



Primary Care Vaccine Roll-out

Provider Bulletin

19 June 2023

Bulletins provide you with regular updates and guidance on the COVID-19 Vaccine Program.

Key Messages

ORDERING UPDATES

Moderna BA.4-5 PFS Allocation Increase

For sites administering Moderna BA. 4-5 pre-filled syringes (PFS) your allocation was increased to 100 doses per fortnight from **10 June 2022**.

If you have a need for additional vaccines, you can place an additional order in CVAS after placing your normal order. There is no limit to the number of doses that can be ordered in an additional order or the number of additional orders that can be placed. If you have any problems placing the order you can contact the VOC on 1800 318 208 or by emailing covid19vaccineoperationscentre@health.gov.au

COVID-19 BOOSTER ADVICE FOR TARGET GROUPS

The primary goal of the Australian COVID-19 Vaccine Program is to minimise the risk of severe disease, including hospitalisation and death from COVID-19. Studies conducted throughout the pandemic identified a higher risk of hospitalisation from all variants, including Omicron and its subvariants of COVID-19, among older adults and adults with immunosuppression or other chronic medical conditions, compared with younger or healthy adults.

Further, although COVID-19 vaccines have been shown to be highly effective at preventing severe illness, there is evidence that the protection wanes over several months, especially in those that have not been previously infected.

As respiratory illnesses are more common in winter, an additional COVID-19 booster dose is anticipated to address waning of protection against severe COVID-19 and provide an increase in protection against severe illness in the targeted groups.

In 2023, booster eligibility has been updated to include:

- recommending a 2023 COVID-19 vaccine booster dose for adults in the following groups, if their last COVID-19 vaccine dose or confirmed infection (whichever is the most recent) was 6 months ago or longer, and regardless of the number of prior doses received:
 - o All adults aged 65 years and over
 - Adults aged 18-64 years who have medical comorbidities that increase their risk of severe COVID-19, or disability with significant or complex health needs.
- considering a 2023 booster dose for adults in the following groups if their last COVID-19 vaccine dose or confirmed infection (whichever is the most recent) was 6 months ago or longer, and regardless of the number of prior doses received, based on an individual risk benefit assessment with their immunisation provider:
 - All adults aged 18-64 years without risk factors for severe COVID-19
 - Children and adolescents aged 5-17 years who have medical comorbidities that increase their risk of severe COVID-19, or disability with significant or complex health needs.

Older adults and adults with medical comorbidities should be encouraged to receive a 2023 COVID-19 booster dose as soon as they are eligible, at a time of 6 months or greater following the most recent COVID-19 vaccine dose or confirmed infection (whichever is the most recent).

To view the 2023 booster recommendations in full, refer to the ATAGI 2023 Booster Advice or the ATAGI Clinical Guidance for COVID-19 vaccine providers.

STORAGE AND HANDLING OF COVID-19 VACCINES

The Vaccine Operations Centre (VOC) continues to receive reports of vaccine administration errors relating to expired vaccines being administered.

Storage of COVID-19 vaccines

All mRNA (Moderna and Pfizer) vaccines delivered **thawed** at refrigerated temperatures (**2°C to 8°C**) will have a sticker applied to the external packaging specifying an accurate vaccine **Use-by Date**.

The **Use-by Date** is:

- calculated for you at the time of thawing by the logistics provider; and
- printed clearly, in red, on the product packaging. An example is presented below.

Example of sticker applied to Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine:

30 days within the

Moderna Bivalent (BA.4-5) 12 years+ (PFS)

Batch: MOD45 Defrost Date: 07/03/2023

Use By Date: 06/04/2023 — 9-month shelf-life Store at 2°- 8°C & protected from light.

at 2 - 8 C & protected from light

DO NOT RE-FREEZE

The vaccine must NOT be administered past this Use-by Date.

Please note, shelf-life extensions do not impact the approved timeframe for vaccines kept at 2°C to 8°C.

Case Study 1:

Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine was administered to 5 patients 33 days after thawing, 3 days after the **Use-by Date** on the sticker applied to the external packaging.

- Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine must be used within 30 days after thawing (thaw use-by date).
- Moderna was contacted and advised revaccination was not required. However, the vaccine provider had to inform the patients of the error as part of open disclosure.

