Australian Government
Department of Health and Aged Care

COVID-19 VACCINATION TRAINING PROGRAM (CVTP)

September 2023

Curriculum Map

Australian Government

COVID-19 Vaccination Training Program (CVTP) – Curriculum Map

The below table illustrates the mandatory training requirements for all authorised immunisation providers to administer specific COVID-19 vaccines as part of the National COVID-19 Vaccination Rollout.

CORE MODULES						ELECTIVE MODULES	
Module 1: COVID-19 an introduction (optional)	**Module 2**: Handling and storage	**Module 3**: Communication and purpose	**Module 4**: Multi-dose vial (MDV) training and delivery	**Module 5**: Documentation and reporting	**Module 6**: Safety surveillance and reporting of adverse event following immunisation (AEFI)	**Additional module 1**: Pfizer (purple cap) *Comirnaty Original (12 years+)*[1]	**Additional module 1a**: Pfizer (grey cap) *Comirnaty Bivalent BA.1 (18 years+)*
							Additional module 1b: Pfizer (grey cap) *Comirnaty Bivalent BA.4-5 (12 years+)*
						Additional module 2: AstraZeneca *Vaxzevria (18 years+)*[1]	
						Additional module 3: Moderna (red cap) *Spikevax Original (12 years+)*[1]	**Additional module 3a**: Moderna (red cap) *Spikevax Original (6 to 11 years)*[1]
							Additional module 3b: Moderna (blue cap, purple label) *Spikevax Original (6 months to 5 years)*[1,2]
							Additional module 3c: Moderna (blue cap, green label) *Spikevax Bivalent BA.1 (18 years+)*[1]
							Additional module 3d: Moderna (pre-filled syringe) *Spikevax Bivalent BA.4-5 (12 years+)*
						Additional module 4: Pfizer (orange cap) *Comirnaty Original (5 to 11 years)*	**Additional module 4a**: Moderna (maroon cap) *Comirnaty Original (6 months to 4 years)*[3]
						Additional module 5: Novavax *Nuvaxovid (12 years+)*	

Notes:

1. This COVID-19 vaccine is no longer available in Australia
2. Additional module 3a was also a pre-requisite
3. Additional module 1 was also a pre-requisite

Useful resources:

- Clinical recommendations for COVID-19 vaccines
- ATAGI recommended COVID-19 vaccine doses
- COVID-19 Vaccines in Australia

Information current as of 22 August 2023.

Module 1 – COVID-19: An Introduction (21/09/2023)

This module is suitable for all applicants.

The recommended time for completion is 25 minutes. Each topic must be completed in order. There are three multi-choice questions to pass before this module is complete and progression to Module 2 can occur.

Learning objectives

At the end of Module 1 it is expected that you will be able to:

- Understand the characteristics of COVID-19 including symptoms and transmission

Understand the most at-risk population groups

Topics covered in Module 1

1. COVID-19
2. Common symptoms
3. Transmission
4. At-risk groups

Topic 1: COVID-19

COVID-19 is the name given to the new disease caused by the SARS-CoV-2 virus.

SARS-CoV-2 is a new strain of a large family of viruses called coronaviruses (CoV). This was named as per the International Committee on Taxonomy of Viruses. Prior to this name it was referred to as 'novel coronavirus 2019' or '2019-nCoV'.

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 is not like the flu. It is more contagious, more deadly and it's spreading across a world where no-one was immune" (Lewandowsky, et. al., 2021, p.3).

Rarely, coronaviruses circulating in animals such as camels, cats and bats can adapt, cross over and infect humans as a new virus (antigenic shift). This antigenic shift occurred with MERS-CoV and SARS-CoV (Communicable Diseases Network Australia [CDNA], 2022).

It is most likely that SARS-CoV-2 originated from an animal (zoonotic) source, probably bats. However, the origin remains undetermined, and investigations continue. The zoonotic source has not yet been confirmed as the intermediate host from animal to human (first infected human) has not yet been identified as of 12 January 2020 (CDNA, 2022).

Brief timeline of identification and spread:

19 December 2019

COVID-19 was first reported in the city of Wuhan in China.

31 December 2019

The World Health Organization (WHO) learned of the new disease when a cluster of pneumonia cases were reported.

25 January 2020

The first reported case in Australia was confirmed in Victoria.

30 January 2020

WHO declared a 'public health emergency of international concern' due to a global pandemic.

10 February 2020

COVID-19 was listed on the National Notifiable Diseases List (NNDL).

27 February 2020

Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19) was activated.

2 March 2020

First Australian locally transmitted Coronavirus cases identified.

18 March 2020

The Governor-General declared a 'human biosecurity emergency' under the Biosecurity Act 2015.

19 March 2020

Australia closed borders to international travellers.

30 April 2020

6,753 COVID-19 cases and 91 deaths in total reported in Australia.

12 August 2020

22,127 COVID-19 cases and 352 deaths in total reported in Australia.

31 December 2020

28,381 COVID-19 cases and 909 deaths in total reported in Australia.

25 January 2021

Pfizer (COMIRNATY) (purple cap) vaccine was provisionally registered by the Therapeutic Goods Administration (TGA) for individuals 16 years and over.

16 February 2021

AstraZeneca (VAXZEVRIA) vaccine was provisionally registered by the TGA for individuals 18 years and over. From March 2023, AstraZeneca (VAXZEVRIA) is no longer available in Australia.

22 July 2021

Pfizer (COMIRNATY) (purple cap) vaccine was provisionally registered by the TGA for individuals 12 years and over.

09 August 2021

Moderna (SPIKEVAX) (red cap) vaccine was provisionally registered by the TGA for individuals 18 years and over. From January 2023, Moderna (SPIKEVAX) (red cap) is no longer available in Australia.

03 September 2021

Moderna (SPIKEVAX) (red cap) vaccine was provisionally registered by the TGA for individuals 12 years and over. From January 2023, Moderna (SPIKEVAX) (red cap) is no longer available in Australia.

27 October 2021

Pfizer (COMIRNATY) (purple cap) vaccine was provisionally approved as a booster dose by the TGA for individuals 18 years and over.

5 December 2021

Pfizer (COMIRNATY) (orange cap) vaccine was provisionally approved by the TGA for children aged 5 to 11 years.

8 December 2021

Moderna (SPIKEVAX) (red cap) was provisionally approved by the TGA as a booster dose for individuals 18 years and over. From January 2023, Moderna (SPIKEVAX) (red cap) is no longer available in Australia.

20 January 2022

Novavax (NUVAXOVID) vaccine was provisionally approved by the TGA for individuals 18 years and over.

28 January 2022

Pfizer (COMIRNATY) (purple cap) vaccine was provisionally approved by the TGA as a booster dose for individuals 16 to 17 years of age.

9 February 2022

AstraZeneca (VAXZEVRIA) vaccine was provisionally approved by the TGA as a booster dose for individuals 18 years and over. From March 2023, AstraZeneca (VAXZEVRIA) is no longer available in Australia.

17 February 2022

Moderna (SPIKEVAX) (red cap) vaccine was provisionally approved by the TGA for individuals aged 6 to 11 years old. From January 2023, Moderna (SPIKEVAX) (red cap) is no longer available in Australia.

7 April 2022

Pfizer (COMIRNATY) (purple cap) vaccine was provisionally approved by the TGA as a booster dose for individuals 12 to 15 years of age.

9 June 2022

Novavax (NUVAXOVID) vaccine was provisionally approved by the TGA as a booster dose for individuals 18 years and over.

19 July 2022

Moderna (SPIKEVAX) (blue cap, purple label) vaccine was provisionally approved by the TGA for individuals aged 6 months to 5 years old. From May 2023, Moderna (SPIKEVAX) (blue cap, purple label) is no longer available in Australia.

28 July 2022

Novavax (NUVAXOVID) vaccine was provisionally approved by the TGA for adolescents aged 12 to 17 years.

29 August 2022

Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine was provisionally approved by the TGA for individuals aged 18 years and older.

20 September 2022

Pfizer (COMIRNATY) (orange cap) vaccine was provisionally approved by the TGA as a booster dose for individuals 5 to 11 years of age.

29 September 2022

Pfizer (COMIRNATY) (maroon cap) vaccine was provisionally approved by the TGA for individuals aged 6 months to 4 years old.

27 October 2022

Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine was provisionally approved by the TGA as a booster dose for individuals 18 years of age and over.

20 January 2023

Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine was provisionally approved by the TGA as a booster dose for individuals 12 years of age and over.

17 February 2023

Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine was provisionally approved by the TGA as a booster dose for individuals 12 years of age and over.

(European Centre for Disease Prevention and Control [ECDC], 2021; CDNA, 2022; Lupton, 2020; TGA, 2021d)

For further information related to the COVID-19 timeline in Australia view the ABC digital story line, *Anatomy of our battle against COVID-19*.

Topic 2: Common symptoms

COVID-19 symptoms vary significantly, ranging from some people being asymptomatic (18 – 42%), to others requiring intensive care treatment and/or potentially dying. As at 13 January 2022, the crude fatality rate (CFR) for confirmed cases reported globally is 1.8% and less than 1% in Australia, compared to the 3.2% of confirmed cases in Australia as at 16 December 2020 (CDNA, 2022).

Most people who become infected with COVID-19 only experience mild symptoms and fully recover without hospitalisation or specific medical treatment (CDNA, 2022). However, it is reported that some people experience persistent symptoms after recovering which impacts their physical abilities and health-related quality of life (Darley, et al., 2020).

Mild symptoms ~ 80% of people

Moderate symptoms ~ 15% of people

Severe symptoms ~ 5% of people

(CDNA, 2022)

Most common symptoms include:

- Fever
- Cough

(CDNA, 2022; Australian Technical Advisory Group on Immunisation [ATAGI], 2021b)

Other symptoms include:

- Runny nose (rhinorrhoea) (<10% of cases)
- Sore throat
- Fatigue
- Shortness of breath (dyspnoea)
- Myalgia (joint and/or muscle aches)
- Headache
- Nausea/Vomiting
- Chills
- Loss of sense of smell (anosmia) (<10% of cases)
- Altered sense of taste (dysgeusia) (<10% of cases)

(ATAGI 2021b; CDNA, 2022)

Atypical symptoms include:

- Chest pain
- Diarrhoea
- Conjunctivitis

(CDNA, 2022)

Older people may present with atypical symptoms including being generally unwell, upset or sleeping more instead of fever or a sore throat. A COVID-19 screening tool for use in aged care services to ensure early identification and response to signs and symptoms of deterioration has been developed by Safer Care Victoria (SCV, 2020).

It takes on average 5-6 days from infection until symptoms present; however, it may take anywhere from 1 to 14 days for symptoms to show. Quarantine is required for 14 days after exposure or potential exposure to COVID-19. This is to account for the maximum time that symptoms can start to show in, reducing the chances of community spread (CDNA, 2022).

If concerned, you can refer your community and your patients to the Department of Health and Aged Care 'Symptom checker' or national coronavirus helpline on 1800 020 080. The Department of Health and Aged Care *Identifying the symptoms* poster may also be helpful.

Topic 3: Transmission

COVID-19 primarily spreads through droplet transmission from direct and close contact with an infected person. Viable viruses from sprayed droplets can exist on surfaces after leaving an infected person's body for up to 72 hours (fomite transmission), although the droplets normally travel less than 1 metre (CDNA, 2022; Department of Health and Aged Care [DHAC], 2020a).

A person who touches a contaminated surface and then touches their face, including eyes, nose or mouth without first washing or disinfecting their hands may transmit the virus to themselves. Viruses cannot enter the body through an intact skin barrier (CDNA, 2022).

Aerosols are small droplets and may be generated in certain in-hospital procedures such as suctioning and intubation and may contribute to transmission in certain circumstances. Singing and shouting may increase the force and range of droplets and aerosols (CDNA, 2022). There is increasing evidence to suggest that COVID-19 transmission is occurring through the inhalation of airborne viruses (Tang, et al., 2021).

In indoor environments which have a low air exchange rate, air coming inside from the outside, small particles may remain suspended or recirculate for longer periods (CDNA, 2022). Ideally good air flow should be maintained when indoors such as by opening windows to reduce the risk of infection from lingering viral particles. If windows cannot be opened then heating, ventilation and air conditioning (HVAC) systems should be adjusted by appropriately trained personnel, or higher levels of respiratory protection employed. Avoiding overcrowding in indoor spaces will also assist to reduce the infection risk (Tang, et al., 2021).

Asymptomatic and pre-symptomatic people (1-3 days before symptoms show) may transmit the virus to others. Viral load (the number of viruses present) is highest at symptom onset and then decreases within 7 days. For contact tracing, a period of 48 hours before symptom development is used to identify an infective period (CDNA, 2022).

Variant Strains

Several SARS-CoV-2 variant strains have been identified. Some variants are associated with higher transmissibility and increased severity or duration of disease. These variants are classified as a Variant of Concern (VOC) or Variant of Interest depending on their attributes (ATAGI, 2021b).

Clinically significant variations in the efficacy/effectiveness of different vaccines against these emerging strains are being closely examined and data reviewed to determine if any changes to vaccines or to vaccine policy are needed (ATAGI, 2021b).

Infection control:

A risk mitigation approach should be taken to reduce the risk of transmission of infection. The Hierarchy of Controls outlines how to minimise the risk from hazards. The Department of Health and Aged Care have published a document, The hierarchy of controls for minimising the risk of COVID-19 transmission.

- The most effective strategy is to **eliminate** the risk, however, this is often not possible in healthcare.
- Next is **substitution,** such as providing telehealth appointments, however, it is not applicable for COVID-19 vaccination.
- Thirdly is **isolation** or **engineering controls** and this includes having adequate ventilation, physical barriers and isolating patients, residents or guests.
- Fourthly **administrative controls** can be implemented, and this includes hand hygiene and staggering work schedules into groups to minimise overlap.
- The final stage is the wearing of **personal protective equipment (PPE)** which includes masks, gloves, gowns, face shields etc, as well as training in donning and doffing the PPE.

(Australian Health Protection Principal Committee [AHPPC], 2020)

For a description of risk minimisation strategies please review the hierarchy of controls document for COVID-19. Multiple control strategies should be used at the same time or following each other until the hazard is eliminated or effectively minimised. Specific measures to keep COVID-19 out of healthcare and residential care include:

- Advising staff and visitors with relevant symptoms to stay away.
- Completing health screening questions before entry.
- Screening body temperature and other measures.

General advice to prevent transmission include:

- Maintain a physical distance of at least 1.5m.
- Avoid physical greetings and close contact with others.
- Practise extra care on public transport.
- Avoid crowds and large public gatherings. When unable to avoid crowds and large public gatherings or maintain a physical distance of 1.5m then medical or surgical masks are recommended.
- Practise good hand hygiene.
- Stay home if you are unwell, even with mild symptoms.
- Get tested even if only mild symptoms are experienced.

(DHAC, 2020c)

The Australian Guidelines for the Prevention and Control of Infection in Healthcare (National Health and Medical Research Council [NHMRC], 2019), developed in conjunction with the Australian Commission on Safety and Quality in Health Care (ACSQHC), must be followed in all clinical practice. Section 3 is standard and transmission-based precautions and will be reviewed here.

Standard precautions should be used as the primary strategy for minimising the transmission of healthcare-associated infections, when caring for patients regardless of infection status. Standard precautions should also be used when handling blood and other bodily substances, non-intact skin and mucous membranes. Standard precautions include:

- Hand hygiene (reviewed in the next section).
- Appropriate use of personal protective equipment (PPE).
- Safe use and disposal of sharps.
- Routine environment cleaning and waste management.
- Aseptic technique.
- Respiratory hygiene and cough etiquette.

(NHMRC, 2019).

Coughing and sneezing into your elbow and avoiding touching your face without first performing hand washing are other important infection control practices.

It is further recommended that surfaces in communal healthcare areas be disinfected regularly. In consulting rooms and similar, the touched surfaces must be disinfected between each episode of patient care (DHAC, 2020d).

Refer to specific guidelines for COVID-19 cleaning within your clinical area from the Department of Health and Aged Care (DHAC, 2020d) *Hygiene and cleaning for the health workforce during COVID-19* webpage. Within this webpage there is access to a 30-minute training module and downloadable resources to display and use in your workplace.

Please review the Infection Control Expert Group (ICEG) statement – Updated recommendations to protect healthcare workers from COVID-19 infection for more information.

Transmission-based precautions should be used in addition to standard precautions when standard precautions alone cannot stop the transmission of infection (NHMRC, 2019).

Hand hygiene:

Figure 1: *Keep the germs away, wash your hands* (DHAC, 2020e)

This poster can be downloaded, printed and put up at your facility/clinic if desired from here.

The 5 Moments For Hand Hygiene should always be performed as part of evidence-based practice in the clinical environment. Hand washing can kill the viruses on your hands, preventing you from infecting yourself or others.

Frequent hand hygiene is a fundamental element of infection control!

Australian Commission on Safety and Quality in Healthcare - What is hand hygiene?

Australian Commission on Safety and Quality in Healthcare - 5 Moments For Hand Hygiene (in all settings)

WHO – How to hand rub
WHO - How to hand wash

Personal protective equipment (PPE):

PPE is a critical part of infection prevention and control. However, PPE should be considered the last line of defence within a broader 'hierarchy of controls' framework as described earlier in this topic.

The use of PPE should be as per your facility and jurisdictional guidelines. Section 3.3 in The Australian Guidelines for the Prevention and Control of Infection in Healthcare (NHMRC, 2019) reviews when PPE should be worn and how to dispose of them correctly.

Gloves should be worn as part of standard precautions if there is a risk of exposure to blood and bodily substances. Gloves may also be required as part of transmission-based precautions. If wearing, gloves they must be changed between each individual and after every episode of care. Hand hygiene must be performed prior to putting on gloves and after gloves have been removed (NHMRC, 2019).

Gloves are not routinely required for immunisation, however, each individual should be assessed following the NHMRC guidelines and the Australian Immunisation Handbook (AIH) recommendations.

For more and specific information on Infection Prevention and Control please refer to the Australian Commission on Safety and Quality Health Care (ACSQHC) website. For specific COVID-19 PPE recommendations including a risk assessment, donning and doffing PPE, please review the *Guidance on the use of personal protective equipment (PPE) for health care workers in the context of COVID-19* document developed by the National COVID-19 Clinical Evidence Taskforce Infection Prevention and Control Panel (IPC).

Topic 4: At-risk populations

Anyone can become infected and ill with COVID-19, regardless of age, race or gender and underlying health status. However, some population groups are at increased risk of exposure and/or developing severe symptoms.

Risk of exposure is related to frequent, close or extended contact with other people who either have contracted or have greater exposure to COVID-19. This includes domestic and international travellers to areas with a high prevalence of COVID-19 and individuals caring for COVID-19 cases (CDNA, 2022).

The individuals at higher risk of exposure often belong to certain occupation groups. This may include:

- International border staff.
- Quarantine and isolation workers and support services.
- International travel crew (air and maritime crew).

- Frontline healthcare and aged care workers.

(CDNA, 2022)

Vulnerable groups are also at increased risk of contracting COVID-19, these include individuals:

- In aged care facilities.
- In detention facilities.
- In group residential settings.
- With a disability.

(Healthdirect, 2021)

Risk of experiencing more severe and fatal disease is cumulative and on a sliding scale. As a person ages, their risk will gradually increase until we quantify this as a high risk at 70 years old. Even though adults under 70 years old are not technically classified as a high risk, it is important to remember that the actual risk does not suddenly escalate when turning 70.

For people over the age of 50, the risk of death from COVID-19 progressively increases throughout each decade of age. From about 2 times as high for those aged 50–59 years to over 10 times higher for those aged over 80 years. Findings were similar when results were adjusted for other risk factors. In Australia, the COVID-19 case fatality ratio increased substantially with age, from 0.6% in those aged 50–64 years, to 7.0% in those aged 65–79 years and 33.8% in those aged over 80 years (ATAGI, 2021b).

Certain comorbidities are associated with an increased risk of severe illness from COVID-19. The level of risk ranges from moderate to high, depending on the condition.

High risk conditions:

- 70 years of age or older.
- Bone marrow transplant in the last 24 months.
- Haematological cancer diagnosed in the last 5 years.
- Receiving immune-suppressive therapy due to a solid organ transplant or graft versus host disease.
- Receiving chemotherapy or radiotherapy.

(DHAC, 2020b)

Moderate risk conditions:

- Chronic liver disease.
- Chronic lung disease (includes severe asthma).
- Chronic renal failure.
- Coronary heart disease or failure.
- Diabetes.
- Hypertension.
- Non-haematological cancer diagnosed in the last 12 months.
- Other primary or acquired immunodeficiency.
- Severe obesity (Body Mass Index [BMI] ≥40kg/m^2).
- Some chronic inflammatory conditions and treatments.
- Some neurological conditions including previous stroke or dementia.

