can be used if this is the supplied and available stock. Care should be taken to draw up the dose volume exactly.[20]

Gathering and preparing the vaccine for use

Always check the handbook, ATAGI statements and the PI before preparation to review the number of doses contained in the vial, the amount of time the vaccine can be out of cold chain for, the maximum time that it can be used after being opened, and any further relevant information.

The steps required to prepare a vial for use include:

1. Perform hand hygiene with either soap and water or an alcohol-based hand rub.
2. Clean and disinfect the dedicated area for preparation and the procedure dish or tray if being used.
3. Collect the required equipment as per the list above.
4. Remove the required vaccine vial (only 1 at a time) and check the temperature while doing so from the cold chain storage system used.

5. Double check you have the correct vaccine before opening the vial, with another health professional if available, and as per your facility, professional scope of practice and jurisdictional policies.
6. Check the expiry date of the MDV or pre-filled syringe (PFS) and the date and time that the MDV was opened.
    - DO NOT use if the time is beyond the maximum time indicated on the PI. If you are opening the MDV for the first time, record the date and time on the vial now, before opening it.
7. Examine the vaccine MDV or PFS gently and ensure there is no discolouration, turbidity or particulate matter (except for undiluted MDV of Comirnaty which may contain white to off-white opaque amorphous particles as per the PI).
8. Perform hand hygiene.
9. Open the vial (if applicable) and check the bung integrity.
10. Disinfect the bung using a 70% isopropyl alcohol wipe.
11. Allow to fully dry for 30 seconds.

Vial dilution

Dilution of an MDV follows the same principles and process as reconstituting a single-dose vial. Before dilution, gently invert the vial 10 times, **DO NOT** shake the vial and contents. The thawed suspension may contain white to off-white opaque amorphous (undissolved) particles.[20] The vaccine does not contain a preservative. It is preferable to administer vaccine doses immediately after dilution.[12]

Dilute the Comirnaty Original vaccines by injecting **ONLY** sterile **0.9% sodium chloride (saline) for injection** into the vial as per the directions below:

1. Using a sterile 2mL or 3mL (preferably Luer-Lock) syringe draw up sterile sodium chloride (0.9%) for injection. It is preferred that a sterile 19-21-gauge bevelled needle be used for dilution.[20]
2. Inject the sodium chloride diluent into the vial through the disinfected and dry bung. Before removing the needle, withdraw the same amount of air as saline injected to equalise the volume and pressure in the vial.

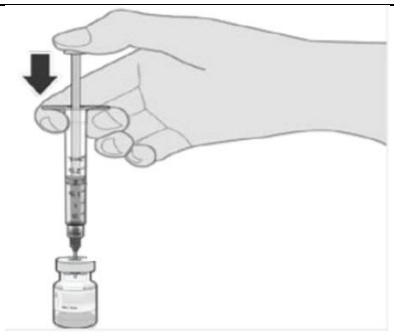


Figure 1. Dilution.[20]

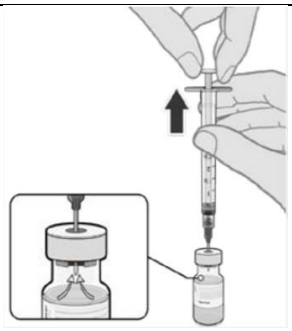


Figure 2. Equalise vial pressure.[20]

3. **DO NOT** shake the diluted suspension; instead invert it gently 10 times again.[20]
4. Label the diluted vial with the date and time of dilution immediately. **Diluted vials must be stored at +2°C to +30°C and discarded six (6) hours after dilution**. Do not freeze the diluted vaccine. The diluted vaccine should look like a white to off-white suspension with no visible particles.[20]

Figure 3. Date and time of dilution.[20]

5. After dilution, the vial contains the number of doses stated in the PI. There will be a small amount of extra vaccine in the vial after withdrawing all doses to account for small wastage associated with each dose drawn up.
6. Any pre-drawn vaccine doses (in syringes) should be used **within 1 hour** if stored between **+8°C and +30°C**, or **within 6 hours** if stored at **+2°C to +8°C**.[12]

After dilution, check and ensure that the date and time has been recorded on the vial without delay for safety.

Dose extraction

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

Following on from either ‘gathering and preparing the vial for use’ or ‘vial dilution’, the dose extraction steps are as follows:

1. Attach a sterile drawing-up needle to a sterile syringe*, unless the alternate method (see below) is being used in which case use the administration needle here instead.
2. Insert the needle through the bung using aseptic technique.
3. Withdraw 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.
4. While keeping the needle in the vial, gently remove air bubbles and check the dose volume in the syringe.
5. Withdraw the needle from the vial. If preparing multiple doses for immediate administration, detach the syringe from the needle at this point, leaving the drawing-up needle in the MDV until all doses are extracted. Never leave the drawing up needle in the vial when returning it to cold chain storage; it can only remain while immediately drawing up doses.
6. Attach a new sterile injection needle to the syringe*.
    - If drawing up multiple doses from a single vial at a time, perform steps 2 to 6 again until all doses are removed from the vial, except attach the syringe to the current drawing up needle still left in the vial rather than using a new one.
7. Place a single pre-drawn dose ready for administration into a procedure dish if being administered immediately to transport it to the administration area.

*Alternate method: in certain mass vaccination situations, it is acceptable to use the same needle to draw-up and administer the vaccine. A new needle must be used for each person. This is the preferred administration technique for the paediatric formulations of Comirnaty vaccines as the proportional loss of volume is greater compared to the adolescent/adult formulations. An aseptic procedure must be used throughout the procedure as there is a potential for a greater frequency of injection site reactions using this mass vaccination one-needle technique. The needle can be recapped using aseptic technique if not being administered immediately.[19] Seek advice from your Public Health Unit (PHU) or immunisation department for when this may be appropriate.

If multiple doses are being made up at once for immediate administration during an immunisation session, each prepared syringe within the container must be appropriately labelled. The syringes should be stored in a suitably sized, clean container 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.
- Expiry time of drawn doses.