Handling of COVID-19 vaccines

COVID-19 vaccines available for use in Australia contain no antimicrobial preservatives.

To minimise the risk of infection:

- once a COVID-19 vaccine multi-dose vial (MDV) is first punctured it should be used within 6 hours; and
- pre-drawn doses from MDVs should be used **within 1 hour** if kept at room temperature, and within 6 hours if kept refrigerated at 2°C to 8°C.
- Moderna pre-filled syringes (PFS) should be opened and have the needle affixed at the time of administration. This reduces the risk of microbial contamination with handling, especially given variability in aseptic technique and environmental factors.

For key differences on the storage, handling and administration requirements between each COVID-19 vaccine, as per the Australian Technical Advisory Group on Immunisation (ATAGI) guidelines, please refer to the COVID-19 Vaccines in Australia poster.

Case Study 2:

A vaccine provider opened and affixed the needles to prefilled syringes of Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine ahead of a vaccination clinic. The vaccines were placed into the fridge, but one wasn't used until the following day, 23 hours after opening.

- Moderna advised that best practice is for the PFS to be opened and the needle affixed at the time of administration. This is to reduce the risk of microbial contamination.
- The patient did not require revaccination. However, the vaccine provider had to inform the patient of the error as part of open disclosure and the patient had to monitor for signs of infection.

Which expiry dates do I need to consider?

If your site receives thawed (2°C to 8°C) vaccines:

 you only need to refer to the Use-by Date labelled on the sticker applied to the external packaging of your vaccines.



If your site receives and stores <u>frozen</u> vaccines:

- a batch (manufacturer) expiry date, referring to the vaccine's shelf-life when stored frozen, is printed on the external packaging and individual vaccine vials/PFS.
 - When the Therapeutic Goods Administration (TGA) extends a vaccine's shelf-life, it is applied to the date of manufacture, extending the batch expiry date.
- Once you thaw frozen vaccines, you must apply the appropriate shelf-life expiry yourself to manage compliant storage, handling, and administration.
 - For allowable timeframes for thawed vaccines, please refer to the TGA Product Information, <u>COVID-19</u> <u>Vaccination Training Program</u>, or <u>COVID-19 Vaccines in Australia</u> poster.



If you need assistance with expiry dates, or believe your site may have administered expired vaccines, please reach out to the Vaccine Operations Centre (VOC) at COVID19VaccineOperationsCentre@health.gov.au or 1800 318 208.

COVID-19 VACCINATION STUDY IN OLDER AUSTRALIANS

Recent study confirms COVID-19 vaccination highly effective against death caused by COVID infection in older Australians

On 17 May 2023, the National Centre for Immunisation Research and Surveillance (NCIRS) publicly released the results of a study with evidence that COVID-19 vaccines were highly effective at protecting against death from COVID-19 in people over 65 years.

It specifically found that the benefit of vaccinations was particularly high for adult residents in aged care where absolute mortality reduction is significantly higher than for the general population.

In adults aged over 65 years, COVID-19 boosters provided more protection than completion of a primary course alone, with one COVID-19 death being prevented among aged care residents for every 157 people boosted between June and November 2022.

Between January to May 2022:

- a 2nd dose received six months or more ago, reduced the risk of death from COVID-19 by 34% compared to those who were unvaccinated.
- a 3rd (booster) dose received in the last three months reduced the risk of death from COVID-19 by 93% compared to those who were unvaccinated.
- between June to November 2022, a 4th (booster) dose received in the last three months reduced the risk of death from COVID-19 by 84%.

While effectiveness wanes after receipt, vaccine effectiveness of boosters remains above 50% even six months after receipt. Given waning effectiveness over time, recency of a booster appears most important in preventing death rather than the total number of boosters received.

For further detail download the study here: Effectiveness of COVID-19 Vaccination Against Covid-19 Specific and All-Cause Mortality in Older Australians.

As at 7 June 2023, 50% of eligible aged care residents have received a 2023 booster dose. This number is increasing each week, but we would all like it to be higher.

Please continue to support residential aged care homes needing primary care led COVID-19 vaccination clinics, by working directly with aged care sites or liaising with your local Primary Health Network.