(DHAC, 2020b)

Age is the strongest independent COVID-19 risk factor for severe outcomes, followed by chronic disease (Australian Government, 2020a; CDNA, 2022).

Having two or more conditions (comorbidities) may also increase a person's risk, even when young. Severe or poorly controlled conditions will increase an individual's risk further in comparison to individuals with milder and controlled conditions.

Other possible risk factors include:

- Being male.
- Living in poverty.
- Smoking.

(DHAC, 2020b)

Further information about COVID-19 is available in the COVID-19 CDNA National Guideline for Public Health Units. Information about Australian epidemiology is available on the Department of Health and Aged Care including regular epidemiological reports. For a list of medical conditions associated with an increased risk of severe COVID-19, review the ATAGI Clinical guidance on use of COVID-19 vaccine in Australia.

"First nations people can be at higher risk in any public health emergency" (CDNA, 2022, n.p.).

At present there is limited evidence on the risk of severe outcomes with COVID-19 in Aboriginal and Torres Strait Islander people. However, as there is a disproportionate number of Aboriginal and Torres Strait Islander people who experience chronic disease or who live in poverty when compared to other Australians, higher risk of severe outcomes of disease and a greater risk of transmission is likely (Australian Government, 2020a).

Specific pages of advice for selected populations are available on the Department of Health and Aged Care website:

- Aboriginal and Torres Strait Islander people and COVID-19
- COVID-19 advice for people in residential aged care home and visitors
- Risk factors for more serious illness
- For people with a disability

Evidence suggests that children and infants experience milder symptoms and are potentially less likely to contract the virus than adults. This was also true for SARS-CoV-1 and MERS-CoV (CDNA, 2022).

Module summary

1. COVID-19 is a viral disease that is related to SARS, MERS and the common cold.

- The most common symptoms are: fever, cough, sore throat, fatigue, shortness of breath or myalgia (joint and/or muscle aches).

2. Symptoms range from asymptomatic to severe and transmission can occur with no symptoms being present.

3. Transmission is primarily through droplets but can also be through aerosols or contact with infected surfaces.
4. Regular hand hygiene is very important in infection control, as it can eliminate the risk of exposure to COVID-19 as well as other infectious agents. Social isolation, physical barriers and ventilation are also other effective strategies to prevent disease spread and should be implemented as a priority where practicable.
5. The main at-risk groups include: adults ≥70 years old, people living with certain comorbidities, Aboriginal and Torres Strait Islander peoples and people with certain occupations.

Multi-Choice Questions:

1. The most common symptoms of COVID-19 include:
    a. A fever, cough, fatigue and myalgia (joint and muscle aches)
    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. Which of the following is NOT a mode of transmission of COVID-19?
    a. Fomite transmission – from touching a contaminated surface and then touching your nose or mouth without washing your hands
    b. Droplet or aerosol transmission – from breathing in contaminated particles in the air
    c. Contact transmission – from touching your nose or mouth with contaminated particles
    d. Food-borne transmission – from eating food that has been contaminated with COVID-19
3. 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 (AIH) 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.

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Module 2 – Handling and Storage

(21/09/2023)

This module is suitable for all applicants.

The recommended time for completion is 40 minutes. Each topic must be completed in order. There are multi-choice questions to pass before this module is complete and progression to Module 3 can occur.

Learning objectives

At the end of Module 2 it is expected that you will be able to:

- Understand the general storage, handling, and transporting requirements for COVID-19 vaccines including relevant national guidelines.
- Understand the processes used in cold chain monitoring and the use of temperature monitoring equipment relevant to COVID-19 vaccines.
- Understand what to do when a cold chain breach occurs and how to report it.
- Understand the requirements for recording wastage and accurate stock levels; using the appropriate system(s) specific to each setting.

Topics covered in Module 2:

1. Thermostability
2. Handling and storage
3. Transport and monitoring
4. Wastage and breaches

Topic 1: Thermostability

Different vaccines have varying degrees of heat stability and sensitivity to freezing. Exposure to temperatures outside the +2°C to +8°C range diminishes the potency of the vaccine. All vaccines in Australia, before the COVID-19 vaccines, had a constant required temperature of +2°C to +8°C throughout the supply chain. Different cold chain requirements may exist for the different COVID-19 vaccines as they roll out based on their thermostability profiles (Department of Health and Aged Care [DHAC], 2019a).

Each vaccine has different thermostability profiles in which potency and efficacy are maintained. The thermostability profile is determined by several factors including the components of the vaccine, the manufacturing process, and the type of vaccine. For example, some vaccines must be kept frozen at ultra-low temperatures (ULT) and can only be brought to routine cold chain temperatures prior to imminent administration.

Any exposure to damaging factors are cumulative and cannot be reversed. In general, vaccines can be damaged, lose potency or destroyed in three ways:

- Being frozen,
- Being warmed, or
- Being exposed to direct UV light including florescent light or direct sunlight (DHAC, 2019a).

All cold chain breaches (CCB) must be reported immediately to the Vaccine Operations Centre (VOC) by emailing a completed CCB reporting form and relevant temperature data to COVID19VaccineOperationsCentre@Health.gov.au. Isolate and label vaccines as 'Do not use, do not discard' until further advice is received from the VOC.

Providers can also contact their local public health unit (PHU) or Healthdirect as per jurisdictional policy.

Topic 2: Handling and storage

Vaccines are delicate, biological substances requiring careful management to ensure their effectiveness to protect our community. To ensure vaccine effectiveness, cold chain storage and transport must be maintained throughout the vaccine supply chain from manufacture to administration (DHAC, 2019a).

Cold chain storage specifically refers to maintaining vaccines within a safe temperature range of +2°C to +8°C during storage and transport (DHAC, 2019a). An ultra-cold chain system is required for some COVID-19 vaccines to maintain temperatures as low as -70°C.

Pfizer (COMIRNATY) (purple cap)

Storing frozen vials

Pfizer (COMIRNATY) (**purple cap)** vaccine vials have a shelf life of 18 months at ultra-cold chain (**-90°C to -60°C**). Vials may be stored at domestic freezer temperatures (-25°C to -15°C) for up to 2 weeks. Vials can be returned to -90°C to -60°C within 2 weeks of storage in a domestic freezer and within the original shelf life.

Storing thawed vials

The **Pfizer (COMIRNATY) (purple cap)** vials must be thawed and then diluted prior to use. **Thawed and unopened vaccines** can be stored at **+2°C to +8°C for up to 31 days** within the 18-month shelf life. Undiluted vaccine vials can be stored **up to +30°C for 2 hours**, including thawing time (ATAGI 2021b).

Storing diluted vials and vaccine doses

After initial puncture for dilution, vials must be kept at **2°C to 30°C** and used within 6 hours from the time of dilution. (ATAGI 2021b). This is in addition to the 2-hour maximum window for storage of an undiluted vial at up to 30°C. 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.

Pfizer (COMIRNATY) (orange cap) and Pfizer (COMIRNATY) (maroon cap)

Storing frozen vials

Pfizer (COMIRNATY) (orange cap) and Pfizer (COMIRNATY) (maroon cap) vaccines vials have a shelf life of 18 months at ultra-cold chain (**-90°C to -60°C**).

Storing thawed vials

Thawed and unopened vaccines can be stored refrigerated at 2°C to 8°C for a single period of up to 10 weeks (70 days) within the 18-month shelf life (TGA, 2022d). After thawing, the shelf life of an unopened vial is 10 weeks at 2°C to 8°C. Vaccine may be stored at temperatures between 2ºC to 30ºC for up to 24 hours, including any time at these temperatures following dilution (TGA, 2022d).

Storing diluted vials and vaccine doses

After initial puncture for dilution, vials can be stored **up to 12 hours** in room temperature **up to +30ºC** and must be used within the 12 hours (Pfizer, Australia, 2021c). 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.

Pfizer bivalent BA.1 (COMIRNATY) (grey cap) and Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)

Storing frozen vials

Pfizer bivalent BA.1 (COMIRNATY) (grey cap) and Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine **vials have a shelf life of 18 months at ultra-cold chain (-90°C to -60°C).**

Storing thawed vials

The **Pfizer bivalent BA.1 (COMIRNATY) (grey cap) and Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)** vaccines are ready-to-use formulations and **DO NOT** require dilution. **Thawed and unopened** vaccines can be stored refrigerated at 2°C to 8°C for a single period of up to 10 weeks (70 days) within the 18-month shelf life (TGA, 2022d; TGA 2023a). Vaccine may be stored at temperatures between 8°C to 30°C for up to 24 hours, including any time within these temperatures following first puncture.

Storing vials and vaccine doses

After initial puncture, vials can be stored **up to 12 hours** in room temperature **up to +30ºC** and must be used within the 12 hours (Pfizer, Australia, 2021c). 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 from the time of initial puncture. Do not re-freeze 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.

Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label)

Storing frozen vials

Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine vials have a shelf life of 9 months at ultra-cold chain (**-15°C to -50°C**).

Storing thawed vials

Thawed and unopened vaccines can be stored refrigerated at 2°C to 8°C for a single period of up to 30 days within the 9-month shelf life (TGA, 2022d). Of this 30 days, 12 hours can be used for transportation, and 24 hours in storage at 8°C to 25°C. Thawed vials can be handled in room light conditions. Dilution is not required.

Storing opened vials

After initial puncture, vials can be stored up to 19 hours at 2°C to 25°C (TGA, 2022d). 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.

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.

Moderna bivalent BA.4-5 (SPIKEVAX) Pre-Filled Syringes (PFS)

Always store the pre-filled syringes in their original carton and packaging until ready to use, to protect the syringes from ultraviolet (UV) light and sunlight.

Storing frozen PFS

Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine may be **stored frozen at -50°C to -15°C** for a maximum of **9 months**. **DO NOT** store below -50°C (TGA, 2023b).

Storing thawed PFS

Unopened, thawed pre-filled syringes can be stored **refrigerated at +2°C to +8°C** for a maximum of **30 days from the thawed date (within the 9-month shelf life)**. The thawed date and thaw use-by date will be clearly displayed on the carton (secondary packaging).

Unopened, thawed pre-filled syringes may be stored at +8°C to +25°C up to 24 hours after removal from refrigerated conditions.

Novavax (NUVAXOVID)

Standard cold chain (+2°C to +8°C) procedures should be followed for all transport, storage and handling of the Novavax (NUVAXOVID) vaccine. Store in the outer carton to protect them from light. Dilution is not required. Do not shake the vial.

The shelf life of Novavax is 9 months at 2°C to 8°C.

Storing opened vials

Do not shake the vial.

After initial puncture, vials can be stored up to 12 hours at 2°C to 25°C (TGA, 2022d). 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 for the Novavax vaccine, 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.

General vaccine storage

Vaccines must be stored in the original boxed packaging which helps to protect the individual vials or pre-filled syringes against temperature fluctuations and UV light until they are ready for use (DHAC, 2019a). Pfizer (COMIRNATY) (purple cap) multi-dose vials will not come in boxed packages, instead, they may be stored in a tray or as individual vials in a plastic box as described above when in the fridge. Pfizer (COMIRNATY) (orange cap), Pfizer (COMIRNATY) (maroon cap), Pfizer bivalent BA.1 (COMIRNATY) (grey cap), Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), Novavax (NUVAXOVID), and Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) multi-dose vials will come in secondary packaging, boxed cartons containing 10 vials each.

The Moderna bivalent BA.4-5 (SPIKEVAX) pre-filled syringes will come in secondary packaging, boxed cartons containing 10 pre-filled syringes each.

Please be aware, Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine packaging is significantly larger than multi-dose vials and will take up significantly more space in your vaccine fridge. Please keep this in mind when ordering vaccines.

The *National vaccine storage guidelines: Strive for 5* guidelines (3rd ed.) by the Department of Health and Aged Care (DHAC, 2019a) should be followed in all instances where cold chain (+2°C to +8°C) must be maintained. This includes large tertiary hospitals, medical practices, pharmacies, mobile services and outreach clinics.

If you are responsible for vaccine storage or monitoring at your facility, ensure that you are familiar with all aspects in the *Strive for 5* guidelines (3rd ed.) (DHAC, 2019a). Additionally, review your facility policy on cold chain management.

If you have not been involved with cold chain management for a while you can review this NSW website highlighting the changes contained in the 3rd edition guidelines released in 2019. Furthermore, the Health Education Training Institute (HETI) as part of NSW Health have developed a free e-learning module with videos and clinical scenarios which is highly recommended for people in all jurisdictions. *NSW Health staff should access this through the My Health Learning platform.*

In addition to the National guidelines, the applicable state and territory and facility policies, procedures and protocols relating to vaccine management must be followed. Please review your State or Territory cold chain policy.

NSW Cold chain management (includes compulsory HETI online module) –

Policy Directive: Vaccine storage and cold chain management

COVID-19 vaccination: information for NSW Health immunisation providers

ACT – Immunisation Providers KIT - 2020

NT – National Strive for 5 guidelines

QLD – See your local Hospital and Health Service contact or contact the QH VCC by emailing QH.VCC@health.qld.gov.au for advice on cold chain management.

All current and future advice for Queensland Health providers can be found here.

TAS (supporting document only) – Quality and safety

VIC – Victorian COVID-19 Vaccination Guidelines

WA (supporting website only) – Cold chain management

SA (supporting website only) – Vaccine storage

Cold chain management should be the primary responsibility of one nominated person on any given day. Best practice is to have many staff at each facility trained and regularly updated on the cold chain protocol and policies. All staff who are responsible for handling vaccines at any point in the supply chain must be trained to understand the importance of the cold chain.

To ensure quality systems are in place, vaccine storage self-audits are required at least every 12 months. The forms are included in the *Strive for 5* guidelines, Appendix 2 (DHAC, 2019a).

General principles for maintaining the cold chain during handling and administration include:

- Minimise the number of times that the door or lid is opened to help maintain a stable temperature.
- Only remove vaccines or diluents as required.
- When the vaccines are out of storage, keep them out of direct sunlight and other sources of heat and UV light such as fluorescent lights prior to being opened.
- Avoid handling the vaccines more than necessary (DHAC, 2019a).

Ultra-cold chain and freezers:

Some vaccines available for COVID-19 require ultra-cold chain (UCC) management at some point along the supply chain. Individual vaccine requirements including thawing will be discussed in the additional modules relevant to each vaccine (available to immunising health professionals only).

Pfizer (COMIRNATY) vaccines can be stored in an ultra-low temperature (ULT) freezer at **-90°C to -60°C** for up to **18 months** (Pfizer Australia, 2021b; Pfizer Australia, 2021c; TGA, 2022d; TGA, 2022e).

Thermal shippers will be used by logistics providers to deliver frozen Pfizer (COMIRNATY) vaccines. The carton is submerged in dry ice pellets and can maintain UCC (-75°C ± 15°C) during transport.

Moderna (SPIKEVAX) vaccines can be **stored frozen at -50°C to -15°C** for a maximum of **9 months**. Once thawed the Moderna (SPIKEVAX) vaccines **CAN NOT** be refrozen.

Some Jurisdictions may have their own UCC policies developed to follow. When known, policies will be added here for your reference, however, you are expected to stay up to date with your current jurisdictional policies and requirements as well.

VIC – Victorian COVID-19 Vaccination Guidelines

QLD – Please contact the QH VCC through QH.VCC@health.qld.gov.au for the latest protocol and agreed transfer process templates.

NSW – COVID-19 vaccination: information for NSW Health immunisation providers: COVID-19 Pfizer (COMIRNATY™) vaccine

WA – Refer to the COVID-19 vaccination information for health professionals.

Storage in refrigerators:

Purpose-built vaccine refrigerators (including portable) must be used for all vaccines (DHAC, 2019a). They should provide a stable temperature, have an alarm for temperature fluctuations, and get back to ideal temperature efficiently after the door has been opened. Portable purpose-built vaccine refrigerators may be used for no more than 3 days (DHAC, 2019a).

Vaccines cannot be stored in normal fridges (DHAC, 2019a).

Non-medical items cannot be stored in a vaccine fridge including food and drink (DHAC, 2019a).

Non-purpose-built appliances cannot be used due to the risk of freezing the vaccines (DHAC, 2019a).

A normal refrigerator with a freezer compartment is also required to store ice or gel packs (DHAC, 2019a).

If necessary, a blood refrigerator may be used as this is kept at +2°C to +6°C. However, routine monitoring must still be carried out (DHAC, 2019a).

Mobile or outreach clinics:

Use vaccine-specific soft-walled or solid-walled insulated coolers with tight sealing lids with a minimum of 10L capacity for transport and storage as required.

Preparation for a mobile or outreach clinic should begin at least 24 hours prior. The number of ice or gel packs in the freezer should be counted and checked to ensure there are enough for the day.

The *Strive for 5* guidelines include a checklist in Appendix 8 specifically for mobile and outreach immunisation clinics that can be printed off and worked through to ensure all important aspects are completed each time.

If there is no vaccine specific fridge at the clinic, or no power supply, you will need an extra cooler box full of spare ice or gel packs to replace melted ones throughout the session. If outside, the cooler should be kept in the shade.

Coolers have a limited 'cold life' and are not recommended for storage more than 8 hours or in extreme conditions. In these cases, a specialised cooler should be used. Polystyrene coolers only offer limited insulation so can only be used for up to 4 hours (DHAC, 2019a).

Packing a cooler:

Gel packs generally stay colder for longer than ice packs. Ensure manufacturer's directions are followed for freezing. Ice and gel packs should be conditioned before packing into a cooler. This is because freezers are much colder than the freezing point of water.

The steps for ice pack conditioning are:

1. Remove ice packs from the freezer.
2. Lay out the ice packs in a row on their side (ideally) 5cm apart.
3. Wait until the ice packs begin to sweat (about 1 hour at +20 °C).

4. Conditioning has been reached when you can hear water moving around within the ice pack (DHAC, 2019a).

To condition gel packs you should follow the manufacturer's instructions as it depends on their weight. Note that this will usually take longer than conditioning an ice pack.

Freezing of the vaccine can occur in any cooler, usually within the first 2 hours, so care must be taken when packing and monitoring. To prevent freezing:

- Ice or gel packs are conditioned before placing in the cooler.
- The cooler should be pre-chilled for a few hours before using it by placing the conditioned packs inside.
- The vaccines should be insulated, in bubble wrap or other insulating material, from the ice or gel packs.
- The temperature must be monitored every 15 minutes for the first 2 hours and then hourly after this and when temperatures are stable (DHAC, 2019a).

Once the cooler is pre-chilled, the ice or gel packs should be removed, and packing can begin. Follow these steps when packing:

1. Place insulation such as polystyrene chips or as a less preferred option, bubble wrap, in the bottom of the cooler to eliminate hot or cold spots.
2. Place the vaccine boxes inside, taking note not to wrap the vaccines tightly to promote airflow.
3. Place a temperature monitoring device as per your jurisdiction recommendations into the centre of the vaccines. Place the probe into an empty vaccine box with the product information left in to prevent it from lying directly on ice.
4. Surround the vaccine boxes with packing material that still allows airflow.
5. Place the conditioned ice or gel packs on top and then close and seal the cooler lid, ensuring no vaccine comes into direct contact with any ice or gel packs. If using a larger cooler, ice or gel packs can be placed around the sides of the cooler as well.
6. Place the display of the temperature monitoring device on the outside of the cooler.

(DHAC, 2019a)

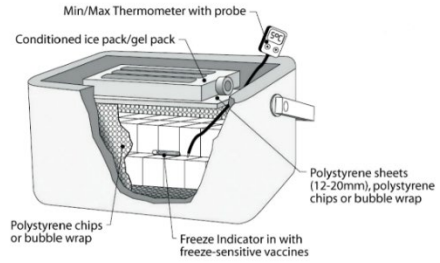

Figure 1. *Example of a packed 10 Litre cooler* (General Practice Queensland, 2010)

Figure 2. *Minimum/maximum thermometer placed in centre of vaccine stock* (DHAC, 2019a)

Once packed, ensure that the contents are secure so that they do not move around during transportation and to avoid the risk of the vaccines coming into direct contact with the ice or gel packs.

Topic 3: Transport and monitoring

Temperature monitoring, recording and reporting must occur throughout the vaccine supply chain. This ensures the maintenance of the cold chain and identifies potential breaches early, therefore ensuring that effective vaccines are administered with minimum wastage.

A vaccine data solution (VDS) is live and allows 'point in time' visibility of where individual vaccines are within the supply chain from point of arrival to the administration. The VDS receives data from the logistics providers and the Australian Immunisation Register (AIR) based on the barcode of individual vials. Data will be collated and reported through an interactive dashboard including displays of wastage and cold chain breaches for internal use (DHAC, 2021a).