Any pre-drawn vaccine doses (in syringes) should be used **within 1 hour** if stored between **+8°C and +30°C**, or **within 6 hours** if stored at **+2°C to +8°C**.[12]

When entering the vial multiple times, ensure that each re-puncture occurs as a different site.

You **CANNOT** draw up leftover content from more than one vial of the same vaccine to make a single dose. If the vial does not contain the required dose, then the vial must be discarded.[20]

Note that both Comirnaty bivalent formulations have a grey cap. However, they are approved for use in different age groups. To minimise the risk of administration errors, providers should preferably prepare and store doses of these vaccines separately. Doses withdrawn in advance of administration should be clearly labelled.

For more information on the preparation of each vaccine you can review each PI and the COVID-19 Vaccines in Australia poster. The ATAGI guidance on the use of multi-dose vials for COVID-19 vaccination can be referred to for more detail on the steps involved.[19]

Post vaccine administration

Equipment is needed at the conclusion of the vaccine encounter as detailed below:

- ✓ Cotton wool ball for the injection site
- ✓ Hypoallergenic tape or latex free bandaid
- ✓ Sharps container
- ✓ Containers for disposal of biohazardous waste

Ensure the vaccine is administered as soon as possible after preparation and within the manufacturer's maximum recommendations. ATAGI recommends 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°C to +8°C, to minimise the risk of infection.[12] Once the vaccine has been administered and a bandaid or cottonwool ball cover in place, the following should be actioned:

- Discard the drawing up needle immediately into an approved sharps container
- Return the vial to cold chain storage if there are remaining doses. Before returning the vial, ensure the date and time of opening are clear
- Clean and wipe the workbench
- Perform hand hygiene
- Ensure all prepared syringes are labelled to identify contents.

Vaccine administration

Intramuscular injection route

Currently, all available COVID-19 vaccines are administered intramuscularly.

For people aged 12 months or older administer the vaccine as an intramuscular injection (IMI) in the deltoid muscle and for infants aged less than 12 months the recommended site is the vastus lateralis muscle in the anterolateral thigh. **DO NOT use the deltoid muscle for infants aged less than 12 months**.[12]

If you are not familiar with these IMI sites, please review these information sheets from the handbook:[12]

- Anatomical markers used to identify the deltoid injection site
- Anatomical markers used to identify the vastus lateralis injection site on the anterolateral thigh

Below are a few important summary points on IMI administration:

- **The injection site should be clean**. If visibly dirty, ideally soap and water should be used to clean. There is no need to use an alcohol wipe as part of normal practice if the skin is visibly clean. If an alcohol wipe needs to be used for cleanliness, ensure the skin is fully dry before administering a vaccination as otherwise this may lead to increased injection site reactions.[12]
- In most cases, a **22 or 23 gauge**, **25mm long needle** is recommended as per the handbook. If the individual is obese, a 38mm length needle is recommended. If using a 25 gauge needle the vaccine must be injected slowly over 5 seconds.[12]
- The vaccine should be inserted at a **90° angle**.[12]
- Infants less than 12 months old should be positioned in a semi-recumbent cuddle position on the parent's/carer's lap.[12]
- Children aged older than 12 months should be positioned in a cuddle position sitting sideways on the parent's/carer's lap or the straddle position where the child may face the parent/carer with their legs straddled over the parent's/carer's lap.[12]
- Older children, adolescents and adults should be sitting on a chair with their arm relaxed.[12]

- Expose the entire shoulder to use anatomical markers to identify the correct injection area. This can be done using the triangle or fingertips methods.[12]
- There is no need to aspirate to check your needle position during IMI vaccinations. However, if blood is seen before injection, withdraw the needle and select a new site for injection.[12]

Possible injection site errors

Expose the entire shoulder as shown in the photos to ensure you have the correct site for injection.

Figure 4. Injection too high.[12]

Figure 5. Injection too low.[12]

Figure 6. Expose the entire arm, correct site for injection.[12]

Shoulder injury related to vaccine administration (SIRVA) is a rare complication that results from incorrect needle insertion too high into the shoulder joint. This can cause bursitis, tendonitis and rotator cuff tears. Using a correct injection technique will prevent SIRVA from occurring. Review the handbook infographic, Avoiding shoulder injury related to vaccine administration for more information.[12]

Injecting in the arm too low may cause radial nerve damage.

Vaccine doses

The vaccine dose varies by brand and age. Review the infographics from the COVID-19 vaccines in Australia poster and ATAGI recommended COVID-19 vaccine doses for details of the dose for each vaccine and age group.[21]

Storage and handling of vaccines

Vaccines are delicate, biological substances requiring careful management to ensure their effectiveness to protect our community. Most COVID-19 vaccines are presented as MDVs and require special handling to maintain viability and sterility. Each vaccine has a different thermostability profile in which potency and efficacy are maintained. Any exposure to damaging factors are cumulative and cannot be reversed.

Cold chain storage specifically refers to maintaining vaccines within a safe temperature range of +2°C to +8°C during storage and transport. An ultra-cold chain (UCC) system is required for mRNA vaccines to be stored frozen as low as −90°C. Once thawed, mRNA vaccines can be stored for specified periods at standard cold chain requirements (+2°C to +8°C) before use.[12]

General advice:

- Thawed vials of frozen vaccine should not be refrozen
- Do not shake the vaccine vials
- Minimise exposure to room light and avoid direct sunlight and ultraviolet light.

As COVID-19 vaccines available for use in Australia contain no antimicrobial preservatives, to minimise the risk of infection ATAGI recommends that:

- once an MDV is punctured, use prepared doses within 6 hours; and
- when possible, pre-drawn doses should be used within 1 hour if kept at room temperature, and within 6 hours if kept at +2°C to +8°C.[12]

Transporting doses for home visits

Transport according to National vaccine storage guidelines: Strive for 5.

If vaccinating at a home visit there are two options available for preparation:

- Preferably, transport the vial at +2°C to +8°C and not exceeding the open vial storage period of 12 hours, and draw up the dose on-site, or
- Pre-drawn doses can be transported only if the cold chain storage and protection from light can be maintained and the vaccine administered as soon as practical and not exceeding the total maximum storage period of 1 hour at room temperature or 6 hours in cold chain conditions.[12]

Expiry dates

Expiry dates must be followed precisely to prevent expired stock being administered. For PFS vaccines the expiry date is printed on both the outer box and the vaccine syringe. For unopened MDVs there are two expiry dates that must be observed on the mRNA vaccines (Comirnaty and Spikevax vaccines); the manufacture (batch) expiry date and the thawed expiry date. Both must be checked prior to every vaccine administration.

- The manufacture (batch) expiry date indicates the expiry for the vaccine vial when stored frozen.
- The thawed expiry date commences at the time the vials are removed from the freezer or UCC storage to commence thawing and may be either on the vial or the secondary packaging (carton) when delivered thawed.

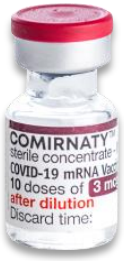
The vaccine must be administered by whichever of the two expiry dates is the EARLIEST.

Figure 7. Comirnaty Original (Pfizer) 5 to 11 years formulation (orange cap) expiry label.

Figure 8. Comirnaty bivalent Original/Omicron BA.1 (Pfizer) (grey cap) expiry label.

To prevent vaccine administration errors all sites should clearly label the expiry dates ensuring this is visible to anyone who will administer the vaccine. Each site must have clear processes to identify and action these expiry dates to prevent vaccine administration errors.

Comirnaty Original 6 months to 4 years formulation



Vial presentation

Each multidose vial has a maroon cap. **It must be diluted before use**.

One vial (0.4 mL) contains 10 doses of 0.2 mL after dilution with 2.2 mL of sterile 0.9% sodium chloride (saline). One dose (0.2 mL) contains 3 micrograms of COVID-19 mRNA vaccine (embedded in lipid nanoparticles).

Figure 9. Comirnaty Original 6 months to 4 years formulation. Images © 2023 Pfizer Inc. All rights reserved.

Appearance

The frozen vaccine is a white to off-white suspension.

Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles. The diluted vaccine should present as a white to off-white suspension with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.

Storing frozen vials

Unopened vials have a shelf-life of **24 months** at −90°C to −60°C.

Thawing vials

If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of +2°C to +8°C to thaw; a 10-vial pack may take 2 hours to thaw. Ensure vials are completely thawed prior to use. Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to +30°C for immediate use.

Upon moving the product to +2°C to +8°C storage, the updated thawed expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out. Once thawed, do not re-freeze.

Storing thawed vials

Once removed from frozen storage, the unopened vial may be stored refrigerated at +2°C to +8°C for a single period of up to **70 days** *within* the 24-month shelf life.

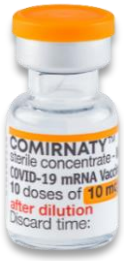
If the vaccine is received at +2°C to +8°C it should be stored at +2°C to +8°C. Check that the expiry date on the outer carton has been updated to reflect the thawed expiry date.

Storing diluted vials and vaccine doses

Chemical and physical stability has been shown with storage for 12 hours at +2°C to +30°C after initial puncture for dilution. However, because this vaccine contains no antimicrobial preservatives, ATAGI recommends that after puncture and dilution, vials must be kept at +2°C to +30°C and used within 6 hours from the time of dilution. Do not freeze the diluted vaccine.

ATAGI recommends that, when possible, pre-drawn doses should be used within **1 hour** if kept at room temperature, and within **6 hours** if kept at +2°C to +8°C, to minimise the risk of infection.

Comirnaty Original 5-11 years formulation



Vial presentation

Each multidose vial has an orange cap. **It must be diluted before use**.

One vial (1.3 mL) contains 10 doses of 0.2 mL after dilution with 1.3 mL of sterile 0.9% sodium chloride (saline). One dose (0.2 mL) contains 10 micrograms of COVID-19 mRNA vaccine (embedded in lipid nanoparticles).

Figure 10. Comirnaty Original 5 to 11 years formulation. Images © 2023 Pfizer Inc. All rights reserved.

Appearance

The frozen vaccine is a white to off-white suspension.

Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles. The diluted vaccine should present as a white to off-white suspension with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.

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Thawing vials

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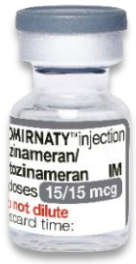
Comirnaty bivalent Original/Omicron BA.1



Vial presentation

Each multidose vial has a grey cap. **Do not dilute**. **Do not shake the vial.**

One vial (2.25 mL) contains 6 doses of 0.3 mL. One dose (0.3 mL) contains 15 micrograms of tozinameran and 15 micrograms of riltozinameran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles).

Figure 11. Comirnaty bivalent Original/Omicron BA.1. Images © 2023 Pfizer Inc. All rights reserved.

Appearance

The frozen vaccine is a white to off-white frozen suspension.

Prior to mixing, the thawed suspension may contain white to off-white opaque amorphous particles. After mixing, the vaccine should present as a white to off-white suspension with no particulates visible. Do not use the vaccine if particulates or discoloration are present.

Storing frozen vials

Unopened vials have a shelf-life of **24 months** at −90°C to −60°C.

Thawing vials

If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of +2°C to +8°C to thaw; a 10-vial pack may take 6 hours to thaw. Ensure vials are completely thawed prior to use. Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to +30°C for immediate use.

Upon moving the product to +2°C to +8°C storage, the updated thawed expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out. Once thawed, do not re-freeze.

Storing thawed vials

Once removed from frozen storage, the unopened vial may be stored refrigerated at +2°C to +8°C for a single period of up to **70 days** *within* the 24-month shelf life.

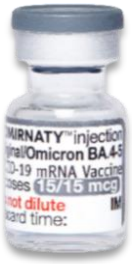
If the vaccine is received at +2°C to +8°C it should be stored at +2°C to +8°C. Check that the expiry date on the outer carton has been updated to reflect the thawed expiry date

Storing vials and vaccine doses

Chemical and physical stability has been shown with storage for 12 hours at +2°C to +30°C after initial puncture. However, because this vaccine contains no antimicrobial preservatives, ATAGI recommends that after puncture, vials must be kept at +2°C to +30°C and used within 6 hours after initial puncture.