Accepting deliveries at a facility

The person responsible for accepting vaccine deliveries must have cold chain training and awareness. All deliveries received at a facility must be accompanied by a cold chain monitor which detects heat and/or freeze breaches.

Deliveries must be checked and stored promptly without delay. Deliveries without a cold chain monitor should not be accepted.

The cold chain monitor (if disposable) must be discarded as it cannot be used to monitor vaccines after delivery.

Vaccine Acceptance reporting

Acceptance of all COVID-19 vaccines must be reported to the Commonwealth on the day of delivery, no later than 9pm local time.

Providers must submit Delivery Acceptance reports through the COVID-19 Vaccine Administrative System (CVAS), on the day of delivery (as soon as possible) to accept vaccine deliveries.

The Delivery Acceptance reports must be submitted in CVAS by all sites receiving COVID-19 vaccine deliveries and completed by the authorised person in charge of accepting deliveries of the vaccine. They are used to notify the Department of Health and Aged Care about any potential issues and are used to close out the order. This also allows the Commonwealth to meet other key obligations.

Novavax (NUVAXOVID) vaccine acceptance

Novavax (NUVAXOVID) vaccines require storage and transport using standard cold chain requirements at +2°C to +8°C as per the national *Strive for 5* guidelines, jurisdictional requirements, and facility policies. Providers should follow the steps above to accept Novavax (NUVAXOVID) vaccine deliveries.

Moderna (SPIKEVAX) vaccine acceptance

Moderna (SPIKEVAX) vaccines may be delivered thawed by logistic providers. Thawed vaccines require storage and transport using standard cold chain requirements at +2°C to +8°C as per the national *Strive for 5* guidelines, jurisdictional requirements and facility policies.

Thawed **Moderna (SPIKEVAX)** vaccines can be stored for a single period of **30 days** within the **9-month shelf life**.

Pfizer (COMIRNATY) vaccine acceptance

Frozen Pfizer (COMIRNATY) vaccine acceptance

Frozen Pfizer (COMIRNATY) vaccines will arrive in thermal shippers to vaccine providers. Each delivery should come with the following:

- Dry ice handling insert.
- Safety data sheet for dry ice.
- Return instructions for GPS loggers and the thermal shipper.
- Blank label to cover 'dry ice' label when container is empty, return shipping label, outbound shipping label and contents label on the inside flap.

When the thermal shipper is received, it should be inspected and accepted as soon as possible and within 24 hours. Any discrepancies found must be reported immediately to the **VOC on 1800 318 208**.

The current, minimum and maximum temperatures must be recorded on a temperature chart by the relevant trained staff member.

Once empty of vaccines and before sending back, the thermal shipper should be left open in a well-ventilated area where the dry ice will readily sublime (melt from solid to gas) into carbon dioxide gas and dissipate. Dry ice should not be left unattended.

Proper personal protective equipment (PPE) including gloves must be worn when handling dry ice. If you are in a facility with ultra-cold chain (UCC) storage, you will receive the required gloves from the Australian Government, Department of Health and Aged Care.

Thawed Pfizer (COMIRNATY) vaccine acceptance

Deliveries of thawed vaccines will be received at **+2°C to +8°C** and must continue to be stored at **+2°C to +8°C**. Thawed **Pfizer (COMIRNATY) (purple cap)** vaccines can be stored for a single period of **31 days** within the **18-month shelf life**. Thawed **Pfizer bivalent BA.1 (COMIRNATY) (grey cap), Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), Pfizer (COMIRNATY) (maroon cap) and Pfizer (COMIRNATY) (orange cap)** vaccines can be stored for a single period of **10 weeks** within the **18-month shelf life**.

Unpacking frozen Pfizer (COMIRNATY) vaccine deliveries

Proper personal protective equipment (PPE) must be worn when handling dry ice. If you are in a facility with UCC storage. Additional dry ice handling material may be received from the manufacturer. However, state and territory guidelines on dry ice handling should also be followed.

The following information details how to unpack frozen Pfizer (COMIRNATY) vaccine deliveries. Most vaccine providers will receive the vaccine thawed from logistics providers so will NOT need to follow the below steps which are for UCC/frozen deliveries only**.**

Frozen deliveries from logistics providers:

1. Proceed with using PPE gloves and safety goggles and open the thermal shipper
2. Turn the TempTale Ultra data logger off.
3. Utilise the bag or blue strapping above the DRY ICE surface and pull the Vaccine tray(s) through the DRY ICE.
4. Place the Vaccine trays into your -90°C to -60°C freezer
5. Please dispose of all DRY ICE from the thermal shipper. The thermal shipper cannot have any DRY ICE when returning.
6. Place the temperature device TempTale Ultra and TrackIT device back into the empty thermal shipper.

Please see Appendix 1 for a more detailed example of how Pfizer (COMIRNATY) vaccine shipments are packed and unpacked here:

If storage of the vials will be in an ULT freezer or fridge for immediate use move the vial trays there now. Then leave the thermal shipper open in a well-ventilated area where the dry ice will readily sublime (melt from a solid to a gas) into carbon dioxide gas and dissipate. Dry ice should not be left unattended.

Additional dry-ice handling material will be received from the manufacturer, however, state and territory guidelines on dry-ice handling should also be followed.

Storage and deliveries

Frozen Pfizer (COMIRNATY) vaccine storage and deliveries

There are up to three options for storing Pfizer (COMIRNATY) vaccines after they have been received and delivery accepted:

1. Transfer the vial trays or packs to a ULT freezer at the facility.
2. Transfer the vial trays to the freezer for up to 2 weeks from transfer at -25°C to -15°C **for Pfizer (COMIRNATY) (purple cap) ONLY**
3. Transfer the vial trays or packs to a vaccine fridge (at +2°C to +8°C) for up to **31 days from transfer for Pfizer (COMIRNATY) (purple cap)** and **10 weeks for Pfizer bivalent BA.1 (COMIRNATY) (grey cap), Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), Pfizer (COMIRNATY) (maroon cap) and Pfizer (COMIRNATY) (orange cap).**

For Pfizer (COMIRNATY) (purple cap) vaccine, if using a Stirling ultra-cold chain freezer, the Pfizer trays may not fit and the vials need to be decanted into the Stirling fridge tray in the freezer.

Please see Appendix 2 for a more detailed example of how to transfer Pfizer (COMIRNATY) vaccines into the Stirling Freezer from the 'pizza' boxes

The fridge or freezer temperature must be recorded when vaccines are finally stored.

When placing the vaccines in the fridge or freezer, the expiry dates must be checked, and stock rotated to ensure vaccines are used prior to expiring. Therefore, stock with the shortest dates must be moved to the front.

Providers must record and check the manufacturer expiry date and the thaw use-by date (if applicable) at the time of completing the Delivery Acceptance forms in the CVAS at health.gov.au/cvas.

Thawed Pfizer (COMIRNATY) vaccine storage and deliveries.

Once received and the vaccine delivery accepted, transfer the vial trays or packs into cold chain storage for a maximum of **31 days** for **Pfizer (COMIRNATY) (purple cap)** or **10 weeks** for **Pfizer (COMIRNATY) (maroon cap), Pfizer (COMIRNATY) (orange cap)**, **Pfizer bivalent BA.1 (COMIRNATY) (grey cap) and Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)** from the thawed date. The thawed date and new use-by date (thawed use-by date within the batch expiry) will be labelled on the carton prior to dispatch from the logistics provider.

The fridge temperature must be recorded when vaccines are finally stored. Rotate stock so that the newest stock is placed at the back and stock with the shortest expiry dates are in front.

Moderna (SPIKEVAX) vaccine storage and thawed deliveries

Thawed Moderna (SPIKEVAX) vaccines require storage and transport using standard cold chain requirements at +2°C to +8°C as per the national *Strive for 5* guidelines, jurisdictional requirements, and facility policies.

Once received and the vaccine delivery accepted, transfer the vials and/or the pre-filled syringes in their original packaging into cold chain storage. Unopened, thawed vials and pre-filled syringes can be stored at **+2°C to +8°C** for a **maximum of 30 days** within the **9-month shelf life**. The thawed date and new use-by date (thawed use-by date within the batch expiry) will be labelled on the carton (secondary packaging) prior to dispatch from the logistics provider.

Thawed vials of frozen vaccine should not be refrozen.

Thawed **vials** can be transported for up to 12 hours at 2°C to 8°C within the 30 days shelf life at 2°C to 8°C (Moderna Australia, 2022).

All thawed Pfizer (COMIRNATY) and Moderna (SPIKEVAX) mRNA vaccines

All deliveries of **thawed mRNA vaccines** will be received at **+2°C to +8°C** and include a label with the thawed date and new use-by date. The label is applied on the carton prior to dispatch from the logistics provider.

The **USE BY** date is the earliest of:

- Thawed use-by date (Thaw date + allowable timeframe at 2°C to 8°C) or
- Manufacturer (batch) expiry date

Freezer monitoring:

Temperature probes are required for freezers to automatically record the temperature including minimum, maximum and the current temperature. An AiroSensor is also required inside the freezer to relay the temperature information to a cloud-based system for internal and external monitoring.

The Australian Government, Department of Health and Aged Care will provide temperature data loggers and new tracking and monitoring devices.

Temperature monitoring from these UCC storage devices will be through wireless technology to a cloud-based system so that they can be monitored locally and remotely. Current, maximum and minimum temperatures must be **recorded at least 4 times per day** and whenever they are accessed. As per standard cold chain monitoring requirements, the thermometer must be reset after each reading.

Staff involved in freezer temperature monitoring in UCC should follow agreed service-based processes and standard operating procedures. Facilities must have a process in place to support the required freezer monitoring as part of the Pfizer hub checklist.

Handling of Pfizer (COMIRNATY) (purple cap) vaccines only:

When transferring **FULL** packaged and unopened vial tray from one ULT freezer or thermal shipper to another, the vaccines may be in room temperatures of **up to +25°C** for a maximum of **5 minutes only** (Pfizer, Australia, 2021b).

When transferring open-lid or incomplete vial trays from one UCC freezer to another, the vaccines may be in room temperature for **up to +25°C** for a maximum of **3 minutes only** (Pfizer, Australia, 2021b).

Any time outside of this recommended storage requirement means a cold chain breach (CCB) has occurred and the CCB must be reported to the VOC by emailing a completed CCB reporting form and relevant temperature data to COVID19VaccineOperationsCentre@Health.gov.au.

Once the vials are transferred, the freezer door or thermal shipper lid must remain closed for a **minimum of 2 hours** before transferring them again (Pfizer, Australia, 2021b).

If a vial is removed from the vial tray, it should then be thawed for use and can remain in cold chain +2°C to +8°C for up to 31 days within the 18-month shelf life (Pfizer, Australia, 2021b).

Fridge monitoring:

Data loggers are required for fridges to record the temperature automatically and should be set to no less than 5-minute intervals. The data loggers may be part of the fridge or a separate device. Reports are stored by the monitoring system and can be downloaded onto computers which should be done at least once a week, or when required due to a possible or suspected temperature excursion or power outage.

If buying or setting up a new fridge or restocking from scratch for any reason, please refer to the *Strive for 5* guidelines on the procedure to follow before storing the vaccines (DHAC, 2019a).

The minimum and maximum temperatures in all refrigerators must be monitored and recorded at least twice daily regardless of the monitoring system used. Recordings need to be completed on a temperature recording chart and then the minimum/maximum thermometer reset. Facilities may have their own recording chart or one can be found in the *Strive for 5* document.

Ideally this is performed at the start and end of the day. However, best practice is for observation and awareness of the temperature to be undertaken whenever the fridge is accessed.

The temperature of the fridge should be checked and recorded after cleaning, performing maintenance or restocking.

Temperature fluctuations are more likely when only using a small portion of the fridge. To stabilise the temperature, cooled but not frozen bottles of water ('cold mass'), maybe placed on unused shelves. Conversely, overcrowding should be avoided (DHAC, 2019a).

Mobile and outreach temperature monitoring

Vaccines must be packed and monitored as recommended during all transport to and at all clinics and facilities. The temperature must be recorded at least hourly during mobile and outreach immunisation clinics. This includes the current minimum and maximum temperature measured with a digital thermometer.

In addition, jurisdictions have different methods and requirements for temperature monitoring during transport. Thermometer accuracy and batteries should be checked at least every 6 to 12 months and documented when reset.

On return to a clinic, any unused vaccines which have not been involved in a breach should be returned to a vaccination fridge as soon as possible (DHAC, 2019a).

Specialised coolers for extreme or long conditions

If the clinic will be held in an extreme climate (environmental temperature is <0°C or >40°C) or if long-term portable storage more than 8 hours is required, a specialised cooler must be used.

Specialised coolers have thicker walls for insulation resulting in a minimum 'cold life' of 120 hours in temperatures of +43 °C if the lid is not opened. Specific recommendations for such advice are made by the World Health Organization (WHO) and can be found here.

Again, if outside, the cooler should be kept in the shade.

Power failure

A clearly documented back-up plan must be available and be included in a vaccine management protocol. The action plan could include a back-up power supply, another fridge available offsite or a cooler as outlined above. **Vaccines stored in alternative storage should be continuously temperature monitored to ensure vaccines remain within cold chain requirements.**

The 'back-up plan' should be practised by all key personnel to ensure preparedness. During the practice, the time taken for the plan to be complete should be noted. There should be ample cooler boxes or alternate fridges available to contain the whole vaccine fridge contents.

The fridge temperature must be noted at the time of or as soon as practical after a power failure is noted.

Refer to the *Strive for 5* Department of Health and Aged Care (2019a) guidelines Section 8 for the recommended best practice if the power goes off during and after business hours. All Jurisdictional policies and procures must also be followed, such as this Cold Chain Back-up Plan in SA.

Ordering stock:

An appropriate amount of stock needs to be ordered at the proper time to minimise wastage and improve vaccine delivery. Stock Management and Stock Acceptance reporting should be completed prior to ordering new vaccines.

Stock Management reporting:

Stock on hand must be reported to the Commonwealth to maintain a holistic overview of the status of the vaccine rollout. This data should be inputted as accurately as possible, to ensure vaccines are efficiently and effectively distributed.

Weekly Stock Management reports must be submitted by no later than 9pm local time every Friday, through the COVID-19 Vaccine Administrative System (CVAS).

The Stock Management reports can be completed by relevant personnel within the administration site by a person who has 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.

Redirection is the term used when vaccines are redistributed from one or more clinics and/or facilities that have an excess of vaccines to other clinics and/or facilities that have a shortage of vaccines.

If your facility has excess unopened vials of vaccines that cannot be used prior to expiry, and you have been unable to locate a nearby site that may be able to receive your excess stock, please contact the Vaccine Operations Centre (VOC) for assistance, on **1800 318 208** or by emailing COVID19VaccineOperationsCentre@Health.gov.au.

Topic 4: Wastage and breaches

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Normally, a cold chain breach is when the storage temperature is outside of the recommended range of +2°C to +8°C, with the optimum temperature being +5°C. All national and jurisdictional cold chain breach protocols and requirements must be followed as these may vary.

Frozen Pfizer (COMIRNATY) vaccines must be stored at **-90°C to -60°C**. **Frozen Moderna (SPIKEVAX)** vaccines must be stored at **-50°C to -15°C.** A UCC breach is considered to be any amount of time outside of these temperatures. Note that Moderna vials and pre-filled syringes **cannot** be stored on dry ice or at temperatures below -50°C.

Thawed Moderna (SPIKEVAX) vaccines require storage and transport using standard cold chain requirements at **+2°C to +8°C for up to 30 days** within the 9-month shelf life as per the national *Strive for 5* guidelines, jurisdictional requirements, and facility policies. Once **opened**, Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine vials can be stored at room temperature between **+2°C and +25°C for up to 6 hours.** Unopened, thawed Moderna bivalent BA.4-5 (SPIKEVAX) **pre-filled syringes** may be stored at **+8°C to +25°C up to 24 hours** after removal from refrigerated conditions (ATAGI, 2021b).

Thawed Pfizer (COMIRNATY) (purple cap) vaccines, require storage and transport using standard cold chain requirements at **+2°C to +8°C for up to 31 days** within the 18-month shelf life as per the national *Strive for 5* guidelines, jurisdictional requirements, and facility policies. Following **dilution**, Pfizer (COMIRNATY) (purple cap) vaccine can be **stored at +2°C to +30°C** and must be used within **6 hours from the time of dilution.** This is in addition to the 2-hour maximum window for storage of an undiluted vial at up to +30°C (ATAGI, 2021b).

Thawed Pfizer (COMIRNATY) (maroon cap) and **Pfizer (COMIRNATY) (orange cap)** vaccines require storage and transport using standard cold chain requirements at **+2°C to +8°C for up to 10 weeks** within the 18-month shelf life as per the national *Strive for 5* guidelines, jurisdictional requirements, and facility policies. Following dilution, the Pfizer (COMIRNATY) (maroon cap) and Pfizer (COMIRNATY) (orange cap) can be **stored at +2°C to +30°C** and must be used within **6 hours from the time of dilution** (ATAGI, 2021b).

Thawed Pfizer bivalent BA.1 (COMIRNATY) (grey cap) and Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccines require storage and transport using standard cold chain requirements at **+2°C to +8°C for up to 10 weeks** within the 18-month shelf life as per the national *Strive for 5* guidelines, jurisdictional requirements, and facility policies. Once opened, the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) and Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccines can be **stored at +2°C to +30°C** and must be used within **6 hours from the time of initial puncture** (ATAGI, 2021b).

Once thawed, mRNA COVID-19 vaccines CANNOT be re-frozen.

Novavax (NUVAXOVID) vaccines are to be stored at standard cold chain requirements, **+2°C to +8°C**. For **Novavax (NUVAXOVID),** the **unopened vials** can be stored at room temperature between **+8°C and +30°C for up to 6 hours** (Novavax, 2022a). Once opened, **Novavax (NUVAXOVID)** vaccines can be **stored at +2°C to +25°C** and must be used within **6 hours from the time of initial puncture** (ATAGI, 2021b).

Please note, that ATAGI's recommendation for storing opened vials is often more conservative than the Product Information **as COVID-19 vaccine do not contain antimicrobial preservatives**.

All cold chain breaches of COVID-19 vaccines must be reported to the Vaccine Operations Centre (VOC) by emailing a completed CCB reporting form and relevant temperature data to COVID19VaccineOperationsCentre@Health.gov.au.

A quick reference poster guide can be used for CCB management including reporting. There is no poster as yet for UCC breaches. Please note the requirement to contact the VOC in the event of a cold chain breach is specific to COVID-19 vaccines, and not stated in the National Vaccine Storage Guidelines.

NB: The reference poster is from Strive for 5 and advises that you contact your State or Territory health department as soon as possible (during business hours).

Vaccines that have been identified as having a CCB should be kept within the appropriate storage requirements, isolated and labelled as **'Do not use, do not discard'** until further advice is received from the VOC on **1800 318 208**.

The cause of the breach should be investigated, corrected when possible and prevented from occurring again. The failure of electronic equipment should be reviewed, and the fridge, freezer or thermal shipper checked with a battery-operated thermometer or additional probe to ensure the logger or other monitoring system are working correctly. Other important areas to check include the

power point being plugged in correctly and turned on, as well as the door closing correctly (DHAC, 2019a).

Once the Department has completed assessment, and if you have been advised that the vaccines must be discarded, the wastage must then be reported via the Wastage report or the Stock Management report depending on the quantity of vials or prefilled syringes wasted in the incident.

The facility must notify the Department of Health and Aged Care within 2 hours of the incident by submitting a Wastage Report in CVAS for any major wastage incidents of 10 or more vials, or 100 or more single dose prefilled syringes, for Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine. Incidents of fewer than 10 vials (or 100 pre-filled syringes) at a time must be reported as minor wastage in the weekly Stock Management Report through the COVID-19 Vaccine Administrative System (CVAS).

Do not discard any vaccines unless instructed to do so by the Department of Health and Aged Care.

Review your State or Territory cold chain breach policies and protocols:

NSW – Cold chain breach protocol

Vaccine storage and cold chain management – Managing a cold chain breach

ACT – Immunisation Providers KIT 2020

NT (report to CDC) – Vaccines wastage report

QLD – Notify the Queensland Health VCC immediately by calling 07 3608 5960. Sites must also submit this data by using the state provided excel template.

TAS – Vaccine management

Forms are provided on contacting the department on notification of a cold chain breach.