ATAGI recommends that, when possible, pre-drawn doses should be used within **1 hour** if kept at room temperature, and within **6 hours** if kept at +2°C to +8°C, to minimise the risk of infection.

Comirnaty bivalent Original/Omicron BA.4/5



Vial presentation

Each multidose vial with a grey cap. **Do not dilute**. **Do not shake the vial.**

One vial (2.25 mL) contains 6 doses of 0.3 mL. One dose (0.3 mL) contains 15 micrograms of tozinameran and 15 micrograms of famtozinameran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles).

Figure 12. Comirnaty bivalent Original/Omicron BA.4/5. Images © 2023 Pfizer Inc. All rights reserved.

Appearance

The frozen vaccine is a white to off-white frozen suspension.

Prior to mixing, the thawed suspension may contain white to off-white opaque amorphous particles. After mixing, the vaccine should present as a white to off-white suspension with no particulates visible. Do not use the vaccine if particulates or discoloration are present.

Storing frozen vials

Unopened vials have a shelf-life of **24 months** at −90°C to −60°C.

Thawing vials

If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of +2°C to +8°C to thaw; a 10-vial pack may take 6 hours to thaw. Ensure vials are completely thawed prior to use. Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to +30°C for immediate use.

Upon moving the product to +2°C to +8°C storage, the updated thawed expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out. Once thawed, do not re-freeze.

Storing thawed vials

Once removed from frozen storage, the unopened vial may be stored refrigerated at +2°C to +8°C for a single period of up to **70 days** *within* the 24-month shelf life.

If the vaccine is received at +2°C to +8°C it should be stored at +2°C to +8°C. Check that the expiry date on the outer carton has been updated to reflect the thawed expiry date.

Storing vials and vaccine doses

Chemical and physical stability has been shown with storage for 12 hours at +2°C to +30°C after initial puncture. However, because this vaccine contains no antimicrobial preservatives, ATAGI recommends that after puncture, vials must be kept at +2°C to +30°C and used within 6 hours after initial puncture.

ATAGI recommends that, when possible, pre-drawn doses should be used within **1 hour** if kept at room temperature, and within **6 hours** if kept at +2°C to +8°C, to minimise the risk of infection.

Spikevax bivalent Original/Omicron BA.4/5

Vaccine presentation

A carton contains 5 clear blister packs containing 2 pre-filled syringes (PFS) in each blister (10 total). **Do not shake or dilute.**

Each pre-filled syringe contains 1 dose (0.5 mL); 25 micrograms of elasomeran and 25 micrograms of davesomeran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles).

Figure 13. Spikevax bivalent Original/Omicron BA.4/5 PFS. Images © 2023 Moderna Inc. All rights reserved.

Appearance

The vaccine is a white to off-white suspension for injection.

One (1) dose of 0.5 mL can be administered from each pre-filled syringe. Do not use the pre-filled syringe to deliver a partial 0.25 mL volume. The prefilled syringe is for single use in one patient only. Discard any residue.

Storing frozen pre-filled syringes

Unopened vaccine has a shelf-life of **9 months** at −50°C to −15°C.

Thawing vaccines

Syringes may be thawed in the blister packs (each blister containing 2 pre-filled syringes) or in the carton itself, either in the refrigerator or at room temperature.

- Frozen cartons can be thawed in a refrigerator (+2°C to +8°C) in 155 minutes, or at room temperature (+15°C to +25°C) in 140 minutes.
- Frozen blister packs can be thawed in a refrigerator (+2°C to +8°C) in 55 minutes, or at room temperature (+15°C to +25°C) in 45 minutes.

Once thawed, the vaccine should not be re-frozen and should be stored at +2°C to +8°C until used.

Upon moving the product to +2°C to +8°C storage, the updated thawed expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out.

Storing thawed pre-filled syringes

The PFS may be stored refrigerated at +2°C to +8°C, protected from light, for a maximum of **30 days** *within* the 9-month shelf life.

If the vaccine is received at +2°C to +8°C it should be stored at +2°C to +8°C. Check that the expiry date on the outer carton has been updated to reflect the thawed expiry date.

Nuvaxovid

Vial presentation

In Australia, Nuvaxovid vaccine is supplied in multidose vials which contain 10 doses of 0.5mL per vial. Do not dilute.

One dose (0.5 mL) contains 5 micrograms of SARS-CoV-2 spike protein and is adjuvanted with Matrix-M.

Figure 14. Nuvaxovid 12 years and over. Images © 2023 Novavax Inc. All rights reserved.

Appearance

Each multidose vial contains a colourless to slightly yellow, clear to mildly opalescent suspension free from visible particles. Visually inspect the contents of the vial for visible particulate matter and/or discolouration prior to administration. Do not administer the vaccine if either are present.

Storing unopened vials

The shelf life of Nuvaxovid is **9 months** at +2°C to +8°C.

Storing opened vials

Chemical and physical stability has been shown for 12 hours at +2°C to +25°C after initial puncture. However, because this vaccine contains no antimicrobial preservatives, ATAGI recommends that after initial puncture, vials must be kept at +2°C to +25°C and used within 6 hours from the time of initial puncture.

Data on the stability of pre-drawn doses in syringes is not available, so storing pre-drawn doses of this vaccine in syringes is not preferred. If pre-drawn doses are used, ATAGI recommends that (where 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°C to +8°C. This is to minimise the risk of infection.

Contraindications and precautions

Contraindications

General true contraindications which apply to all COVID-19 vaccines are:

Anaphylaxis to vaccine components

- documented anaphylaxis after a previous dose of a COVID-19 vaccine from the same class, e.g., anaphylaxis after one mRNA COVID-19 vaccine is a contraindication to all other mRNA COVID-19 vaccines
- documented anaphylaxis after any component of that COVID-19 vaccine, e.g., Comirnaty and Spikevax vaccines would be contraindicated in someone with anaphylaxis to polyethylene glycol (PEG), and Nuvaxovid would be contraindicated in someone with anaphylaxis to polysorbate 80.