VIC – Victorian COVID-19 Vaccination Guidelines

WA – Cold chain management

SA – Cold chain breach report and Managing a Cold Chain Breach

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Wastage:

To ensure early access to safe and effective COVID-19 vaccines, all Australian healthcare professionals and responsible staff must all take responsibility for enforcing cold chain principles. Wastage and the subsequent potential shortage of vaccines or the administration of less potent vaccines will contribute to a loss of consumer confidence in the COVID-19 vaccine program.

Vaccine wastage refers to the loss of vaccine doses due to cold chain breaches, expired vaccine or other damage (Australian Government, 2017). Wastage occurs during vaccination for various reasons. Action should be taken to minimise this as it carries significant loss and can reduce public confidence in the vaccination program.

Wastage may be increased when using multi-dose vials (MDVs). One reason that more wastage is likely to occur when using MDVs is that opened vials expire quickly and any remaining doses must be discarded once expired.

Wastage due to ultra-cold chain and cold chain breaches may be higher in the initial stages due to the temperature requirements and multiple doses lost per wasted vial. If substantial wastage

occurred due to handling, storage, transport and monitoring failure then a vaccine shortage and reduced confidence in the vaccine program could occur.

Specific planning in program delivery is required to reduce the likelihood of wastage. This is particularly important for clinics and areas where opportunistic vaccination occurs often or the clinic is small and full MDVs may not be used each day. In these facilities and services, mass vaccination clinics are recommended rather than relying on opportunistic vaccination.

For immunising healthcare professionals, all procedures and guidelines provided in Module 4 must be followed to minimise wastage. This includes using the recommended equipment to minimise leakage and dead space loss.

Wastage of equipment includes the loss of damaged or compromised packaging, contamination, and incorrect preparation. At least 10% extra of consumable resources should be prepared for clinics and outreach programs to account for this potential loss.

Any unused vaccine or waste material should be disposed of in accordance with local requirements in a clinical waste bin and the Vaccine Operations Centre (VOC) should be notified by following the Stock Management Report guidance in *Topic 3: Ordering stock*, where the Stock Management report contains a section on vaccine wastage.

Major Wastage (10 or more vials)

A major wastage incident (e.g. damaged vials, expired vaccines or breach of cold chain requirements) is classified as one that includes 10 or more vials at a time.

If more than 10 vials at a time are wasted, providers must submit a Wastage Report through the COVID-19 Vaccine Administrative System (CVAS) within 2 hours of the incident. You are no longer required to call the VOC to additionally report the wastage incident.

Any wastage of fewer than 10 vials in one incident should be reported through the minor wastage section of your weekly Stock Management report in CVAS (due no later than 9pm local time Friday every week).

Disposal and wastage of Moderna bivalent BA.4-5 (SPIKEVAX) (PFS)

In cases of wastage, any unused vaccine or waste material should be disposed of in accordance with local requirements in a clinical waste bin and should be recorded through the COVID-19 Vaccine Administrative System (CVAS) in line with wastage thresholds.

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.

If 100 or more pre-filled syringes are wasted, providers must submit a Wastage Report through the COVID-19 Vaccine Administrative System (CVAS) immediately after the event, but within at least 2 hours of the incident. You are no longer required to call the VOC to additionally report the wastage incident.

Incidents of fewer than 100 pre-filled syringes at a time must be reported as minor wastage in the weekly Stock Management Report in CVAS (due no later than 9pm local time Friday every week).

Module summary

For any further cold chain management information, please review the *Strive for 5* guidelines (DHAC, 2019a). Frequently asked questions are covered in Appendix 4.

- *Strive for 5* guidelines refer to the ideal temperature for vaccines being +5 °C, with an acceptable range between +2°C and +8°C.
- National and State and Territory policies and requirements must be followed.
- Cold chain is everyone's responsibility.
- Vaccines must be stored in a vaccine-specific fridge or cooler box with a data logger or thermometer.
- Manual and digital minimum and maximum temperature recordings must be recorded.
- All CCBs must be reported immediately to the VOC. Vaccines should be isolated and labelled as 'Do not use, do not discard' until further advice is received from the VOC.

Multi-choice Questions:

1. Standard cold chain requirements can be used for Novavax (NUVAXOVID) 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
    b. Ideally +5 °C with an acceptable range of +3 °C to +7 °C
    c. Ideally -70 °C with an acceptable range of -85 °C to -65 °C
2. Who is responsible for following and maintaining cold chain recommendations and policies?

    a. The nominated person at the facility
    b. All healthcare professionals working with the vaccine
    c. All non-healthcare staff who may have contact with the vaccine such as people accepting deliveries or recording temperatures from storage devices
    d. All of the above
3. Which of these storage devices is **NOT** acceptable to store vaccines in for any period of time?

    a. A vaccine-specific refrigerator
    b. A cooler box packed as per the *Strive for 5* guidelines
    c. A blood fridge
    d. A standard refrigerator at the facility
4. What is the maximum time a standard cooler box can be used in non-extreme temperatures for outreach and mobile clinics?

    a. 24 hours
    b. 6 hours
    c. 8 hours
    d. 12 hours
5. A cold chain breach has been identified when you walk into the facility on a Monday morning. The fridge is alarming and the temperature in the fridge shows +10^{o}C. Which are the correct steps to follow?

a. Place any affected vaccines in quarantine and label as 'DO NOT USE, DO NOT DISCARD', and secure within cold chain requirements. Report the CCB to the VOC and wait for the outcome of the assessment and advice on whether the vaccines are safe to use. If a major wastage event has occurred (wastage of 10 or more vials or 100 or more pre-filled syringes), a Wastage Report must be submitted in CVAS within 2 hours.
b. Isolate and label the vaccines as 'DO NOT USE'. Keep them in their current storage area and refrain from opening the door. Call your State or Territory Health Department to inform them of the breach and then send them the vaccines to review. VOC does not need to be contacted for any wastage.
c. Nothing urgent needs to be done as +10 °C is still within cold chain allowances. Try to fix the fridge or put the vaccines in the staff room fridge temporarily to keep them cool and then continue to use them today.

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Module 3 – Communication and purpose of the COVID-19 vaccination program

(21/09/2023)

This module is suitable for all applicants.

The recommended time for completion is 40 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete and progression to Module 4 can occur (as applicable).

Learning objectives

At the end of Module 3 it is expected that you will be able to:

- Understand and apply appropriate communication for addressing common consumer concerns relating to COVID-19 vaccinations and measures to manage these concerns/risks.
- Understand and apply appropriate communication, including for priority populations in specific settings related to the COVID-19 vaccination program roll-out and eligibility.
- Understand and apply appropriate communication on risks and suitability of COVID-19 vaccination for relevant population groups. This includes concerns relating to the use of live vaccines, particularly in certain population groups.
- Understand the relevant vaccination schedules, including the need to provide reminders on the timing of second doses and the appropriate spacing or co-administration with other vaccines.
- Understand informed consent in the context of COVID-19 vaccination while addressing different cultural needs and levels of health literacy.

Topics

1. Vaccine hesitancy and consumer confidence
2. Vaccine approval process
3. Common consumer concerns
4. Consumer specific and appropriate communication
5. Eligibility for vaccine roll-out
6. Recommended schedule and follow-up
7. Informed consent

Topic 1: Vaccine hesitancy and consumer confidence

The Australian Government aims to ensure the delivery of safe, timely and effective vaccination to protect everyone in Australia from the harm caused by COVID-19. The vaccines will be given in line with best practice vaccine manufacturer and government guidance to achieve this aim (Australian Technical Advisory Group on Immunisation [ATAGI], 2020).

Media coverage of the COVID-19 pandemic and the subsequent vaccination program has been vast and has come from many different sources. The internet and social media, in particular, allow for articles, personal beliefs and news to travel quickly across the globe. Amongst the spread of information, there have been many unsubstantiated theories, myths and untruths which may lead to vaccine hesitancy (O'Neil, 2020).

Healthcare professionals will be faced with many questions, particularly around the safety of COVID-19 vaccines. It is imperative that we use consistent and clear answers to these questions to establish and maintain consumer confidence.

Healthcare professionals may also have regulatory obligations regarding vaccine education and promotion of vaccination as a population health benefit. Nurses and midwives, for example, are governed by the Nursing and Midwifery Board of Australia (NMBA), which has published a *Position statement on nurses, midwives and vaccination* stating that the NMBA "expects all registered nurses, enrolled nurses and midwives to use the best available evidence in making practice decisions" (2016, n.p). Nurses and midwives are not permitted to share anti-vaccination material which contradicts best available scientific evidence and is false, misleading or deceptive professionally or personally, including using personal social media accounts (NMBA, 2016).

Vaccine hesitancy may occur for many personal reasons. Whatever the reason, the approach and response must be systematic and person-centred (individualised). For some populations this may firstly require the development of trust, due to a history of obstacles and inequalities or negative healthcare experiences (Lewandowsky, 2021).

People are more likely to vaccinate when:

- The vaccine is convenient, easy and free.
- They have confidence in the system of delivery and safety of the vaccine.
- Healthcare professionals recommend the vaccine.
- Friends, family and their role models have been vaccinated.
- Individuals are aware of how their actions can foster immunity for others in their community.
- The risk of disease is recognised and vaccination is understood to be a solution to that risk.

(Lewandowsky, 2021).

The Sharing Knowledge About Immunisation (SKAI) website has detailed resources and an e-learning module in conjunction with the National Centre for Immunisation Research and Surveillance (NCIRS) and the National Prescribing Service (NPS MedicineWise) to assist healthcare professionals in responding to general vaccination queries. The module is free and highly recommended for all healthcare professionals who may need to answer consumer specific questions.

While it is noted that SKAI is directly targeted to parents and their concerns regarding National Immunisation Program (NIP) vaccines, all questions and responses are easily adaptable to adults as a consultation guide is given to follow. SKAI identifies three types of consumers for vaccine readiness:

those who are accepting, hesitant or declining vaccination. You can review these resources now by going to the e-learning module link and scrolling down to find the Health Professionals website.

MumBubVax is a website similar to SKAI for mothers including during pregnancy. There is also a health professionals' section for midwives and general practitioners (GPs) to register and gain access to e-learning modules and resources. While there is not currently any COVID-19 specific information here, there may be in the near future.

The Australian Government have released a *COVID-19 vaccination – Shared decision making guide for women who are pregnant, breastfeeding, or planning pregnancy*.

The public will require reassurance that the COVID-19 vaccines used in Australia have been thoroughly and independently assessed for safety. The vaccine approval process will be discussed in the next topic to help you explain this process confidently to people who ask.

As new information and research emerges, it will be imperative that you stay up to date with the latest evidence-based information. You will be required to view and read updates as they are released through this training program.

Providers may refer patients to information on the Department of Health and Aged Care's website, including 'Is it true? Get the facts on COVID-19 vaccines', which may be helpful in addressing vaccine hesitancy and consumer confidence.

Topic 2: Vaccine approval process

All medicines in Australia must be rigorously tested on thousands of people before being registered and available for use by the Therapeutic Goods Administration (TGA). The TGA is responsible for assessing all COVID-19 vaccines before they can be used in Australia to ensure the benefits of each vaccine are much greater than the risks. Getting a new vaccine through the provisional approval pathway involves many steps to ensure safety including analysing clinical trial data (TGA, 2020).

These are the steps required:

1. Laboratory research.
2. Animal studies.
3. Human clinical trials phase 1 (a few dozen healthy adult volunteers). The purpose is to establish safety and ensure an immune response is induced.
4. Human clinical trials phase 2 (hundreds of volunteers including at-risk and target groups). The purpose is to test the efficacy of developing immunity and confirm that only a few minor side effects are experienced.
5. Human clinical trials phase 3 (thousands of volunteers). The purpose is to see if the vaccine stops people from contracting the disease. Safety and side-effects are also closely monitored. This may include comparing a placebo control group.

   > One of the reasons why COVID-19 vaccinations have been able to be developed so quickly is that some phases overlapped each other in timeframes. As soon as the preliminary data were available the trials were able to progress.

6. Passing the TGA rigorous assessment and approval process. The TGA looks at safety, quality and effectiveness. International collaboration is also occurring with COVID-19 vaccines.

(Department of Health and Aged Care [DHAC], 2020g)

The TGA constantly monitors vaccines through pre- and post-marketing assessment and monitoring. Vaccines are regulated based on the assessment of risks and benefits from receiving and not receiving the product (TGA, n.d.).

The full vaccine approval process includes:

1. Pre-application for provisional determination.
2. Application following provisional determination, supply information on clinical studies, non-clinical and toxicology studies, manufacturing, chemistry and risk management.
3. Evaluation following submission accepted, formal evaluation process including advice from the Advisory Committee on Vaccines (ACV).
4. Decision regarding provisional registration based on safety, quality and effectiveness.
5. Registration. Following approval, the vaccine will be recorded in the Australian Register of Therapeutic Goods (ARTG). Product and consumer information is made available. Provisional registration lasts for 2 years with up to two extensions permitted.
6. Active monitoring. The TGA has robust procedures in place to investigate any potential issues promptly.

(TGA, 2020).

For further information please review the TGA's *COVID-19 vaccine approval process* webpage (2020).

Adverse events reported post-marketing (since being provisionally registered in Australia) by consumers and healthcare professionals are monitored and assessed against the benefit of receiving the medicine. This process helps to meet the expectation of the community and the goal of the Department of Health and Aged Care, that therapeutic goods in the marketplaces are high quality, efficacious and safe (TGA, 2020).

The Australian Technical Advisory Group on Immunisation (ATAGI) continues to meet regularly to review emerging data on thrombosis with thrombocytopenia (TTS) and the previously supplied COVID-19 vaccine AstraZeneca (VAXZEVRIA).

Weekly safety reports are provided by the Therapeutic Goods Administration (TGA) on TTS in Australia.

ATAGI have formed a COVID-19 working group who are advising the Australian Government on an implementation strategy to ensure the effective and equitable delivery of COVID-19 vaccines in Australia. They report to the Minister of Health on the design and implementation of the Australian COVID-19 vaccination program, clinical resources, updating of the Australian Immunisation Handbook (AIH), and policies and procedures. The working group are focusing on three separate areas:

- Technical and clinical advice.
- Immunisation landscape
- Safety monitoring

Various other groups are also involved and vital to the registration and ongoing monitoring of medicines and vaccines in Australia. Some of the other important groups are listed here. If you are not familiar with any of these it is recommended that you view the links below:

- Communicable Diseases Network Australia (CDNA)
- The Advisory Committee on Vaccines (ACV)

- National Immunisation Committee (NIC)
- National Centre for Immunisation Research and Surveillance (NCIRS)
- National Aboriginal and Torres Strait Islander Health Protection AHPPC Sub-committee
- AusVaxSafety

Topic 3: Common consumer concerns

In this topic we will focus on some common consumer questions and concerns that you may receive regarding COVID-19 vaccination. The purpose of this is to help you communicate effectively with members of the public, maintaining consumer confidence. Eligibility of vaccines is discussed further on in Topic 5.

A few frequently asked questions (FAQ) have been summarised below:

1. The various vaccines have been developed too quickly – How can we be sure it is safe?
    a. The TGA has approved this vaccine after an in-depth and independent full assessment was undertaken (NCIRS, 2020; TGA, 2020; Healthdirect, 2020).
    b. An unprecedented amount of resources and number of international researchers have been working towards the same clinical goal and have achieved this due to the devastating impact COVID-19 has had (NCIRS, 2020; Healthdirect, 2020).
    c. The same number of trials and tests has been undertaken with COVID-19 vaccines as expected with any other new medicines. The vast number of trial participants in target groups has allowed this to happen more quickly than usual (NCIRS, 2020).
    d. Pharmaceutical companies invested in manufacturing early on, so there was no delay between completion of trials and safety testing and the roll-out (NCIRS, 2020).
    e. Technology has evolved to be able to manufacture vaccines faster including sequencing the genetic code of the virus (Healthdirect 2020; NCIRS, 2020; Lewandowsky, et. al., 2021).
    f. Vaccine safety is monitored in several ways in Australia. One way is passive safety surveillance where adverse events are reported by health professionals, the general public and pharmaceutical companies. The other is active safety surveillance through a system called AusVaxSafety which gathers deidentified data from surveys sent out through a text message (ATAGI, 2021f).
2. What are the possible side-effects of the vaccines?
    a. All vaccines can cause side-effects. Usually, only mild effects may be experienced which disappear quickly (Lewandowsky, et. al., 2021; NCIRS, 2020).
    b. Common side effects are reported to be very similar to those that you may experience with other vaccines. These are normal as your immune system is being activated within the first 48 hours. Examples include:
        a. Muscle soreness, redness or swelling at the injection site.
        b. Fever and chills.
        c. General tiredness for a few days
        d. Headache (ATAGI, 2021b; Healthdirect, 2020; ATAGI, 2021f).
    c. Very rarely anaphylaxis has been reported between 1 to 5 cases per 1 million vaccine doses administered.
    d. There is a likely, rare link between the AstraZeneca (VAXZEVRIA) vaccine and very rare cases of clots and reduced platelet (clotting element) levels referred to as

thrombosis with thrombocytopenia syndrome (TTS). From March 2023, AstraZeneca (VAXZEVRIA) is no longer available, so no further cases of AstraZeneca (VAXZEVRIA)-related TTS can occur in Australia. For more information please refer to the joint statement from ATAGI and the Thrombosis and Haemostasis society of Australia and New Zealand (THANZ) found here.

e. There is a likely, rare link between mRNA vaccines such as Pfizer (COMIRNATY), and Moderna (SPIKEVAX) vaccines, and pericarditis and myocarditis (ATAGI, 2021b).
f. The risk of myocarditis or pericarditis following Moderna bivalent (SPIKEVAX) and Pfizer bivalent (COMIRNATY) vaccines has not yet been characterised, as these vaccines have not been used extensively in large populations. ATAGI states there is no reason to believe the safety of the Moderna bivalent (SPIKEVAX) and Pfizer bivalent (COMIRNATY) vaccines are any different to other Moderna (SPIKEVAX) or Pfizer (COMIRNATY) mRNA vaccines (ATAGI, 2022m; ATAGI, 2022o).

3. Was it safe to get the AstraZeneca (VAXZEVRIA) vaccine?

a. The AstraZeneca (VAXZEVRIA) vaccine was considered highly effective in protecting people against the serious health effects of COVID-19 – including death.
b. The AstraZeneca (VAXZEVRIA) vaccine was used in adults aged 18 to 59 years old when the benefits were likely to outweigh the risks for that individual and the person made an informed decision based on an understanding of the risks and benefits (ATAGI, 2021e; ATAGI, 2021n).
More information about the benefits and risks regarding the AstraZeneca (VAXZEVRIA) vaccine can be found here.
c. Pfizer (COMIRNATY), Moderna (SPIKEVAX), or Novavax (NUVAXOVID) vaccines were preferred over AstraZeneca (VAXZEVRIA) for people aged under 60 years. This was based on the higher risk and observed severity of a rare side effect called thrombosis with thrombocytopenia (TTS) after receiving AstraZeneca (VAXZEVRIA) in people aged under 60 years compared with people aged 60 years or older (ATAGI, 2021).

4. Can you get COVID-19 from the different vaccines, and can the vaccines change your genetic code?

a. No. None of the COVID-19 vaccines contains live coronaviruses. Therefore, the virus is unable to replicate and grow to cause an infection (DHAC, 2021f; ATAGI, 2021f).
b. The mRNA genetic material in the Pfizer (COMIRNATY) and Moderna (SPIKEVAX) vaccines are broken down and the mRNA does not enter the human cell nucleus which is where our DNA is located and cannot alter your DNA or genetic make-up (Centres for Disease Control and Prevention [CDC], 2021).
c. The Novavax (NUVAXOVID) vaccine is a recombinant spike protein vaccine. This vaccine cannot spread or multiply throughout the body or alter your DNA or genetic make-up.
d. Receiving a vaccine will not result in a positive COVID-19 swab test. However, it is possible for a person to catch COVID-19 just before or after a vaccination and therefore return a positive test due to an active infection acquired before the vaccine was effective (CDC, 2021).
e. Some side effects from COVID-19 vaccination might be similar to symptoms of COVID-19. It is important to still get a COVID-19 test performed at your local

testing centre if you have any of the respiratory COVID-19 symptoms including a runny nose, cough, sore throat, loss of smell or taste, even after you have been vaccinated (DHAC, 2021f).

f. You may not need to get tested or isolate if you develop general symptoms only such as fever, headache or tiredness in the first two days of vaccination. You should check the current guidelines in your jurisdiction for the most up-to-date information, if in doubt, seek medical assessment (DHAC, 2021f).