Serious adverse event recognised as vaccine-related and assessed as likely to recur with future doses

This includes:

- any other serious adverse event attributed to a previous dose of a COVID-19 vaccine that has been reported to State/Territory adverse event reporting programs and/or the TGA.

AND

- has been determined following review by, and/or on the opinion of, an experienced immunisation provider/medical specialist to be a contraindication to future doses based on a risk of recurrence with repeat vaccine doses.[12]

Precautions

Specific allergies

The following people should be assessed to check they are suitable for vaccination:[12]

- People with immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (such as urticaria/hives) to a previous dose of a COVID-19 vaccine, without anaphylaxis
- People with a generalised allergic reaction (without anaphylaxis) to any component of the COVID-19 vaccine to be administered
- People with a history of anaphylaxis to a previous vaccine or drug (injectable or oral) where a common component such as PEG (for mRNA vaccines) or polysorbate 80 (for Nuvaxovid) may have been the cause
- People with a history of confirmed mastocytosis with recurrent anaphylaxis that requires treatment.

Assessment may be done in consultation with an allergist/immunologist or specialist immunisation clinic.

People in these categories may need one or more of the following:[12]

- to be vaccinated in a facility with capacity to manage acute anaphylaxis
- to be observed for at least 30 minutes following administration of a COVID-19 vaccine dose
- to be vaccinated with an alternative brand of COVID-19 vaccine.

Refer to the Australasian Society of Clinical Immunology and Allergy (ASCIA) Guide: Allergy and COVID-19 Vaccination for more information.

People with a suspected allergy to a previous dose

People who are suspected to have had an allergic reaction to their first dose of a COVID-19 vaccine should seek advice from the State/Territory specialist immunisation service or a specialist allergist/immunologist. These people may need a clinical assessment before any additional vaccine doses.[12]

Before and during each vaccination session, check that up-to-date protocols, equipment, medicines and trained staff to manage anaphylaxis are available.

Refer to Preparing an anaphylaxis response kit.[12]

Cardiac precautions

People with a history of any of the following conditions can receive a COVID-19 vaccine, but advice should be sought from a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:[12]

- recent (within the past 3 months) myocarditis or pericarditis
- acute rheumatic fever or acute rheumatic heart disease (with active myocardial inflammation)
- acute decompensated heart failure.

People who develop myocarditis and/or pericarditis after a COVID-19 vaccine should defer further doses and discuss options for further COVID-19 vaccination with their treating doctor.

For more information, refer to the Joint ATAGI-CSANZ (Cardiac Society of Australia and New Zealand) Guidance on Myocarditis and Pericarditis after COVID-19 vaccines.

Vaccine specific adverse events

Comirnaty Original

Children aged 6 months to 4 years

The most frequently reported adverse events in children aged 6–23 months in a clinical trial were irritability (in about 40-50%), drowsiness (in about 25%), injection site tenderness (in about 15%), and fever (in about 7%).[22] Adverse events occurred at similar frequencies after the first and second dose and were slightly less frequent after the third dose.

In children aged 2–4 years, adverse events occurred at similar frequencies after the first, second and third doses.[22] The most frequently reported adverse events in a clinical trial were injection site pain and fatigue (in about 25–30%). Fever was reported in about 5% of recipients.

Children aged 5–11 years

The most commonly reported adverse event after Comirnaty Original in children aged 5–11 years in a clinical trial was injection site pain (in about 70–75%), followed by fatigue (in about 35%) and headache (in about 20–30%).[15] Fever occurred in about 3% of children after the first dose and about 6.5% of children after the second dose.

Comirnaty bivalent Original/Omicron BA.1

The most commonly reported local and systemic adverse events following a second booster dose of Comirnaty bivalent Original/Omicron BA.1 in adults aged over 55 years were injection site pain (in about 60%), fatigue (in about 50%), headache (in about 35%) and muscle pain (in about 20%).[23]

Comirnaty bivalent Original/Omicron BA.4/5

The most commonly reported local and systemic adverse events in a clinical trial were injection site pain (in about 70%), fatigue (in about 55%), headache (in about 40%) and muscle pain (in about 25%).[24] The suggestion of an increased risk of ischaemic stroke in adults aged 65 years and older following receipt of Comirnaty bivalent Original/Omicron BA.4/5 has emerged from a single US safety surveillance system, but has not been validated by other analyses in the USA and other countries.[25,26] Currently, this is not considered to be a true clinical risk.[27]

Spikevax bivalent Original/Omicron BA.4/5

The most frequent adverse reactions reported after a booster dose of Spikevax bivalent Original/Omicron BA.4/5 were injection site pain (in about 82%), fatigue (in about 60%), headache (in about 50%), muscle pain (in about 45%), joint pain (in about 35%) and axillary swelling or tenderness in about 20%.[28]

Nuvaxovid

The most frequent adverse events reported after Nuvaxovid in a clinical trial were injection site tenderness (75%), injection site pain (53%), muscle pain (51%), headache (50%), malaise (41%), joint pain (24%) and nausea or vomiting (15%).[17] Adverse events occurred at a similar frequency in adolescents aged 12–17 years and in adults aged 18 years and over.

Managing adverse events following immunisation

An adverse event following immunisation (AEFI) is any negative reaction that follows vaccination. It does not necessarily have a causal relationship with the vaccine.[12] The most common AEFIs are minor, mild and short lived, recovering without intervention. The most common minor AEFIs are injection site reactions such as pain or a burning feeling, redness, swelling and itching.[12]

For Comirnaty, the median time of onset of systemic adverse events was 1 to 2 days after vaccination. Symptoms resolved in a median of 1 day. For Spikevax, the median onset of systemic adverse events was 0 to 1 days after vaccination for most participants. Symptoms continued for about 3 days on average.[29] For Nuvaxovid, the median time of onset of systemic adverse events was 1-2 days after vaccination. Symptoms resolved in a median of 2 days or less.[30]

Anaphylaxis

Anaphylaxis is the most serious and immediate AEFI, usually occurring within 15 minutes of vaccination. Anaphylaxis after COVID-19 vaccines is rare and occurs at a similar rate to other common vaccines. In a study that included Comirnaty Original and Spikevax Original, the overall rate of anaphylaxis was around 10 per million doses.[31] The rate of anaphylaxis after Nuvaxovid is not yet known. Vaccination providers must have the skills to identify and manage this reaction.

For a review on how to identify, treat and manage anaphylaxis refer to the handbook.[12] ASCIA offer anaphylaxis e-learning training modules for health professionals for free. To refresh your knowledge on anaphylaxis management visit their Health Professionals e-training page.

For further assistance setting up and preparing an anaphylaxis kit, please review the handbook.[12]

Vasovagal episode

The most common AEFI for adults and older children is a vasovagal or fainting episode. This usually occurs immediately or soon after vaccination. The treatment for a vasovagal episode is to lay the person down until they feel better.[12]

Infants and younger children rarely faint, any loss of consciousness should be assumed anaphylaxis, especially if their pulse is not strong. Unlike anaphylaxis where the central pulse is weak or absent, during a vasovagal episode or convulsion the central pulse is strong. See the handbook for a table of clinical features that may help differentiate between a vasovagal and anaphylaxis reaction.[12]

Myocarditis and Pericarditis

Myocarditis and/or pericarditis following vaccination with a COVID-19 vaccine is very rare but has been reported following receipt of all currently available COVID-19 vaccines. The highest incidence has been reported in adolescent males after a second dose of an mRNA vaccine (Comirnaty or Spikevax), although cases have been reported in male and female adults of all ages and after any dose of a COVID-19 vaccine.[32,33]

For more information, including reporting rates for individual vaccines, refer to ATAGI Guidance on myocarditis and pericarditis after COVID-19 vaccines, and the TGA COVID-19 vaccine safety reports.

Program requirements and reporting

The COVID-19 vaccine is voluntary and free. Any information collected regarding COVID-19 vaccination is strictly protected. The COVID-19 Vaccine and Treatment Strategy is compliant with the *Privacy Act 1988* and the secrecy provisions of the *Australian Immunisation Register Act 2015*. For more information view the COVID-19 vaccines privacy and security information webpage.

Informed Consent

Informed consent is required before administering any COVID-19 vaccine dose and providers are required to document consent in a patient's medical record. Verbal or written consent is acceptable depending on facility policy. Vaccination providers can access interpreters from Translating and Interpreting Service (TIS National) on **131 450** to assist in their consultations with patients and ensure informed consent is given for COVID-19 vaccines.

An example of a consent form for COVID-19 vaccination is available at the Department of Health and Aged Care website if required. This form should be used in combination with the handbook, which will assist in discussions around consent and any medical contraindications or issues that may arise in your conversations with patients.

Consent in children and adolescents

In general, a parent or legal guardian of a child or adolescent has the authority to consent to that child or adolescent being vaccinated. Each jurisdiction has different legislation around the age of consent to medical treatment, check with your State or Territory health authority. The common law (Mature Minor or Gillick competence) applies if there is no specific legislation in place.[12]

Combined COVID-19 vaccine information and consent forms are available for parents and guardians on the following webpages, COVID-19 vaccines for children and COVID-19 vaccination – Patient resources.

Reporting to the Australian Immunisation Register (AIR)

It is mandatory under the Australian Immunisation Register Act 2015, for vaccination providers to report all vaccinations administered in Australia to the Australian Immunisation Register (AIR). COVID-19 vaccines should be entered into the AIR ideally **within 24 hours** and no later than **10 working days** after vaccination. Vaccine codes can be found on the Services Australia website.

Adverse Events Following Immunisation (AEFI)

Adverse Events Following Immunisation (AEFIs) should be reported promptly as surveillance is an integral part of providing safe and trusted vaccines in Australia. A higher standard of safety is expected of vaccines compared to other medications as they are administered to healthy people.

Normally, mild, common and very common AEFIs which are expected are not reported. However, as these COVID-19 vaccines are new medicines, they are subject to additional monitoring. Report any adverse events after COVID-19 vaccination through the usual reporting mechanisms. The TGA and State and Territory governments will actively monitor COVID-19 vaccine safety.

Accidental overdose

If an accidental overdose occurs, it is recommended to observe vital signs and, if symptomatic, to treat the symptoms. This vaccine administration error (VAE) must be recorded through your normal jurisdictional medication error reporting systems. For more information, the Poisons Information Centre may be contacted on **131 126**.

Vaccine administration errors (VAE)

A VAE occurs when a COVID-19 vaccine is given outside the current handbook guidance. Immunisation providers should ensure that best practice is followed, and training is undertaken to minimise the risk of VAEs occurring.[34]

The ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors document provides advice on the management of a range of VAEs, including when a repeat dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered.[34]

Clinicians are encouraged to report VAEs to the Vaccine Operations Centre (VOC) on **1800 318 208** who can provide advice and guidance to clinicians regarding the management of VAEs.

To reduce the risk of VAEs, different COVID-19 vaccines should be stored separately from each other in clearly marked areas, including in dedicated containers in separate spaces (e.g., on different shelves in a vaccine fridge or in separate vaccine fridges where possible). Prepared syringes should be labelled using colour-coded labels to differentiate between paediatric and adolescent/adult doses.[19]

Cold chain breach (CCB)

Suspected COVID-19 vaccine CCBs must be reported to the VOC for assessment. If a CCB has occurred within the clinical setting or during transit, complete the following steps:

1. Place any affected vaccines in quarantine, secured within cold chain storage requirements.
2. Mark stock as 'Do not use, do not discard'.
3. Report the CCB to the VOC by emailing a completed CCB reporting form and relevant temperature data to COVID19VaccineOperationsCentre@Health.gov.au.
4. Wait for the outcome of the assessment and advice on whether the vaccines are safe to use.

Please note the requirement to contact the VOC in the event of a CCB is specific to COVID-19 vaccines, and not stated in the National Vaccine Storage Guidelines.

The COVID-19 Vaccine Administrative System (CVAS)

Delivery Acceptance reporting

It is mandatory to complete a Delivery Acceptance Report on the day of vaccine delivery by the authorised person through the COVID-19 Vaccine Administrative System (CVAS). You will need to complete a Stock Management report for each vaccine your site is approved to administer, even if you do not receive any deliveries or administer any doses in that week.