5. Now that I have received the vaccine, do I still need to follow physical distancing and wear a mask when recommended?

    a. Yes, all COVID-19 safe preventative measures such as wearing masks, physical distancing and frequent hand washing should still be followed after receiving the vaccine (NCIRS, 2020). This is because the vaccine program will take a while to be rolled out and for the effect to be seen. If the vaccine program is effective and a large proportion of people are immunised then restrictions may be able to ease if herd immunity develops but it is not yet known to what extent vaccination protects against transmission (NCIRS, 2020; ATGI, 2021f).
    b. Herd immunity is when enough people in a population are vaccinated and immune to prevent person to person transfer of a particular disease. Achieving this requires a large proportion of the population to be vaccinated and the vaccine to provide effective, long-term protection. As we learn more about COVID-19 vaccines, we will learn if herd immunity can be achieved (NCIRS, 2020).

6. Should I take paracetamol or ibuprofen before and after the COVID-19 vaccination?

    a. Paracetamol or ibuprofen are not recommended routinely before or after vaccination. There is currently no evidence on the benefit of painkillers for the prophylactic prevention of immunisation injection pain or systemic reactions following COVID-19 vaccination. Paracetamol and ibuprofen can, however, be considered for the management of adverse events (e.g., pain or fever, respectively) if they occur after vaccination for a short time (e.g., 1 to 2 days) (ATAGI, 2021b; ATAGI, 2021f).

7. Can I get my influenza vaccine at the same time as my COVID-19 booster vaccine?

    a. Yes, COVID-19 vaccines can be co-administered (i.e., on the same day) with an influenza vaccine (ATAGI, 2021b; ATAGI, 2023a).

8. Will the vaccines prevent COVID-19 infection or just severe symptoms?

    a. The COVID-19 vaccines currently in use in Australia provide significant protection against symptomatic disease. Clinical trials have shown that in addition to substantially reducing an individual's chance of contracting COVID-19, these vaccines also provide protection against severe illness. There is promising evidence that COVID-19 vaccination results in a significant reduction in the chance of transmitting the virus.

9. I have had my full primary COVID-19 vaccine course, what happens if I don't get a booster as recommended?

    a. A recommended COVID-19 vaccine course (2 doses for most people, and 3 doses if severely immunocompromised) will provide protection against COVID-19, however, this protection is likely to be of shorter duration without a booster dose.

For optimal protection against COVID-19, a booster is recommended 6 months after the last primary course dose is given (ATAGI, 2021b; ATAGI, 2023a).

b. There is no upper time limit for the administration of a booster dose. However, vaccine effectiveness wanes over time, and timely receipt of boosters is encouraged.
c. Some states and territories may have different requirements, however, and you are encouraged to check the requirements with your local department of health.

10. I have received one dose of a COVID-19 vaccine which is not available in Australia currently, what should I do?

    a. People who received a first dose of a COVID-19 vaccine that is not available in Australia can be offered an alternative vaccine brand to complete their primary vaccination course (DHAC, 2021i; ATAGI, 2021b).
    b. For additional guidance please refer to the ATAGI Clinical recommendations for COVID-19 vaccines.

11. Which COVID-19 vaccine can I have for my 2023 booster dose?

    a. All currently available COVID-19 vaccines are anticipated to provide benefits as a booster dose, however, bivalent mRNA booster vaccines are preferred over other vaccines. These include Pfizer bivalent BA.1 (COMIRNATY) (grey cap), Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) or Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccines (ATAGI, 2023a).
    b. Novavax (NUVAXOVID) is not registered by the TGA for use as a booster dose in adolescents aged 12 to 17 years; however, ATAGI has advised that this vaccine can be used as a booster dose if no other COVID-19 vaccine brand is suitable for that individual (ATAGI, 2022l).
    c. For people aged 5 to 11 years, Pfizer (COMIRNATY) (orange cap) is the only vaccine registered and recommended for use as a booster.
    d. The TGA has provisionally approved Novavax (NUVAXOVID) as a booster for individuals 18 years and older; however, ATAGI recommends that Novavax (NUVAXOVID) should only be used for people who have a contraindication to mRNA vaccines or for people who do not prefer an mRNA vaccine (TGA, 2021e; TGA, 2022b; ATAGI, 2021z; ATAGI, 2022m).

12. What are the benefits of an additional booster dose (2023 booster)?

    a. ATAGI advises that an additional COVID-19 booster dose is anticipated to address waning of protection against severe COVID-19 prior to winter and provide an increase in protection against severe illness in those individuals who are 65 years and older and those who are severely immunocompromised (ATAGI, 2023a).
    b. The increase in protection against severe illness from COVID-19 following a booster dose is most beneficial for people at higher risk of severe illness, i.e., older adults and those with relevant medical risk factors. Studies conducted throughout the pandemic have identified a higher risk of hospitalisation from all variants, including Omicron and its subvariants of SARS-CoV-2, among older adults and adults with immunosuppression or other chronic medical conditions, compared with younger or healthy adults (ATAGI, 2023a).

13. What are the potential risks of having a bivalent mRNA booster dose?

a. ATAGI advises that the decision to receive a 2023 COVID-19 booster dose should consider an individual's age, risk factors for severe COVID-19, number and timing of previous doses or previous infection, and risk factors (predominantly age) for myocarditis and pericarditis following vaccination (ATAGI, 2023a).
b. Adolescents and younger adults have a lower age-related risk of severe COVID-19, and a comparatively higher risk of myocarditis following vaccination. The risk of myocarditis is highest in people aged 16-30 years (peak 16-18 years) and is higher in males than females. The risk of myocarditis appears to be lower after COVID-19 booster doses in comparison with dose 2 of the primary course. See COVID-19 vaccination – Guidance on myocarditis and pericarditis after COVID-19 vaccines for more information (ATAGI, 2023a).

14. What is ATAGI's rationale for recommending a 2023 booster dose for all people aged 65 years and over as opposed 50 years and over?

    a. The risk of severe disease with current high population levels of hybrid immunity in adults aged 50-64 years without risk factors is now considered to be lower than when previous ATAGI booster advice was issued (ATAGI, 2023a).
    b. For people under 65 years, their risk of severe illness is affected by multiple factors including the timing of any previous infections, any relevant medical risk factors, and their risk of exposure (ATAGI, 2023a).

15. Should I get another COVID-19 vaccine dose if I have missed one of my previous recommended doses?

    a. ATAGI continues to recommend a primary course of vaccination against COVID-19, followed by a booster dose for those eligible under the updated recommendations, even in individuals who have had past infection (ATAGI, 2023a).
    b. Adults who have already been infected with an Omicron subvariant and vaccinated with 2 or 3 doses of COVID-19 vaccine are at lower risk of reinfection and hospitalisation compared to those who have been infected but not vaccinated (ATAGI, 2023a).
    c. A "catch-up" schedule is not required if you missed a booster dose (i.e. 1st or 2nd booster doses). A 2023 booster dose is recommended for eligible people if their last COVID-19 vaccine dose or confirmed infection was 6 months ago or longer, and regardless of the number of prior doses received (ATAGI, 2023a).

16. Why are children less than 5 years of age not recommended to receive a 2023 booster dose?

    a. Severe SARS-CoV-2 infection in children is extremely rare, even among children with underlying conditions. Most at-risk children aged 6 months to under 5 years have been offered a primary course of the COVID-19 vaccine within recent months and a booster dose is not considered necessary at present (ATAGI, 2023a).
    b. Serological studies suggest that >80% of children less than 5 years old have had the SARS-CoV-2 infection, many of which have been asymptomatic (ATAGI, 2023a).

17. Can all children and adolescents aged 5 years and older receive a 2023 COVID-19 booster dose?

    a. ATAGI advises that a booster dose is **not recommended** at this time for children and adolescents aged less than 18 years of age who do not have any risk factors for severe COVID-19 (ATAGI, 2023a).

b. A booster dose should be considered for children and adolescents aged 5-17 who have medical comorbidities that increase their risk of severe COVID-19, or disability with significant or complex health needs, if their last COVID-19 vaccine dose or confirmed infection was 6 months ago or longer, and regardless of the number of prior doses received (ATAGI, 2023a).

ATAGI has published an immunisation provider guide to obtaining informed consent for COVID-19 vaccines for those aged 12 years and above which contains suggested discussion points with COVID-19 recipients and additional common questions providers may receive.

Combined COVID-19 vaccine information and consent forms are now available for parents and guardians on the following webpages, COVID-19 vaccines for children and COVID-19 vaccination – Patient resources. The consent forms require the parent/guardian to confirm that they have the authority to provide consent on behalf of that child.

The National Centre for Immunisation and Research Surveillance (NCIRS, 2020) has a web page, *COVID-19 vaccines: Frequently asked questions* (FAQ) which are useful to review.

Healthdirect also have a FAQ section for COVID-19 vaccines which can be accessed here. Another helpful general COVID-19 website is the Department of Health and Aged Care *COVID-19 vaccines* page.

Common COVID-19 vaccination questions for Aboriginal and Torres Strait Islander peoples are available on the Department of Health and Aged Care website.

For the Department of Health and Aged Care marketing campaign materials visit this link.

How to speak to kids about COVID-19 vaccines has been developed to assist in communication with children regarding vaccination.

Topic 4: Consumer specific and appropriate communication

To maximise vaccine uptake and therefore minimise the effect of COVID-19 on people in Australia, the vaccination service needs to be accessible. Accessibility not only includes physical availability and affordability, but also cultural safety and acceptability.

It is recommended that individual service providers liaise and consult with their local community to ensure the service is acceptable and accessible for them (Australian Institute of Health and Welfare [AIHW], 2013). Healthcare professionals are highly trusted and are influential on vaccination decisions made by the public. Furthermore, a recommendation to vaccinate from a healthcare provider is one of the strongest determinants in vaccine acceptance.

At-risk and priority populations may need more time for communication and interactions with healthcare professionals to promote equity of care. This may include groups with a medical or socioeconomic risk, or specific communication requirement, such as, individuals:

- Who are Aboriginal and Torres Strait Islander peoples.
- From culturally and linguistically diverse (CALD) communities.
- Who are refugees.
- Within detention centres, jails or prisons.
- With a disability.
- Who are rough sleeping or living in temporary accommodation.

- Who are asylum seekers.
  (Danchin, Biezen, Manski-Nankervic, Kaufman, & Leask, 2020).

Some general strategies to improve cultural competence, acceptability, accessibility and appropriateness of services to at-risk and priority populations include:

- Use a holistic or whole-person care model (total wellbeing, physical, mental, social, cultural and emotional approach) of health and wellbeing rather than the biomedical model (the standard medical approach on individual systems and diseases). That is, health is more than the absence of disease and is not just physical (AIHW, 2013)
- Have a focus on building therapeutic and clinical relationships based on mutual respect and trust.
- Employ Aboriginal and/or Torres Strait Islander health workers and practitioners to promote and deliver culturally safe services in their community.
- Employ CALD health workers suitable and applicable to the community
- Support cultural safety through appropriate communication styles and working with community organisations, groups and Elders.
- Provide services in culturally safe settings that are appropriate and accessible for the community e.g. outreach vaccination services at local cultural events, community halls, prisons, or religious gatherings etc (AIHW, 2013).
- Provide systems and services which are accessible and inclusive to support equity of access for people with disability e.g. ensure vaccination sites are physically accessible for people with mobility difficulties.

Communication must meet the needs of the people we are interacting with. Given Australia's diverse population, there is no easy way to always meet these needs. Instead, it is necessary to have a continual conversation with individuals and communities.

Communication is more than just words and phrases. Culture influences the meaning of language and if not considered, may result in miscommunication and ineffective care. Do not assume that fluency in English corresponds with effective communication (AIHW, 2013).

Appropriate health services are comprehensive and non-discriminatory while supporting the complex health needs of those they are servicing (AIHW, 2013).

A person's social and cultural values affects their communication needs and decision-making process on health-related matters. We all have values that affect perspectives of how we see others; these values may differ from those we are vaccinating (Forster, 2016).

The general principles and skills of good communication can be applied to all situations:

- Respect.
- Empathy.
- Listening.
- Being responsive and flexible to a person's circumstances (Forster, 2016).

Aboriginal and Torres Strait Islander peoples:

Aboriginal and Torres Strait Islander peoples are one of the priority populations for the roll-out of COVID-19 vaccinations. A 'one-size-fits-all' approach to pandemic strategies is unlikely to work (Massey, Pearce, Taylor, Orcher, Saggers, Durrheim, 2009). All communication with Aboriginal and Torres Strait Islander peoples should be respectful and culturally sensitive.

Research indicates that the most successful and culturally appropriate communication strategy with Aboriginal and Torres Strait Islander people is Clinical Yarning. To ensure effectiveness of clinical Yarning with Aboriginal and Torres Strait Islander peoples this technique should be delivered in consultation with regional specific Aboriginal and/or Torres Strait Islander specific cultural awareness/cultural appreciation training for health workers delivering the vaccine. This is a person-centred approach consisting of three core elements:

- Social yarning.
- Diagnostic yarning.
- Management yarning (Lin, Green & Bessarab, 2016).

Figure 1: *Keep our mob safe stop the spread* (DHAC, 2020h).

All people must be given the opportunity to identify as an Aboriginal and/or Torres Strait Islander person as well as the opportunity to access an Interpreter at each vaccination encounter. The Australian Institute of Health and Welfare (AIHW) has developed best practice guidelines for ensuring Indigenous identification is captured. A factsheet is available here. **Engagement with Aboriginal and Torres Strait Islander people:**

Aboriginal and Torres Strait Islander people should be engaged in the process from the outset and be active participants in determining and guiding decision-making on community needs and priorities.

- Building trust with Aboriginal and/or Torres Strait Islander peoples is an important element in communicating important public health messages.
    - Health professionals should ensure inclusivity through listening to Aboriginal and/or Torres Strait Islander perspectives and experiences to inform, guide, implement and disseminate communication strategies and messages.
- Aboriginal and/or Torres Strait Islander Health Workers are key in delivering information to community, explaining it in a way that can be understood, and debunk misinformation.
    - Health professionals should utilise Aboriginal and Torres Strait Islander Health Workers who are trusted and respected to deliver health messages. This may ensure a better chance of relaying messages in a culturally appropriate and efficient way.

- Access to an interpreter and culturally appropriate communication should be developed in Aboriginal and Torres Strait Islander languages, so that it is inclusive of people where English is a second language.
- Understanding regional/community issues affecting Aboriginal and/or Torres Strait Islander peoples by participating in cultural awareness/cultural appreciation will complement the application of clinical yarning within the practice.

Understand that there are differences in language styles between Aboriginal and/or Torres Strait Islander communities, particularly in rural and regional locations. Problem solving may be required to provide effective messaging and convey culturally appropriate communication. For example, some language groups may not have a word for 'illness' or 'vaccine' so respectable messaging will need to be considered.

For further information and guidance on cultural safety and how to best communicate with Aboriginal and Torres Strait Islander peoples, the following websites and articles are recommended:

Cultural safety in health care for Indigenous Australians: monitoring framework - AIHW web report.

Step 3: Cultural safety, skill development and communication - National Cancer Nursing Education Project (EdCaN) – learning resources for nurses.

Patient-centred care: Cultural safety in Indigenous health – The Royal Australian College of General Practitioners (RACGP), Australian Family Physician, 37(12).

Communicating effectively with Aboriginal and Torres Strait Islander people - Queensland Health.

Culturally and linguistically diverse (CALD) populations:

Australia is a multicultural and linguistically diverse society. Cross-cultural communication may involve the use of free healthcare interpreters, translated resources and community partners. Family members or friends should not be used as interpreters. Service providers are encouraged to register and use the Free Interpreting Service (TIS), and if required, contact them on 1300 131 450, to refer the public to this service please provide the number 131 450.

The TIS National Free Interpreting Service has temporarily been extended to cover non-Medicare patients receiving their COVID-19 vaccine. Additionally, medical practices can also book onsite interpreters on weekends for COVID-19 vaccination purposes by emailing tis.freeinterpreting@homeaffairs.gov.au. Telephone interpreting services are available 24 hours a day and 7 days a week.

People from CALD groups may fall into a priority group and may need resources in their own languages. The eligibility checker is now translated into 15 languages and provides access to the National Translating and Interpreting Service. More languages and content will continue to be translated on this webpage.

The Department of Health and Aged Care has developed a Multicultural Outreach Stakeholder pack which contains resources to use and share with vaccine recipients regarding the COVID-19 vaccine program. The pack is particularly aimed as communicating information to people from culturally, ethnically and linguistically diverse backgrounds. Resources include a video in over 19 different languages, posters, fact sheet, social media resources and audio clips (DHAC, 2021h).

Communication with CALD groups can be complex. As mentioned in the previous section we bring our own culture, values and beliefs with us when we communicate with others and it is essential

that we acknowledge and reflect on these. Stereotyping and classification of people into groups is not acceptable.

Communication strategies that build rapport and support person-centred care are important with CALD groups. Some strategies include being empathetic, active listening, asking for clarification and sitting down to be at the same level as consumers.

All people must be given the opportunity to access an interpreter at each vaccination encounter. COVID-19 vaccine information and other translated resources are available in over 60 languages on the Department of Health and Aged Care's website.

The National Coronavirus Helpline can also assist people to find out if they are eligible and provide information for people to book their own COVID-19 vaccination. People who do not speak English can contact TIS National on 131 450 and ask to be connected to the National Coronavirus Helpline on 1800 020 080.

People with disability

There are around 4.4 million people with disability in Australia (AIHW 2020). The disability population is diverse and encompasses people with varying types and levels of disability across all socio-economic and demographic groups (AIHW 2020).

People with disability living in residential support settings which have two or more people with disability and people with disability who also have an underlying medical condition are priority populations for the roll-out of COVID-19 vaccinations.

People with disability may also fall into other priority populations and/or may be Aboriginal and Torres Strait Islander peoples or from culturally and linguistically diverse communities (CALD).

A short learning package with videos on disability awareness can be accessed here.

To ensure that people with disability can fully participate in decision making about COVID-19 vaccinations, information and communications will need to be in accessible formats such as:

- Easy Read and visual aids.
- Auslan.
- Braille.
- Microsoft Word format (for screen readers).
- Captioned videos with transcripts made available.

Some general communication strategies that are important when communicating with people with disability include:

- Speak directly to the person with a disability and as a person first.
- Do not make assumptions about a person's disability.
- Do not make assumptions about what a person's disability can or cannot do.
- Provide the person with disability with all relevant information so they can make informed decisions.
- Ensure the person with disability is involved in all stages of the decision-making process.
- Ask if and what assistance may be needed. Do not assume you know what assistance is required.

- People with a disability are not invisible, do understand what is being said to them, and can speak for themselves. Do not attempt to speak, or finish a sentence, for the person you are speaking to.

For further information and guidance on how best to communicate with people with disability, including communicating with someone who has a vision impairment or who has a guide, hearing or assistance dog, the following websites and articles are recommended:

Better communication – Queensland Government resource

Communicating effectively with people with disabilities – National Disability Coordination Officer Program

Communication with people with disabilities – Australian Federation of Disability Organisations

Further information about COVID-19 vaccines for people with disability can be found on the Department of Health and Aged Care website. There are resources for people with disability and disability service providers.

General communication and resources:

Language use is very important in establishing trust and disseminating information. People may not be aware of the medical words or phrases used regarding the COVID-19 vaccinations. Alternately, an incorrect or incomplete understanding of certain medical terms can result in miscommunication.

As healthcare professionals, we must be informed and answer all questions truthfully with transparency and accuracy to improve vaccine uptake and reduce hesitancy (O'Neil, 2020). When necessary you can refer people to appropriate printed or online resources such as:

- NCIRS – COVID-19
- DHAC – Coronavirus (COVID-19) resources for the general public
- TGA – COVID-19 vaccine: Information for consumers and health professionals
- DHAC – COVID-19 vaccines
- DHAC – Consent information and patient resources
- DHAC – Clinical guidance and information for COVID-19 vaccination providers
- NCIRS – COSSI reports and publications
- DHAC – Translated resources
- Department of Home Affairs – Translating and interpretation service
- DHAC – Find out more about each COVID-19 vaccine
- COVID-19 vaccine information for teens and parents/guardians

For further information about COVID-19 vaccines, how to communicate risks and benefits, and how to communicate with different people in the community with evidence-based responses, review *The COVID-19 Vaccine Communication Handbook*.

Topic 5: Eligibility for vaccine roll-out

The vaccine is free for everyone in Australia who chooses to receive the vaccine (DHAC, 2020f; Australian Government, 2020b).

Moderna (SPIKEVAX) (blue cap, purple label), Moderna (SPIKEVAX) (red cap) and AstraZeneca (VAXZEVRIA) vaccines are no longer available in Australia (ATAGI, 2021b).

Primary course recommendations:

COVID-19 vaccination is recommended for all people aged 5 years or older to protect against COVID-19. COVID-19 vaccination is recommended for children aged 6 months to under 5 years with severe immunocompromise, disability, and those who have complex and/or multiple health conditions that increase the risk of severe COVID-19.

For most people, a primary vaccination course consists of 2 doses. A third primary dose is recommended for people aged 6 months or older with severe immunocompromise.
See Considerations for special populations: people who are immunocompromised.

COVID-19 vaccination with a full primary course is mandatory for residential aged care workers. All state and territory governments will implement mandatory boosters for residential aged care workers consistent with arrangements already in place through state and territory public health orders and equivalent arrangements (DHAC, 2022a).

The Northern Territory, South Australia, Victoria and Western Australia have already mandated boosters as a condition of employment for residential aged care workers. This adds an extra layer of protection to aged care residents who have already been offered vaccinations. Some states and territories may have different requirements, however, and you are encouraged to check the requirements with your local DoH (DHAC, 2022a).

Booster dose recommendations

ATAGI **recommends** 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 (ATAGI, 2023d):

- 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.

ATAGI advises the following groups should **consider** a 2023 booster dose 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 (ATAFI, 2023d).

- 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.

ATAGI advises that a booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19 and the 2023 booster dose is not a seasonal recommendation.

Development of seasonal immunisation policy to manage COVID-19 is limited as the evolution, as well as duration and strength of protection against serious SARS-CoV-2 illness is uncertain at this time (ATAGI, 2023a).

Booster doses are not currently recommended for children aged under 5 years, or for children aged 5 to 17 years who are not at increased risk of severe disease as defined above. Severe COVID-19 in children is uncommon and the primary course of COVID-19 vaccines generates a strong immune response. The benefit from additional doses of vaccine is likely to be small. Current evidence does not suggest that booster doses are needed at this time.

Booking a vaccine

There are a range of delivery sites being utilised to provide vaccinations. Sites include, general practice vaccine sites, Aboriginal and Torres Strait Islander Community Controlled Health Services (ACCHs), Commonwealth Vaccination Clinics (CVCs) (also known as General Practitioner led Respiratory Clinics), pharmacies and state and territory operated vaccination clinics. The Australian Defence Force will also provide the vaccines for their staff (DHAC, 2021e).

For ATAGI recommended COVID-19 vaccine doses, most appointments will be made through the National Booking Service or the providers own booking system. Individuals can also contact the vaccine helpline on 1800 020 080 for assistance in navigating the booking system.

Vaccine roll-out program:

All COVID-19 vaccinations must be recorded on the Australian Immunisation Register (AIR). Consumers will be identified by using their Medicare number (if available) when entering data into the AIR. For those who don't have a Medicare number, such as people on temporary visas, we encourage using an Individual Health Identifier (IHI) to record their vaccine administration into the AIR. More information on applying for an IHI can be found here.

Topic 6: Recommended schedule and follow up

Each vaccine brand may have different recommended schedules and dose requirements. This is because the vaccines use different antigen components and interact with the immune system differently.

Further detail is given in the additional modules about specific vaccines available to health professionals who will be administering COVID-19 vaccines.

Primary course: vaccine preference recommendations

Children aged 6 months to 4 years who are recommended COVID-19 vaccination can receive Pfizer (COMIRNATY) (maroon cap) for their primary course. Pfizer (COMIRNATY) (maroon cap) is recommended in a 3-dose schedule, with each dose 8 weeks apart (ATAGI, 2021b).

All children aged 5-11 years are recommended Pfizer (COMIRNATY) (orange cap) primary course. People aged 12-17 years are recommended to receive a BA.4-5-containing bivalent vaccine primary course i.e. Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) or Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) primary course. The recommended schedule for the primary course for all vaccines in people aged 5 years and over is 2 doses, 8 weeks apart (ATAGI, 2021b; ATAGI, 2023d).

People aged 18 years and older are recommended to receive a bivalent mRNA vaccine primary course (either a BA.1-containing bivalent vaccine or a BA.4-5-containing bivalent vaccine). These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)
- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS)
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap)
- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label)

Although the bivalent mRNA vaccines are registered for use as booster doses, ATAGI considers them suitable for use in a primary course. For further information, refer to ATAGI advice on the

preferential use of bivalent COVID-19 vaccines for primary vaccination of people aged 12 years or older.

Adults who have started their course with an original (ancestral-based) vaccine are recommended to complete the course with a bivalent mRNA vaccine. Original (ancestral) vaccines i.e. Pfizer (COMIRNATY) (purple cap) and Novavax (NUVAXOVID) continue to be available for individuals aged 12 years and older who either prefer to not receive a bivalent primary course; or who cannot or choose not to have an mRNA vaccine.

As with vaccines on the National Immunisation Program (NIP) Schedule, there is no maximum interval between doses of COVID-19 vaccines, only a minimum and recommended interval. The schedule **DOES NOT** need to be restarted if a significant time passes between presenting for the first and second dose. (ATAGI, 2021b).

ATAGI advises that the absolute minimum interval between the first and second dose of any COVID-19 vaccine is 14 days. Dose intervals of at least 14 days are considered acceptable and valid, and the person will be considered fully vaccinated in the Australian Immunisation Register (AIR) (ATAGI, 2021b).

A second dose of a COVID-19 vaccine administered less than 14 days after the first dose is considered an invalid dose. An additional COVID-19 vaccine dose should be administered as a replacement dose (ATAGI, 2021b).

Booster dose recommendations

Any age-appropriate COVID-19 vaccine, including original (ancestral) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer-lasting protection against severe disease (ATAGI, 2021b).

However, bivalent mRNA vaccines are preferred over other vaccines for people aged 12 years and older. These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), for people 12 years and above.
- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS), for people 12 years and above.
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap), for people 18 years and above.
- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label), for people 18 years and above.

(ATAGI, 2021b)

Although not preferred, Novavax (NUVAXOVID) can be used as a booster dose in people aged 18 years and older in the following circumstances:

- people who have a contraindication to mRNA vaccines (including those who have had a serious adverse event following mRNA vaccines, such as a history of anaphylaxis or myocarditis attributed to an mRNA vaccine)
- people who do not prefer an mRNA vaccine.

(ATAGI, 2021b)

Although not TGA-registered as a booster in this age group, Novavax (NUVAXOVID) can be used as a booster in people aged 12 years or older if no other COVID-19 vaccine brand is suitable for that person (ATAGI, 2021b).

Pfizer (COMIRNATY) (orange cap) can be used in children aged 5 to 11 years (ATAGI, 2021b).

The evidence underpinning booster dose recommendations will continue to be reviewed and this clinical guidance may be refined. For more details see: COVID-19 vaccine information.

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Topic 7: Informed consent

Ensuring informed consent is gained is an ethical, legal and professional requirement for all medical procedures including getting a vaccination. Informed consent supports person-centred (individualised) care (Australian Commission on Safety and Quality in Health Care [ACSQHC], 2020). The time spent with an individual before and while gaining consent can be used to generate trust through open communication.

As with all other vaccines, informed consent is required before administering each COVID-19 vaccine dose (ATAGI, 2021). This may be given as verbal or written consent depending on facility policy. All clinic or facility policies and procedures as well as the Australian Immunisation Handbook (AIH) recommendations must be followed to gain and record consent.

It is not considered necessary to change the manner of recording informed consent for the purpose of COVID-19 vaccination.

Following a thorough pre-screening as per your facility or clinic policy, consent should be documented in the clinical records, including electronic medical records at each vaccination encounter.

At some facilities this may include written consent, however, this is not a legal requirement for any vaccination including COVID-19 vaccination in Australia (ATAGI, 2021f). *A COVID-19 vaccination - Consent form for COVID-19 vaccination* is available at the Department of Health and Aged Care website if required.

Combined COVID-19 vaccine information and consent forms are now available for parents and guardians on the following webpages, COVID-19 vaccines for children and COVID-19 vaccination – Patient resources. The consent forms require the parent/guardian to confirm that they have the authority to provide consent on behalf of that child.

As part of seeking informed consent before each vaccination, you should also advise patients that their vaccination details must be reported to the Australian Immunisation Register (AIR). This will include some personal information (name, DOB, contact details and some Healthcare identifiers for example).

For the COVID-19 vaccine, the Australian Government Department of Health and Aged Care will use **de-identified** immunisation information to report on how the vaccine rollout is progressing. Patients who wish to opt out of further uses of their information from the AIR can do so via Services Australia but should be aware that this will also limit medical provider access to their immunisation history. For more information on how personal information is managed for the COVID-19 Vaccine Strategy implementation, please visit the Department of Health and Aged Care COVID-19 vaccines privacy and security information page.

Valid consent must be:

- Informed by having the potential risks and benefits explained and understood.

- Given voluntarily without coercion.
- Given by an individual who has the legal and intellectual capacity to do so.
- For a specific procedure (ATAGI, 2022q; ACSQHC, 2020).

View the Australian Commission on Safety and Quality in Health Care (ACSQHC, 2020) *Informed consent in health care factsheet* for more information as part of the National Safety and Quality Health Standards (NSQHS).

Obtaining valid and informed consent is essential before providing any medical treatment or procedure and failure to do so could result in legal action for battery (Staunton & Chiarella, 2017).

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 at which a child can give consent to medical treatment, check with your state or territory health authority about these laws. The common law applies in the states and territories that do not have specific legislation relating to children's consent to medical treatment. This common-law position is often referred to as Mature Minor or Gillick competence (ATAGI, 2022q).

If a child or adolescent refuses a vaccination that a parent or guardian has given consent for, respect the child's or adolescent's wishes, and inform the parent or guardian.

Consent on behalf of an adult lacking capacity

Carefully assess an adult's capacity to give valid consent to vaccination. If the adult lacks capacity, refer to relevant jurisdictional laws for obtaining consent from a substitute decision-maker. For example, this may occur when vaccinating an elderly person with dementia. See the enduring guardianship legislation in your state or territory for more details (ATAGI, 2022q).

Informed consent

Consent must be obtained for each vaccination encounter and should be completed after establishing that the vaccine is recommended and appropriate for this person (ATAGI, 2022q; ATAGI, 2021f).

For people whose first language is not English, translations and properly recognised interpreters or cultural support people should be engaged to ensure a valid legal consent is obtained (ATAGI 2022q).

Due to potential cultural, social and language barriers, it is important to ensure informed consent is being made for members of CALD groups and Aboriginal and Torres Strait Islander peoples.

Refer to Topic 4 in this module for communication techniques and a list of recommended online resources for consumers.

ATAGI recommends that any verbal information is also supplemented with written information or by providing a list of relevant online resources. This should include information about possible adverse events, how common they are and what to do if they should occur (ATAGI, 2022q).

As a summary, information and areas to be covered when obtaining informed consent for COVID-19 include:

- The benefits of vaccination, and that it is still possible to get sick from COVID-19 after vaccination.
- Requirement of 2 doses of vaccine for optimal protection.
- Safety of COVID-19 vaccination and safety surveillance including the continuation of public health measures other than vaccination.
- Post-vaccination care and management of common side effects and when to seek medical attention after vaccination.
- Continuation of other public health measures to prevent COVID-19 infection.
- Reporting all COVID-19 vaccinations to the Australian Immunisation Register (AIR) and the collection of personal details.

(ATAGI, 2021f)

If the person does not consent, their decision must be respected. They may be directed to further resources to discuss their decision.

If the withdrawal of consent is confirmed, then the date, time, and the name of the person should be documented, along with any other relevant information.

Module summary

- Individuals may have attitudes accepting, hesitant or declining vaccination. There are specific communication techniques recommended for each type to assist with gaining informed consent and maximising vaccine uptake.
- The TGA has a stringent, independent and regulated processes for approving vaccines for use in Australia and will continue to monitor the safety of COVID-19 vaccines during the roll-out.
- Many organisations, working parties and government groups are working together to coordinate this vaccine roll-out to ensure the best evidence-based guidelines and safety are upheld.
- Individuals will have questions about the COVID-19 vaccine. Resources in this module will be helpful in having confidential discussion with them.
- Cultural safety is of the utmost importance. Culturally safe care can only be determined by the person or people receiving the care and requires ongoing self-reflection by the healthcare worker/practitioner to do so.
- Communication should be personalised, particularly for those who are at-risk or vulnerable. Use the resources in this module to assist you.
- Clinical yarning is an evidence-based communication tool to assist you communicate with Aboriginal and Torres Strait Islander peoples.
- Informed consent is a legal requirement prior to receiving the vaccine. It must be valid and confirmed at each vaccine encounter.

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Multi-choice Questions:

1. 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 (Australian Government)

2. 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

3. Key principles for providing culturally safe care include:

    a. Building relationships, including with the individual and the community
    b. Having access to and applying regional specific cultural awareness
    c. Having access to an interpreter if the individual chooses
    d. All of the above

4. How can individuals schedule their COVID-19 vaccination appointments?

    a. Through their clinic, general practice or pharmacy as normal.
    b. Through existing online booking systems linked to the national booking system.
    c. State and territory clinics which will link to the national booking system.
    d. All of the above.

Module 4 – Multi-dose vial (MDV) training and delivery

(21/09/2023)

This module is suitable for health professionals administering COVID-19 vaccines.

The recommended time for completion is 25 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete and progression to Module 4 can occur.

Learning objectives

At the end of Module 4 it is expected that you will be able to:

- Understand the risk of infection associated with multi-dose vial (MDV) use.
- Understand the risk of potential wastage associated with the use of MDVs, and how to minimise this wastage.
- Understand what safe and appropriate use of MDVs for COVID-19 vaccination involves and be able to use this knowledge to adhere to infection control and aseptic techniques to prepare, store and administer vaccines from MDVs.

Topics covered in Module 4

1. Equipment and consumables
2. Practical use, guidelines and administration
3. Key issues of MDVs

Topic 1: Equipment and consumables

Normal practice for vaccines on the National Immunisation Program (NIP) in Australia is that they are dispensed as a single-use vial or pre-filled syringe (PFS). The only usual exception is the Bacilli Calmette-Guérin (BCG) vaccine which comes as a multi-dose vial (MDV). MDVs were also used during the 2009 influenza pandemic (H1N1) (ATAGI, 2021a).

Initially, COVID-19 vaccines were only manufactured in MDV with various doses per vial (Australian Technical Advisory Group on Immunisation [ATAGI], 2022q; ATAGI, 2021a).

Moderna bivalent BA.4-5 (SPIKEVAX) Pre-Filled Syringe (PFS) vaccine is the only COVID-19 vaccine currently available as a PFS. Please see Additional Module 3d for more information.

The advantages of using the MDV in a mass vaccination program are that they are:

- More cost-effective,
- Quicker to manufacture,
- More efficient for distribution and delivery, and

- Take up less storage room (ATAGI, 2022q; ATAGI, 2021a).

This module acknowledges that different healthcare professionals will be administering this vaccine in various settings. Some adaptations may be required for smaller immunisation services and outreach clinics as appropriate (ATAGI, 2021a). Always seek advice from your facility if you have any questions about your available equipment, procedures and standard operating policies (SOP) concerning equipment.

The Australian Technical Advisory Group on Immunisation (ATAGI) have advised a recommended and minimum checklist for the equipment used to administer one (1) dose to one (1) person.

MDV Vaccine administration checklist per person:

- 1 x unexpired vaccine MDV containing at least 1 dose stock (with diluents, if applicable).
- 1 x sterile single-use syringe (the recommendation is to use a 1mL syringe for doses < 0.5mL; a 2mL or 3mL syringe may be used for doses ≥0.5mL) (latex-free). Luer-Lock rather than Luer-Slip are highly recommended.
- 1 x sterile bevelled drawing up needle, 19 to 21 gauge preferred (reduces coring) (not required if using the same needle to draw up and administer the vaccine*).
- 1 x sterile single-use 22 to 25 gauge injecting needle. 25mm length except for persons with obesity when 38mm is recommended. Safety needles are strongly recommended.
- 1 x 70% isopropyl alcohol wipe (for vials, not the person's arm).
- 1 x cotton wool ball.
- 1 x hypoallergenic tape or hypoallergenic latex-free band aid.
- 1 x procedure dish or tray for the drawn-up vaccine (e.g., kidney dish) (optional).

*The drawing-up needle is NOT routinely recommended to be used as the administration needle due to infection prevention and control concerns but may be necessary in some circumstances (see "Drawing up the vaccine" below).

It is important when preparing clinics and calculating total requirements to allow for wastage in case stock and equipment need to be discarded.

You may carry a dose in a syringe with a capped administration needle that has just been withdrawn from a vial from the vaccine preparation area to the administration area.

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

The recommended equipment checklist also includes recommended general items that should be in stock at an immunisation clinic for safety and administration purposes:

- Labels for the syringes (if the COVID-19 vaccine is prepared in advance of administration) and clean container to store the prepared doses in within the fridge/cooler box.
- Personal Protective Equipment (PPE) as per the Australian Immunisation Handbook (AIH), national, jurisdictional and institutional requirements.
- Disinfectant cleaning supplies for the work surface and equipment.
- Basic vital signs monitoring equipment including a stethoscope and blood pressure monitor (optional).
- Labels for opened MDV to record the date and time the MDV was first accessed.
- Approved, suitable sharps disposable container (one per vaccinator).
- Biohazardous and other waste bins.
- Hand hygiene facilities and supplies and alcohol hand rub supplies.

- Virucidal supplies and/or genetically modified organisms (GMO) spill kit in case of spillages.
- Resuscitation or anaphylaxis response kit.

Personal Protective Equipment (PPE):

As per the Australian Immunisation Handbook (AIH), PPE is not specifically recommended when preparing or administering vaccines unless an additional infection risk exists (ATAGI, 2022q).

PPE may be required for other reasons unrelated to the preparation and administration of the vaccine such as infection prevention and control. Please check with your state and territory and facility policies and requirements for PPE on a regular basis as these can change rapidly.

In areas with no or low community transmission of COVID-19, standard infection prevention and control measures should be observed, and PPE is not required. In areas with community transmission the use of PPE should be as per jurisdictional and facility policies.

PPE which may be considered, depending on circumstances, includes:

- Disposable gloves (latex free when possible) which must be changed after interaction with each person
- Medical/surgical masks (for immunisers and consumers)
- Face protection including safety glasses, goggles or face shields
- Gowns

Consumers with acute respiratory symptoms, particularly if consistent with COVID-19 infection symptoms should be advised not to attend the vaccination appointment until their symptoms have resolved and/or they have a negative COVID-19 test.

Resuscitation or anaphylaxis response kit:

Each facility or clinic where vaccinations are being administered is required to have a resuscitation or anaphylaxis response kit available (ATAGI, 2022q). This must include all items as stated within the AIH under 'V*accination procedures'* and '*Preparing for vaccines'.* Please review this section of the AIH.

As a summary the minimum required equipment is:

- 3 x adrenaline (1:1000) ampoules which are in date.
- 3 x drawing up needles.
- 3 x 1mL syringes.
- 3 x 25mm, 22-25 gauge needles for intramuscular injection.
- 3 x cotton swabs.
- Pen and paper for documenting the resuscitation events.
- 1 x laminated copy of the '*Table. Doses of intramuscular 1:1000 adrenaline for anaphylaxis'* from the AIH.
- 1 x laminated copy of the '*Table. Recognising and treating anaphylaxis'*.

For further assistance setting up and preparing a kit, please review the infographic produced by ATAGI (2022q).

The Australasian Society of Clinical Immunology and Allergy (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.

Topic 2: Practical use, guidelines and administration

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.

This topic will cover the steps to draw up and administer vaccines from a MDV. Different vaccines may have different specific requirements or specifications. Always follow the ATAGI recommendations and the manufacturer's product information which are summarised in other modules.

A clean preparation area is required for drawing up the vaccine dose(s) from an MDV away from direct consumer contact and distraction.

Gathering and preparing the MDV for use:

1. Perform hand hygiene with either soap and water or an alcohol-based hand rub.
2. Clean and disinfect the separate area for preparation and procedure dish or tray if being used.
3. Collect the required equipment (as outlined earlier in this topic in the 'vaccine administration checklist per person').
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 vial and the date and time that the MDV was opened. **DO NOT** use if the time is beyond the maximum time indicated on the product information. If you are opening the MDV for this first time, record the date and time on the vial now, before opening it.
7. Examine the vaccine vial gently and ensure there is no discolouration, turbidity or particulate matter (except for undiluted vials of Pfizer (COMIRNATY) (purple cap), Pfizer (COMIRNATY) (orange cap) and Pfizer (COMIRNATY) (maroon cap)) as per the product information. If you are unsure of its appearance, label as **DO NOT** use and seek advice from the Vaccine Operations Centre (VOC) on **1800 318 208**.
8. Perform hand hygiene.
9. Open the vial (if applicable) and check the bung (also known as the septum/stopper/diaphragm) integrity.
10. Disinfect the bung using a 70% isopropyl alcohol wipe.
11. Allow to fully dry for 30 seconds.
12. If the vaccine needs dilution i.e., Pfizer (COMIRNATY) (purple cap), Pfizer (COMIRNATY) (orange cap) and Pfizer (COMIRNATY) (maroon cap), please review 'drawing up the vaccine' checklist located further on in this topic. If not, move on to 'drawing up the vaccine' and always follow the manufacturer's product information (ATAGI, 2021a).