Providers must record and check the manufacturer expiry date and the thawed use-by date (if applicable) at the time of completing the Delivery Acceptance Reports.

The delivery acceptance process is used to notify the Department of Health and Aged Care of acceptance and any potential issues. This also allows the Commonwealth to meet key obligations.

Vaccine Stock Management Report

It is mandatory to complete the Vaccine Stock Management Report for all vaccine stock held in the clinic by Friday 9pm local time each week through CVAS. Stock management reports can be completed by relevant personnel within the administration site who have access to CVAS for that account.

Stock levels may also be recorded by your jurisdiction. If required, ensure you follow all jurisdictional reporting requirements as well as Commonwealth requirements.

Vaccine ordering

Vaccine orders are also placed through CVAS and must be placed by 11:59pm Friday local time for delivery the following fortnight (note that new orders can only be placed if the previous week's stock management report has been completed).

Wastage reporting

Wastage can occur for many different reasons and should be minimised. Wastage can be substantially reduced by following all policies and procedures as outlined throughout this training module. Also, ensure each manufacturer's guidelines, the handbook and ATAGI statements are followed for preparation and administration.

In cases of wastage, any unused vaccine or waste material should be disposed of in accordance with local requirements in a clinical waste bin. Prior to disposal, the carton (secondary packaging) should be defaced by striking through at least one panel of the carton with a sharpie or similar marker.

Any wastage of 10 or more vials (or 100 or more PFS) in one incident must be reported via the Wastage Reporting tab in CVAS, within 2 hours of the wastage occurring.

Any wastage of fewer than 10 vials (or less than 100 PFS) in an incident should continue to be reported in your weekly Stock Management Report as a minor wastage.

While sites are encouraged to try and minimise wastage, it is understood that wastage is an inevitable part of the COVID-19 Vaccine Program moving forward, as we move to a more opportunistic model of vaccination.

Self-assessment

1. The most common symptoms of COVID-19 include:
    a. A runny nose, sore throat, sneezing and headache
    b. Fatigue, headache, loss of appetite and urinary frequency
    c. A fever, loss of sense of smell, sore throat and headache
    d. Shortness of breath, diarrhoea, fatigue and runny nose

2. Personal protective equipment (PPE) needs to be worn in certain circumstances to protect either the healthcare professional or the consumer. Which of these statements regarding PPE and COVID-19 vaccinations are CORRECT?
    a. Gloves are required when preparing and administering all COVID-19 vaccinations.
    b. Gloves, a gown and a mask are required when administering all COVID-19 vaccinations.
    c. Gloves are not routinely required for COVID-19 vaccinations; however, the NHMRC Guidelines for the Prevention and Control of Infection in Healthcare and Australian Immunisation Handbook recommendations should always be followed.
    d. When administering COVID-19 vaccinations, at least gloves should be worn, these do not need to be changed between each individual that is vaccinated.

3. Standard cold chain requirements can be used for Nuvaxovid (Novavax) and thawed mRNA vaccines. What is the ideal and, acceptable range of temperatures required to maintain cold chain?
    a. Ideally +5 °C with an acceptable range of +2 °C to +8 °C
    a. Ideally +5 °C with an acceptable range of +3 °C to +7 °C
    b. Ideally -70 °C with an acceptable range of -85 °C to -65 °C

4. Who is responsible for approving and registering medicines such as vaccines in Australia?
    a. The TGA (Therapeutic Goods Administration)
    b. The PBS (Pharmaceutical Benefits Scheme)
    c. ATAGI (Australian Technical Advisory Group on Immunisation)
    d. The Department of Health and Aged Care (Australian Government)

5. Who is the specialist team responsible for making COVID-19 vaccination recommendations in Australia?
    a. The TGA (Therapeutic Goods Administration)
    b. The PBS (Pharmaceutical Benefits Scheme)
    c. ATAGI (Australian Technical Advisory Group on Immunisation)
    d. The Department of Health and Aged Care (Australian Government)

6. Valid and informed consent is required before each immunisation encounter. Which of these is NOT required?
    a. Giving consent voluntarily without coercion
    b. Written consent
    c. The individual has the legal and intellectual capacity
    d. Discussing the potential risks and benefits of the vaccination

7. Which of these answers is CORRECT regarding the needle sizes to be used when drawing up and administering vaccines from MDVs as intramuscular injections?
    a. 19 or 21 gauge needle for drawing up and a 22 to 25 gauge needle for administration which should be 25mm long unless the recipient has obesity (38mm).
    b. 21 or 23 gauge needle for drawing up and a 21 to 25 gauge needle for administration which should be 25mm long unless the recipient has obesity (32mm).
    c. 19 or 21 gauge needle for drawing up and a 21 to 23 gauge needle for administration which should be 15mm long unless the recipient has obesity (38mm).
    d. 21 or 23 gauge needle for drawing up and administration (same needle) which should be 25mm long unless the recipient has obesity (38mm).

8. When preparing COVID-19 vaccinations, which of the following is CORRECT?
    a. MDVs should be labelled with the date and time first accessed.
    b. A 2mL or 3mL syringe should be ideally used for vaccine administration, unless the required volume is less than 0.5mL in which case a 1mL syringe should be used.
    c. If you are going to administer multiple doses immediately, you can prepare all doses from a single MDV at the same time.
    d. All of the above

9. When should an alcohol wipe be used to clean the bung of a MDV?
    a. Every time, before it is accessed with a needle.
    b. From the second access point, before it is accessed with a needle.
    c. An alcohol wipe is not needed unless you accidentally touch the bung before it is accessed with a needle.
    d. Every time, before and after it is accessed with a needle.

10. Which of the below are absolute contraindications to receiving a COVID-19 vaccine?
    a. Being pregnant or breastfeeding
    b. Anaphylaxis reaction after exposure to one of the vaccine components previously
    c. Previously been diagnosed with COVID-19
    d. All of the above

11. Reporting the administration of a COVID-19 vaccine is…
    a. Mandatory into the AIR and ideally within 24 hours
    b. Recommended into the AIR and ideally within 24 hours
    c. Mandatory through the TGA within 48 hours
    d. Optional as the AIR is designed for childhood vaccines

12. Anaphylaxis signs and symptoms can appear similar to a vasovagal episode. Which of these signs and symptoms would identify that a person was having an anaphylactic reaction rather than a vasovagal episode?
    a. Weak radial pulse
    b. Weak and rapid central pulse
    c. Loss of consciousness
    d. Hypotension

13. Which of the AEFIs should be reported through your State or Territory reporting network for COVID-19 vaccinations?
    a. Injection site redness
    b. Nausea and vomiting
    c. Headaches
    d. Anaphylaxis
    e. All of the above

14. Where can you find always find the product information (PI) documents of COVID-19 vaccines?
    a. Inside the vaccine packaging
    b. On the TGA website
    c. Within the handbook
    d. All of the above

15. When preparing a COVID-19 vaccine which resources/s must be checked if you are unsure of the steps involved?
    a. ATAGI advice including the handbook
    b. The product information of the vaccine
    c. The outer packaging of the vaccine
    d. The Department of Health COVID-19 vaccines webpage

16. When should you check the date and time has been recorded clearly on the vial?
    a. When your vaccines are delivered
    b. When you do vaccine stocktake
    c. Just after you have first punctured the vial
    d. After administering a vaccine dose

17. Which of the following about MDVs are INCORRECT?
    a. MDVs contain multiple doses, only a single dose should be drawn up and administered to each person
    b. You can mix MDV contents of the same vial and batch number to make a full dose if there is excess left that is less than a full dose and the vial is not expired
    c. MDVs can be used for a maximum for 12 hours once opened

18. Pre-drawn vaccine doses (in syringes) should be used within…
    a. 6 hrs if stored between +8ºC to +30ºC or 12 hrs if stored between +2ºC and +8ºC
    b. 1 hr if stored between +8ºC to +30ºC or 6 hrs if stored between +2ºC and +8ºC
    c. 6 hrs if stored between +8ºC to +30ºC or 24 hrs if stored between +2ºC and +8ºC
    d. 1 hr if stored between +8ºC to +30ºC or 12 hrs if stored between +2ºC and +8ºC

19. Which expiry date determines the date by which the vaccine must be used to prevent VAEs?
    a. The latest date of the manufacture (batch) and thawed expiry date
    b. The earliest of the manufacture (batch) and thawed expiry date
    c. The manufacture (batch) expiry date
    d. The thawed expiry date

20. Once removed from frozen storage, the unopened Comirnaty (Pfizer) MDVs can be stored in cold chain (+2ºC to +8ºC) for a single period of up to how many days within the 24-month shelf life?
    a. 100 days
    b. 31 days
    c. 70 days
    d. 30 days

21. Once removed from frozen storage, the Spikevax (Moderna) PFS can be stored in cold chain (+2ºC to +8ºC) for a single period of up to how many days within the 9-month shelf life?
    a. 100 days
    b. 31 days
    c. 70 days
    d. 30 days

22. Which of the following steps are recommended to reduce the risk of VAEs occurring?
    a. Use colour-coded labels to differentiate between paediatric and adolescent/adult doses
    b. Different vaccines/vials should be stored separately from each other in clearly marked areas
    c. Each clinic should only hold and administer one COVID-19 vaccine formulation at any one time
    d. Different vaccines/vials should be stored in dedicated containers, ideally on different shelves in the vaccine fridge or different fridges where possible.

Self-assessment answers

1. A
2. C
3. A
4. A
5. C
6. B
7. A
8. D
9. A
10. B
11. A
12. B
13. D
14. B
15. A & B
16. C
17. B
18. B
19. B
20. C
21. D
22. A, B & D

Useful resources

- **COVID-19 vaccines: frequently asked questions** – Refer to the National Centre for Immunisation Research and Surveillance (NCIRS) FAQs for answers on the vaccination program and rollout, vaccine safety, vaccine development and about being vaccinated for consumers.
- **Australian Immunisation Handbook** – Refer to the handbook for all general vaccine administration questions including vaccine preparation, administration and post-vaccination care as well as all specific COVID-19 vaccination recommendations and considerations. The handbook also contains storage and handling recommendations for COVID-19 vaccines including variations from product information, transporting doses for home visits and recording vaccinations.
- **National Vaccine Storage Guidelines 'Strive for 5'** – Refer to this guideline or an in-depth review of the National policies and guidelines on maintaining cold chain, temperature monitoring and other steps to prevent breaches as well as cold chain breach reporting.
- **ATAGI guidance on the use of multi-dose vials for COVID-19 vaccination** – Refer to this document for in-depth review on MDVs including mass administration and the alternative method of administration.
- **ATAGI clinical guidance on COVID-19 vaccine administration errors** – Refer to this document for a summary of potential errors that could occur and the appropriate steps to correct these if necessary.
- **COVID-19 Vaccines in Australia – A3 poster** – Refer to this poster for a summary of the vaccines available, primary dose schedule and vaccine storage requirements.
- **ATAGI recommended COVID-19 vaccine doses – poster** – Refer to this poster for a summary of vaccine recommendations for people with and without risk factors. The poster includes primary course and booster dose recommendations across all age groups.
- **COVID-19 vaccination – Consent form** – Refer to this document for a generic tick-box consent form for gaining written consent with people who are able to give consent, it includes a page to record vaccines administered.
- **AIR vaccine codes** – Refer to this website for a list of all the AIR vaccine codes.
- **Immunisation contacts** – Refer to this website for the immunisation health service contact numbers and websites for each State and Territory.
- **TGA Product Information** – Use this website to search for the PI of any COVID-19 vaccine. Note that this should be read in conjunction with ATAGI vaccine preparation advice and the handbook.
- **Reporting Adverse Events** – Refer to this website for information on how to report suspected AEFI associated with a COVID-19 vaccine.
- **Cold Chain Breach reporting form** – Refer to this form for assistance with reporting a potential cold chain breach of COVID-19 vaccines.

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