Always check ATAGI advice and the manufacturer's specifications before preparation to review the number of doses contained in the MDV, the amount of time the vaccine can be out of cold chain for and the maximum time that it can be used after being opened etc.

Please watch this brief instructional video for a summary of the above steps
https://share.viostream.com/bfxgwogd945u5d?t=t-d417yzw

Diluting a vaccine:

Dilution will not be reviewed in detail here as it will be discussed individually for each vaccine in the applicable additional modules. The additional modules will only become available after core Modules 1 to 6 are complete.

The AIH has a chapter within '*Vaccination procedures'*, entitled '*Administration of vaccines'*. If you are unfamiliar with or need a refresher on how to reconstitute a MDV for injection, please review the AIH now.

Dilution of a MDV follows the same principles and process as reconstituting a single-dose vial. After mixing in the required diluent, it is recommended that you withdraw that same volume of air from the vial.

After dilution the opening date and time **MUST** be recorded on the vial without delay.

Drawing up the vaccine using a standard 1mL, 2mL or 3mL syringe:

This information is summarised from the ATAGI MDV guideline (2021a). Specific vaccine drawing up instructions will be in the appropriate additional module, this guide is for general information.

The below steps build on the first set of instructions for 'gathering and preparing the MDV for use'. In this case hand hygiene has already been performed and the bung wiped with 70% alcohol and left to dry completely.

1. Attach a sterile drawing up needle to a sterile syringe as per the specified equipment requirements. It is recommended a **1mL syringe be used if the required dose is <0.5mL** and a **2mL or 3mL syringe is used for 0.5 mL doses**. **Low dead-volume syringes and/or needles** are recommended when available for all Pfizer (COMIRNATY) vaccines. (*If completing the alternate method, 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. Remove air bubbles and check the dose volume.
4. 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.
5. Attach a new sterile injection needle* to the syringe as per the equipment checklist.
    - If drawing up multiple doses, 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.
6. Place a single pre-drawn dose ready for administration into a procedure dish or tray unless being administered immediately (ATAGI, 2021a). (*This will require the needle to be re-sheathed using safe aseptic technique).

* 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 Pfizer (COMIRNATY) as the proportional loss of volume is greater for the lower volume paediatric dose compared to the adolescent/adult dose. 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 steps to complete this process are exactly the same as described in this section, except the needles are not changed. The needle can be recapped using aseptic technique if not being administered immediately (ATAGI, 2021a). Seek advice from your Public Health Unit (PHU) when this may be appropriate.

If multiple doses are being made up at once for immediate administration during an immunisation session, 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.

Each prepared syringe within the container must also be appropriately labelled.

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°C to 8°C, to minimise the risk of infection. This is to minimise any remote potential risk of infection (ATAGI, 2021b; ATAGI, 2021g; Department of Health and Aged Care [DHAC], 2021). Vaccine doses (pre-drawn doses in syringes) are treated differently than diluted or open vials. Please refer to the ATAGI Transport, storage and handling webpage for ATAGI recommendations on diluted or open vials.

To reduce the risk of administration error, different COVID-19 vaccine MDVs and prepared doses should be stored separately from each other in clearly marked areas, including in dedicated containers in separate spaces (e.g. in different shelves in a vaccine fridge or separate vaccine fridges where possible). Syringes prepared from MDVs should be labelled using colour-coded labels to differentiate them (ATAGI, 2021g).

Watch this video as a review of how to draw up a dose from a MDV:
https://share.viostream.com/bfxgwogd945w8i?t=t-d417yzw

After preparation clean-up:

1. Discard the drawing up needle immediately into an approved sharps container.
2. Return the MDV to the cold chain if there are remaining doses. Before returning the vial, ensure the date and time of opening are clear.
3. Clean and wipe the workbench.
4. Perform hand hygiene.
5. Ensure all prepared syringes are labelled to identify contents if the preparer is not also administering the vaccine.
6. The vaccine should be administered as soon as possible after preparation and within the manufacturer's maximum recommendations.

All healthcare professionals must adhere to their facility practices, policies and operational procedures in addition to those discussed here.

The '*vaccination procedures*' section within the Australian Immunisation Handbook should be referred to for general aspects and expectations of vaccine administration including pre, during and post-vaccination.

Administration:

Please note: COVID-19 vaccine vials contain multiple doses. Do not administer the entire contents of a vial to a single patient (ATAGI, 2021g).

All COVID-19 vaccines currently approved by the Therapeutic Goods Administration (TGA) in Australia are recommended to be administered by intramuscular injection. For people **>12 months** administer the vaccine as an intramuscular injection (IMI) in the deltoid muscle and for infants **<12 months** the recommended site is the vastus lateralis muscle in the anterolateral thigh. **DO NOT** use the deltoid muscle for infants <12 months (ATAGI, 2022q). If you are not familiar with intramuscular injections at this site for adults, please review the in-depth information sheets and information available within the AIH.

Anatomical markers used to identify the deltoid injection site

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

(ATAGI, 2022q)

As a few important summary points on IM administration:

- The person's arm (for those >12 months) or thigh (for those < 12 months) 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.
- In most cases, a 25mm length needle is recommended as per the AIH '*Table. Recommended needle size, length and angle for administering vaccines'.* If the individual is obese, a 38mm length needle is recommended.
- Older children, adolescents and adults should be sitting on a chair with their arm relaxed.
- Infants aged <12 months should be positioned in a semi-recumbent cuddle position on the parent's/carer's lap.
- Children aged ≥12 months should be positioned in a cuddle position sitting sideways on the parent's/carer's lap.
- The straddle position can also be used for an older child where the child may face the parent/carer with their legs straddled over the parent's/carer's lap.
- The vaccine should be inserted at a 90^{o} angle.
- There is no need to withdraw to check your position during IM vaccinations. However, if blood is seen before injection, withdraw the needle and select a new site for injection.
- The vaccine should be injected slowly over a count of 5 seconds if using a 25 gauge needle.

ATAGI does not recommend routinely aspirating (drawing back) needles before injection. This practice was rejected some decades ago, due to several disadvantages including prolonging the procedure, potentially associated pain, and increasing the risk of needle-syringe disconnection**. Not aspirating is supported by the current advice in the Australian Immunisation Handbook** (ATAGI, 2022q).

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.

Injecting in the arm too low may cause radial nerve damage. Expose the entire shoulder to use anatomical markers to identify the correct injection area. This can be done using the triangle or fingertips methods.

Figure 1 – 3. *Expose the entire arm*. (ATAGI, 2019).

Review the Australian Immunisation Handbook infographic, *Avoiding shoulder injury related to vaccine administration* infographic for more information.

Administration of vaccines under sedation

Procedural guidelines for administration of vaccines under sedation in practice have been developed or are currently being developed in some health services. ATAGI advises that detailed clinical guidance should be developed collaboratively with input from anaesthetic groups, jurisdictional health services and relevant specialists (ATAGI, 2022g).

More information can be found in the ATAGI advice on use of sedation for COVID-19 vaccination.

See Appendix 3 for the Vaccine preparation and Vaccine administration checklist below

Vaccine administration errors (VAEs)

A vaccine administration error occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training undertaken to minimise the risk of errors occurring (ATAGI, 2022a).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible vaccine administration errors, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022a). The VOC on **1800 318 208** is available to provide advice and guidance to clinicians regarding the management of VAEs.

Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

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

Please see Appendix 4 for the steps to be followed if a Vaccine administration error occurs.

Topic 3: Key issues of MDVs

Multidose vaccine containers are in widespread use in low and middle-income countries' immunisation programs and have their advantages. However, **MDV use is not without risks.**

For infection prevention and control, the World Health Organization (WHO) and the National Health and Medical Research Council (NHMRC) recommend that when possible single-use vials are used for medication administration. However, in exceptional circumstances such as when a health emergency is declared and there may be a delay in single-dose vaccinations becoming available, MDVs may be the only appropriate way to vaccinate a large population (ATAGI, 2021a).

When entering the MDV multiple times, ensure that each re-puncture occurs at a different site on the bung.

Without training there is a higher chance of wastage and infection arising from misuse of MDV. This topic will cover these two key issues and outline how they can be reduced.

Infection risk:

When used correctly, MDVs are safe and cost-effective. However, infection is the primary risk associated with MDVs. This risk can be mitigated through infection prevention and control training and practice including:

- Aseptic preparation,
- Proper storage, and
- Aseptic administration.

Infection may be introduced by inserting a non-sterile needle into the vial or introducing infection into the vial from the surface (ATAGI, 2022q).

There have been reported cases of vial contamination and then transmission of infectious disease with MDVs including:

- Human Immunodeficiency Virus (HIV)
- Hepatitis B
- Hepatitis C
- *Staphylococcus aureus*
- *Streptococcus pyogenes (ATAGI, 2021a)*.

When using MDVs, ensure you follow the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (NHMRC, 2019). Please review pages 49-50, section 3.1.2 on MDVs and pages 91-95, section 3.1.6 aseptic technique now.

Additionally, if you are in an office-based practice including general practices, refer to the Royal Australian College of General Practitioners (RACGP, 2016), *Infection prevention and control standards for general practices and other office-based and community-based practices* (5th edition).

Mitigating infection risk with MDVs:

1. Establish a dedicated medication preparation area separate from all other work areas.

2. Follow all ATAGI advice and manufacturer's recommendations for storage, use, expiry dates and administration.
3. Draw up each dose using a sterile 19 – 21 gauge bevelled needle and syringe.
4. Only have 1 vaccine vial in the working environment at one time.
5. Discard any open and unused vials at the end of each vaccination session, or as per the ATAGI advice and the manufacturer's instructions.
6. Discard any vials if integrity or sterility is compromised or thought to be possibly compromised, ensuring to follow wastage reporting requirements as per Module 2 (ATAGI, 2021a).

Expiry dates must be followed precisely to prevent expired stock being administered. There are two expiry dates for unopened MDVs that must be observed on the mRNA vaccines (Pfizer (COMIRNATY) and Moderna (SPIKEVAX) vaccines) the manufacture 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 thaw 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**.

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.

This is also relevant for pre-drawn doses and open MDVs specific to each vaccine brand. All ATAGI recommendations should be adhered to for each vaccine brand. Refer to ATAGI recommendation on Transport, storing and handling COVID-19 vaccines for more information.

If vaccines are administered outside of any expiry date, it is considered a vaccine administration error (VAE) (ATAGI, 2022a). The VOC on **1800 318 208** is available to provide advice and guidance to clinicians regarding the management of VAEs. Refer to ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors for further information.

Potential wastage:

As discussed in Module 2, wastage is a potential issue due to the current deficit in worldwide supply of vaccines relative to the demand. The main concern regarding wastage is not having sufficient doses to vaccinate the Australian community in a timely manner to offer maximum protection.

Each MDV may have a different number of doses that can be extracted, as per manufacturer's recommendations.

Wastage can occur for many different reasons and should be minimised. Some examples of sources of wastage include:

- If the MDV is contaminated or loses integrity before all available doses are drawn up.
- A cold chain breach outside of acceptable limits.

- The vaccine expires before being utilised.
- Using incorrect equipment with high dead spaces resulting in fewer doses being extracted from each MDV.
- Withdrawing a greater volume from the vial than is required.

Wastage can be substantially reduced by following all policies and procedures as outlined throughout this training program. Also, ensure each manufacturer's guidelines and ATAGI advice are followed for preparation and administration.

More specific information on each vaccine will be provided within the applicable additional modules.

Module summary

- MDVs are advantageous for delivering many vaccine doses to a large population, particularly during a pandemic.
- Use the equipment checklist to ensure preparedness for vaccination clinics and sufficient stock is available.
- Follow all ATAGI and AIH recommendations for vaccine administration, including following infection control guidelines.
- A standard 2mL or 3mL syringe is recommended for use to administer vaccines of a volume 0.5mL or greater. A 1mL syringe should be used if the volume required is less than 0.5mL.
- The largest risks of MDV use are wastage and infection control. Both can be mitigated by following all policies and procedures for best practice.
- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

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Multi-choice Questions:

1. The two main potential risks when using MDVs are:

    a. Infection risk and wastage.
    b. Infection risk and incorrect dose being administered.
    c. Incorrect dose being administered and cold chain breaches.
    d. Cold chain breaches and wastage.

2. 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 obese (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).

3. 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

4. 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.

5. When preparing and administering a MDV, hand hygiene should occur. Hand washing should occur during which steps of the vaccine preparation and administration procedure?

    a. Right at the beginning as the first step before gathering the equipment and after checking that the vial is correct and before the vial is opened.
    b. After cleaning the bung, but before accessing the vial and when changing needles
    c. When changing the drawing up needle to the administering needle and after administration
    d. Between every preparation step if the vial is placed down and picked up again.

Module 5 – Documentation and reporting

(21/09/2023)

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 25 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete and progression to Module 6 can occur.

Learning objectives

At the end of Module 5 it is expected that you will be able to:

- Understand how to identify the vaccine recipient, check their eligibility and suitability for the vaccine (before vaccination) using relevant systems and specific to each setting
- Understand how to report vaccine administration details to the Australian Immunisation Register (AIR), potentially through several reporting channel options dependent on the setting, including vial number or barcode scanning.

Topics

1. Authority to vaccinate
2. Contraindications, precautions and suitability
3. Pre-vaccination screening
4. The Australian Immunisation Register (AIR) reporting requirements
5. The AIR 'how to' guide

Topic 1: Authority to vaccinate

There are national requirements and guidelines. However, the authority to administer medications is also governed by each jurisdiction.

Vaccines are Schedule 4 (S4) medications and as such can be administered by healthcare professionals who are approved to administer S4 medications or have the specific vaccine incorporated into their scope of practice (Australian Government, 2021a).

Completion of the five (5) compulsory core modules in this training program and the associated additional module for each vaccine administered is a national requirement for all healthcare professionals administering COVID-19 vaccinations in Australia.

"Healthcare professionals will not be able to administer any COVID-19 vaccines without having first complete the training modules" (Australian Government, 2021b, p.3).

The COVID-19 vaccination program is different to the administration of National Immunisation Program (NIP) vaccines due to the mass numbers of vaccination required over a short time frame. Therefore, the authority to vaccinate may differ from current standard practice.

Ensure you check your jurisdictional requirements for administering COVID-19 vaccination as additional training or requirements may be required.

As a healthcare professional you are responsible for ensuring that you observe the requirements relating to registration and scope of practice as well as the legislation relating to jurisdictional Drugs and Poisons regulations.

Visit your state or territory policy to review who can administer COVID-19 vaccines and in what capacity and circumstances. As information may change frequently, it is your professional responsibility to check your state and territory immunisation and other relevant pages for any updates relevant to scope of practice.

ACT – Nurse and Midwife Immunisers.

Pharmacist Vaccinations.

NSW – Poisons and Therapeutic Goods Regulation 2008

Authorised Nurse Immuniser and Authorised Midwife Immunisers

Authority to Supply Poisons and Restricted Substances – Registered Nurses and Registered Midwives

Pharmacist Initiation and Administration of Vaccines and NSW Pharmacist Vaccination Standards

Authority to supply poisons and restricted substances – Defence Medical Technician

NT – Immunisation: health professionals

QLD – Medicines and Poisons Act 2019

Extended Practice Authority for 'Registered Nurses'.

SA – Vaccine Administration Code.

TAS – Poisons Regulations 2018.

Information for Immunisation Providers.

Tasmanian Immunisation Program Guidelines

VIC – Victorian COVID-19 Vaccination Guidelines

Drugs, Poisons and Controlled Substances Act 1981 and Regulations 2017.

Medicines and Poisons – Public Health Emergency Orders

WA – Structured Administration and Supply Arrangements (SASA), information found under 'CEO of Health SASA'.

For Aboriginal and Torres Strait Islander Health Workers and Practitioners, the following table shows the current scope of practice regarding administering and supplying COVID-19 vaccines. This table is up–to date as at 4 November 2021 and may only be applicable in specified locations to people who have completed all other requirements. The table should only be used as a guide.

Table 1. Aboriginal and Torres Strait Islander Health Workers and Practitioners supplying and administering COVID-19 vaccines.

Jurisdiction	Professional title	Can administer	Can supply
ACT	Aboriginal and Torres Strait Islander Health Practitioner	✗	✗
	Aboriginal and Torres Strait Islander Health Worker	✗	✗
NSW	Aboriginal and Torres Strait Islander Health Practitioner	✓	✗
	Aboriginal and Torres Strait Islander Health Worker	✓	✗
SA	Aboriginal and Torres Strait Islander Health Practitioner	✓	✗
	Aboriginal and Torres Strait Islander Health Worker	✗	✗
NT	Aboriginal and Torres Strait Islander Health Practitioner	✓	✓
	Aboriginal and Torres Strait Islander Health Worker	✗	✗
QLD	Aboriginal and Torres Strait Islander Health Practitioner in isolated practice areas (hospitals, health services and community-controlled health services)	✓	✓
	Aboriginal and Torres Strait Islander Health Worker in isolated practice areas (hospitals and health services)	✓	✓
TAS	Aboriginal and Torres Strait Islander Health Practitioner	✓	✓
	Aboriginal Health Worker	✓	✓
VIC	Aboriginal and Torres Strait Islander Health Practitioner	✓	✓
	Aboriginal Health Worker	✗	✗
WA	Aboriginal and Torres Strait Islander Health Practitioner	✓*	✓
	Aboriginal Health Worker	✓*	✓

*Limited to supply or administration in accordance with an individual medical direction for each person being vaccinated or a SASA issued by the employing Aboriginal Health Service.

In some of jurisdictions, specific training is required to allow either or both of these professions to administer and/or supply. In some cases, these authorisations are only available to practitioners within the jurisdiction's health system.

Before administering any COVID-19 vaccines ALL health professionals are responsible for checking their state and territory legislation (drug and poisons acts) and facility policies to ensure they meet the required standards.

Pharmacists

States and territories have legislative responsibility for who can vaccinate, with what vaccines and when vaccinations can begin, following initial assessment by the Australian Government Department of Health.

Refer to the COVID-19 Vaccine Roll-out through Community Pharmacies onboarding pack for all information related to the administration and set-up process.

Topic 2: Contraindications, precautions and suitability

Contraindications:

Anaphylaxis is an absolute contraindication to receiving COVID-19 vaccines. This could be anaphylaxis experienced either:

- After a previous dose of the same COVID-19 vaccine, or
- After previous exposure to any of the vaccine components. See the product information for each vaccine for identification of all vaccine components.

Anaphylaxis or angioedema after exposure to other antigens is not a contraindication to receiving this vaccine. However, caution and specialist advice may be recommended. Please contact your state or territory specialist immunisation servicesand/or public health units (PHU) if assistance or assessment is required.

Previously, there were two (2) other true contraindications to receiving the AstraZeneca (VAXZEVRIA) vaccine, which is no longer supplied in Australia:

- Experiencing major venous and/or arterial thrombosis in combination with or separate to thrombocytopenia following vaccination with any COVID-19 vaccine.
- Previous episode of capillary leak syndrome (AstraZeneca, 2021a).

Information on vaccine components to be aware of will be updated as new vaccines are registered for use in Australia.

Precautions:

As COVID-19 vaccines are relatively novel, safety testing in all population groups has not yet been achieved. Currently in Australia, the COVID-19 vaccines are not recommended for the following populations:

- People under 6 months of age
- People who have allergies to any of the ingredients in the vaccines.
- People who are acutely unwell with a fever (≥38.5°C) or respiratory symptoms.

Vaccine recommendations

Moderna (SPIKEVAX) (blue cap, purple label), Moderna (SPIKEVAX) (red cap) and AstraZeneca (VAXZEVRIA) vaccines are no longer available in Australia (ATAGI, 2021b).

COVID-19 vaccination is recommended for children aged 6 months to under 5 years with severe immunocompromise, disability, and those who have complex and/or multiple health conditions that increase the risk of severe COVID-19. Pfizer (COMIRNATY) (maroon cap) is recommended in a 3-dose schedule, with each dose 8 weeks apart (ATAGI, 2021b).

COVID-19 vaccination is recommended for all people aged 5 years or older to protect against COVID-19. All children aged 5-11 years are recommended Pfizer (COMIRNATY) (orange cap) primary course. The recommended schedule for the primary course for all vaccines in people aged 5 years and over is 2 doses, 8 weeks apart (ATAGI, 2021b).

People aged 12-17 years are recommended to receive a BA.4-5-containing bivalent vaccine primary course i.e. Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) or Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) primary course (ATAGI, 2021b; ATAGI, 2023d).

People aged 18 years and older are recommended to receive a bivalent mRNA vaccine primary course (either a BA.1-containing bivalent vaccine or a BA.4-5-containing bivalent vaccine). These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)
- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS)
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap)
- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label)

Although the bivalent mRNA vaccines are registered for use as booster doses, ATAGI considers them suitable for use in a primary course. For further information, refer to ATAGI advice on the preferential use of bivalent COVID-19 vaccines for primary vaccination of people aged 12 years or older.

Original (ancestral) vaccines continue to be available for individuals aged 12 years and older who either prefer to not receive a bivalent primary course; or who cannot or choose not to have an mRNA vaccine.

A third primary dose is recommended for people aged 6 months or older with severe immunocompromise. See considerations for special populations: people who are immunocompromised.

As per ATAGI 2023 booster advice, any age-appropriate COVID-19 vaccine, including original (ancestral virus-based) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer-lasting protection against severe disease.

However, bivalent mRNA vaccines are preferred over other vaccines for people aged 12 years and older. These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)
- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS)
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap)
- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label)

Although not preferred, Novavax (NUVAXOVID) can be used as a booster dose in people aged 18 years and older in the following circumstances:

- people who have a contraindication to mRNA vaccines (including those who have had a serious adverse event following mRNA vaccines, such as a history of anaphylaxis or myocarditis attributed to an mRNA vaccine)
- people who do not prefer an mRNA vaccine.

Although not TGA-registered as a booster in this age group, Novavax (NUVAXOVID) can be used as a booster in people aged 12 years or older if no other COVID-19 vaccine brand is suitable for that person.

COVID-19 vaccines can be co-administered (i.e., on the same day) with an influenza vaccine. COVID-19 vaccines can also be co-administered with other vaccines if required. However, given the current limited evidence on the concomitant use of COVID-19 vaccines with other vaccines, providers need to balance the opportunistic need for co-administration with giving the vaccines on separate visits (ATAGI, 2021b).

There is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time. Co-administration or near administration (e.g., within days) with another vaccine may also make the attribution of potential adverse events more challenging. New evidence base demonstrates the safety and immunogenicity of co-administration of COVID-19 and influenza vaccines. There are no data on the safety of co-administering COVID-19 vaccines with other vaccines (ATAGI, 2021b).

Specific precautions for each COVID-19 vaccine being administered in Australia will be covered within the additional modules, accessible after all core modules are completed.

Allergies:

Anaphylaxis or severe allergy to a vaccine is a rare occurrence. This is the reason all vaccinated people must remain at the vaccination clinic for at least **15 minutes** following administration. Including people with a history of allergy; anaphylaxis to food, drugs, venom, or latex; or allergic conditions, including asthma, atopic dermatitis (eczema) or allergic rhinitis (hay fever) (ATAGI, 2021b).

If a person has a hypersensitivity or allergic reaction to their first COVID-19 vaccination within four hours including urticaria/hives, providers should seek expert advice from their public health unit (PHU) regarding the requirement for specialist immunisation services. If a person in this category is vaccinated, they may require vaccination in a facility with medical staff in attendance, and to be observed for 30 minutes following administration of a COVID-19 vaccine dose (ATAGI, 2021b).

A potential allergen in mRNA vaccines (Pfizer (COMIRNATY) and Moderna (SPIKEVAX)) is polyethylene glycol (PEG), also known as macrogol. While allergy to this is rare, it can result in anaphylaxis (ATAGI, 2021b). PEG is often found in bowel preparation products, laxatives, tablets, hand sanitiser gels, cosmetics, skincare products and some food and drink (Australasian Society of Clinical Immunology and Allergy [ASCIA], 2021). Polysorbate 80 is chemically related to PEG, there is a rare link of allergy that can result in anaphylaxis from this which is an ingredient in the previously supplied AstraZeneca (VAXZEVRIA) vaccine and the available Novavax (NUVAXOVID) vaccine (ASCIA, 2021).

The following individuals should be assessed for suitability for vaccination before being given a vaccine dose, if necessary, in consultation with an allergist/immunologist or specialist immunisation clinic:

- People with a generalised allergic reaction to any COVID-19 vaccine component, such as PEG or Polysorbate 80, or
- People with a prior history where these components could conceivably be the cause of an anaphylactic reaction to previous vaccines and/or multiple drugs,

If people in these categories are vaccinated, they may require vaccination in a facility with medical staff in attendance, and to be observed for 30 minutes following administration of a COVID-19 vaccine dose (ATAGI, 2021b).

Before a person with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment is vaccinated, they should be assessed for suitability for vaccination before given a vaccine dose. If they are vaccinated, they may require vaccination in a facility with medical staff in attendance, and to be observed for 30 minutes following administration of a COVID-19 vaccine dose (ATAGI, 2021b).

For further information on precautions and recommendations for individuals with allergies please review the Australasian Society of Clinical Immunology and Allergy (ASCIA) *Allergy, Immunodeficiency, Autoimmunity and COVID-19 Vaccination Position Statement*. This statement includes recommendations based on current knowledge regarding allergic reactions to COVID-19 vaccines.

Also, the precautions 'specific allergies' section can be reviewed within ATAGIs Clinical Guidance for COVID-19 vaccine providers.

Pregnancy and breastfeeding:

The Australian Government has released a *COVID-19 vaccination – Shared decision making guide for women who are pregnant, breastfeeding, or planning pregnancy*.

ATAGI recommend that pregnant women are routinely offered a mRNA COVID-19 vaccine at any stage of pregnancy. This is because the risk of severe outcomes from COVID-19 is significantly higher for pregnant women and their unborn baby.

Pregnant women with COVID-19 have a higher rate of hospitalisation, ICU care and mechanical ventilation, but not death, than age-matched non-pregnant women. The risk of preterm delivery is also increased. There is no evidence to suggest that SARS-CoV-2 infection in pregnancy increases the risk for congenital anomalies (ATAGI, 2021b).

Other precautions:

Immunocompromised individuals - The current COVID-19 vaccines do not use live vaccines and therefore pose no risk to people who are immunocompromised including people with Human Immunodeficiency Virus (HIV). ATAGI released a COVID-19 vaccination decision guide for people with immunocompromise resource to provide additional information to immunisation providers.

ATAGI recommends a third primary dose of COVID-19 vaccine in severely immunocompromised populations to address the risk of suboptimal or non-response to the standard 2 dose schedule. The third dose is intended to maximise the level of immune response to as close as possible to the general population (ATAGI, 2021w).

Protection from 3 primary doses in severely immunocompromised individuals may still be lower than the general population. People should continue risk mitigation strategies such as mask-wearing and social distancing even after receipt of a third dose (ATAGI, 2021w).

Antibody testing is not recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination, including in immunocompromised individuals after a second or third dose. There are no serological assays that provide a definitive correlate of immunity to SARS-CoV-2 (ATAGI, 2021w).

For more information on conditions and therapies for which a third primary dose is recommended please review the ATAGI statement on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Myocarditis and Pericarditis - A risk of myocarditis and pericarditis has been observed in people who have received mRNA COVID-19 vaccines (including Pfizer (COMIRNATY) (purple cap) and Pfizer (COMIRNATY) (orange cap)) in overseas studies, particularly in males under 30 years of age after the second vaccine dose. The cases have been mild, and the people have recovered quickly (ATAGI and the Cardiac Society of Australia and New Zealand [CSANZ], 2021).

The risk of myocarditis or pericarditis, a very rare adverse effect following bivalent mRNA vaccines has not yet been characterised, as these vaccines have not been used extensively in large populations. ATAGI states there is no reason to believe the safety of bivalent mRNA vaccines are any different to other mRNA vaccines (ATAGI, 2022m).

Myocarditis refers to inflammation of the heart muscle, and pericarditis refers to inflammation of the thin sac that surrounds the heart. These conditions can occur separately or together (myopericarditis). Myocarditis and/or pericarditis have been reported as rare side effects after mRNA COVID-19 vaccines in adults, particularly young adults, in several countries including the USA, Israel, UK and Italy (ATAGI & CSANZ, 2021).

Symptoms typically appear within 1-5 days of vaccination and include chest pain, palpitations (irregular heartbeat), syncope (fainting) or shortness of breath. People who experience any of these symptoms after having an mRNA COVID-19 vaccine should seek prompt medical attention (ATAGI & CSANZ, 2021).

For further information refer to the Clinical guidance for COVID-19 vaccine providers and the Guidance on myocarditis and Pericarditis after mRNA COVID-19 vaccines (ATAGI & CSANZ, 2021; ATAGI, 2021b).

Bleeding disorders - As the COVID-19 vaccinations are administered by intramuscular injection, there is a potential bleeding risk for those with bleeding disorders (ATAGI, 2021b).

Unless warfarin or low molecular weight heparin (LMWH) doses are stable, the appropriate levels should be checked in people receiving anticoagulants before they receive a vaccine, if possible.

Defer intramuscular injections if the INR is >3.0 (warfarin) or the anti-Xa (LMWH) level 4 hours post-dose is >0.5 units/mL (ATAGI, 2022q).

Advice should be sought from your state and territory public health unit (PHU) on how to proceed if levels are outside of the recommended guidelines.

Thrombosis with thrombocytopenia syndrome (TTS) - TTS is a newly described serious condition, with unusual blood clots in the brain (cerebral venous sinus thrombosis (CVST)) or in other parts of

the body, associated with low platelet levels. The previously supplied AstraZeneca (VAXZEVRIA) vaccine appears likely to have a rare link with TTS.

The rate of TTS reported in Australia and overseas, although rare, may be higher in younger adults than older adults and it may be more common in women. However, cases have been reported in men and older people (ATAGI, 2021j). mRNA vaccines (Pfizer (COMIRNATY) and Moderna (SPIKEVAX)), and Novavax (NUVAXOVID) are not associated with a risk of TTS (ATAGI, 2021b).

For more information please review the Department of Health and Aged Care Vaxzevria (AstraZeneca) vaccine and thrombosis with thrombocytopenia (TTS) webpage.

Previous COVID-19 infection – Past infection is not a contraindication to a booster dose. ATAGI recommends that vaccination should be deferred for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19 (ATAGI, 2023a).

People who have received an anti-SARS-CoV-2 monoclonal antibody or convalescent plasma should defer future doses of COVID-19 vaccine for at least 90 days (ATAGI, 2021b).

State and territory health authorities:

If required, the immunisation specialists in each jurisdiction may be contacted for further advice through your public health unit (PHU). As previously mentioned, the National Centre for Immunisation Research and Surveillance (NCIRS) have collated all contact details for each jurisdiction including adverse events reporting which will be presented in the final core Module 6.

View the link below to note your specialist contacts and clinics: Specialist immunisation services - NCIRS.

Medical exemption:

Vaccinations may reasonably be temporarily deferred for individuals with some acute major medical conditions (e.g. undergoing major surgery or hospital admission for a serious illness). Typically, these are time-limited conditions (or the medical treatment for them is time-limited) and therefore temporary exemptions are considered appropriate.

These exemptions are only to be given where a suitable alternative COVID-19 vaccine is not readily available for the individual for either the primary or booster doses; all COVID-19 brands must be selected on the medical exemption (IM011) form (ATAGI, 2021v).

- For mRNA COVID-19 vaccines this includes: Inflammatory cardiac illness within the past 6 months, e.g., myocarditis, pericarditis, endocarditis; acute rheumatic fever or acute rheumatic heart disease (i.e., with active myocardial inflammation); or acute decompensated heart failure.
- For all COVID-19 vaccines: ATAGI recommends that vaccination can be deferred in those with PCR-confirmed SARS-CoV-2 infection until complete recovery from the acute illness (which may be up to 6 months), regardless of disease severity. Chronic symptoms following COVID-19 ("Long COVID") is not a contraindication to COVID-19 vaccines but does warrant a clinical discussion with the patient.
- For all COVID-19 vaccines: Serious adverse event attributed to a previous dose of a COVID-19 vaccine and without another cause identified.

(ATAGI, 2021v)

Only eligible health professionals can submit immunisation medical exemptions to the AIR (form IM011). This includes:

- A general practitioner.
- Paediatrician.
- Clinical immunologist.
- Infectious disease physician.
- Public health physician.

For more information review the ATAGI expanded guidance on acute major medical conditions that warrant a temporary medical exemption relevant for COVID-19 vaccines.

Topic 3: Pre-vaccination screening

Before any vaccination is administered a pre-screening checklist must be completed. There is a standard checklist that should be read through and discussed with the person receiving the vaccine. This can be found within the Australian Immunisation Handbook (AIH). If you are not familiar with this checklist, ensure you view the *pre-vaccination screening* section (ATAGI, 2022q).

Additionally, collated resources can be located on the Department of Health and Aged Care's website. A consumer orientated pre-screening checklist can be found on page 2 of the Australian Government consent form for COVID-19 vaccination which is available for optional use.

Combined COVID-19 vaccine information and consent forms are now available for parents and guardians on the following webpages, COVID-19 vaccines for children and COVID-19 vaccination – Patient resources. The consent forms require the parent/guardian to confirm that they have the authority to provide consent on behalf of that child. The consent forms require the parent/guardian to confirm that they have the authority to provide consent on behalf of that child.

The below questions are outlined to ensure contraindications and precautions have been addressed specifically for COVID-19 vaccination and need to be used in addition to the pre-vaccination screening section of the AIH. These questions are based on the precautions discussed in Topic 2 and the individual vaccine characteristics. Pre-vaccination screening should only occur after eligibility for vaccination has been established as outlined in Module 3, Topic 6.

It is important for healthcare professionals to familiarise themselves with pre-vaccination checklists and processes used in your clinic or facility.

Questions which highlight contraindications:

- Have you had a COVID-19 vaccination previously and did you have an anaphylactic reaction to that vaccine? (Confirm via the AIR – Topic 4)
    - If yes, then vaccination is contraindicated and CANNOT be given.
- Have you had an anaphylactic reaction to any component of this COVID-19 vaccine in the past?
    - If yes, then vaccination is contraindicated and CANNOT be given.

Questions which highlight precautions requiring noting and discussion with vaccine provider:

- Are you acutely unwell? (e.g., have a fever of ≥38.5◦C)
    - If yes, then vaccination should be delayed until they are asymptomatic for at least 48 hours.

- Have you had a generalised allergic reaction to a previous dose of a COVID-19 vaccine or to one of the components of the COVID-19 vaccine? This includes prior anaphylaxis to a previous vaccine or multiple drugs where PEG or polysorbate 80 may conceivably be the cause.
    - If yes, please note we require you to stay at the clinic for 30 minutes after your vaccination today. (If the vaccine provider has any concerns, they should check with a specialist immunisation clinic).
- Do you have a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment?
    - If yes, please note we require you to stay at the clinic for 30 minutes after your vaccination today. (If the vaccine provider has any concerns, they should check with a specialist immunisation clinic).
- Do you have a bleeding disorder or are receiving anticoagulant therapy (a blood thinner)?
    - If yes, are they stable and established?
        - If yes, they can continue with vaccination.
        - If no, they should have a blood test to confirm their INR or anti-Xa.
- Do you have a history of the following cardiac conditions? Recent inflammatory cardiac illness (e.g., myocarditis, pericarditis, or endocarditis in the last 3 months), acute rheumatic fever, acute rheumatic heart disease or acute decompensated heart failure? * *For mRNA vaccines only.*
    - If yes, mRNA vaccines can still be received, however, consultation should occur with a GP, immunisation specialist or cardiologist about the best timing of the vaccination and whether any additional precautions are recommended (ATAGI & CSANZ, 2021).
- Are you pregnant, planning to become pregnant, or breast feeding?
    - If yes, pregnant women should be routinely offered a mRNA COVID-19 vaccine at any stage of pregnancy. People who cannot access an mRNA vaccine can consider vaccination with Novavax (NUVAXOVID) if the benefits to the individual outweigh the potential risks. Women who are trying to become pregnant do not need to delay vaccination or avoid getting pregnant after vaccination.
    - Health professionals should refer to the additional information is provided in the COVID-19 vaccination shared decision guide for women who are pregnant, breastfeeding or planning pregnancy.
- Are you immunocompromised?
    - If yes, vaccination should continue unless they have any precautions or contraindications. The person may have a reduced response to vaccines and may be recommended a third primary course dose.
- Do you currently have, or have you recently been diagnosed with COVID-19?
    - If yes, they should be advised to leave the vaccination clinic due to the risk of exposure to others.
    - People who have received an anti-SARS-CoV-2 monoclonal antibody or convalescent plasma as part of treatment for COVID-19 should defer future doses of COVID-19 vaccines for at least 90 days.
    - People with SARS-CoV-2 infection are recommended to be vaccinated **6 months** after a confirmed SARS-CoV-2 infection.
- Do you have any respiratory symptoms?
    - If yes, vaccination may need to be delayed.

Topic 4: The Australian Immunisation Register (AIR) reporting requirements

The AIR is an important national record of vaccines given to individuals of all ages in Australia. This includes school vaccination programs, pregnancy vaccinations, booster doses, the annual influenza vaccine and now the COVID-19 vaccines.

Entering in all administered doses of COVID-19 vaccinations into the AIR promptly is mandatory, ideally within 24 hours (ATAGI, 2021b). A new required field when submitting a record to the AIR is the serial number (if available) as well as the existing batch number field, this will be critical to tracing COVID-19 vaccines in the community. The *Australian Immunisation Register Act 2015* has been updated to include the mandatory requirement to record COVID-19 vaccination and is available here.

The AIR serves many purposes including:

- Keeping an up-to-date electronic database of vaccinations given to individuals, for individuals and vaccine providers to review.
- Evaluating vaccination coverage across Australia and identifying at-risk areas due to low coverage.
- Monitoring the effectiveness of vaccines in preventing vaccine-preventable diseases.
- Notifying individuals of due vaccines and acknowledging when vaccination courses are complete.

Keeping the AIR up to date for the COVID-19 vaccine helps:

- Determine an individual's immunisation status, regardless of where they received their vaccination.
- Allow for one central access point which can be accessed by consumers to download an immunisation history statement to prove their immunisation status for childcare, school, employment or travel purposes.
- Monitor immunisation coverage levels and service delivery, which can help to identify regions at risk during disease outbreaks.
- Measure vaccination coverage at a local, state and national level

(Services Australia, 2020).

The AIR has a variety of uses and functions including:

- Record individual immunisation information.
- Update or correct some data already entered.
- Request reports of individuals who are due or overdue for a vaccination.
- Report immunisation medical exemptions (if eligible to do so).
- Get information payments for the provision of certain vaccinations (if eligible to do so)

(Services Australia, 2020).

If a third primary dose or booster dose of COVID-19 vaccine is required, it can be entered into the AIR as per usual practice as there are no restrictions in place for this. The AIR is unable to differentiate between third primary course doses and booster doses. Entering additional doses does not affect an individual’s vaccination status.

Medical exemptions: COVID-19 vaccines are not mandatory and are not associated with 'no jab, no pay' or 'no jab, no play' policies. However, some workplaces may request vaccination or their employees if at high risk, it may be required for future travel or to visit an aged care facility etc.

It is therefore necessary to identify any medical criteria for COVID-19 vaccination to be deferred or an exemption applied and entered into the AIR. Medical exemptions can be applied for in the same way as currently done as the IM011 form is currently been updated.

For further information on acute major medical conditions which warrant a temporary medical exemption relevant for COVID-19 vaccines please review the ATAGI Expanded Guidance on temporary medical exemptions for COVID-19 vaccines.

COVID-19 booster doses

ATAGI recommends a primary course of vaccination against COVID-19, followed by a booster dose for those eligible under the updated recommendations, even in individuals who have had past infection. Adults who have already been infected with an Omicron subvariant and vaccinated with 2 or 3 doses of COVID-19 vaccine are at lower risk of reinfection and hospitalisation compared to those who have been infected but not vaccinated. The recommended interval between the last COVID-19 vaccine dose or confirmed SARS-CoV-2 infection and the 2023 booster dose is 6 months or longer, regardless of the number of prior doses received.

There is no upper time limit between the administration of doses. The schedule should always be continued from where last left off and NOT repeated or started again. However, vaccine effectiveness wanes over time, and timely receipt of boosters is encouraged.

Topic 5: The AIR 'how to' guide

Several options and methods will be available for vaccine providers to log into and enter information into the AIR. These methods include:

- Directly through a Provider Digital Access (PRODA) account.
- Through practice management software.
- Through My Health Record.
- Through the Clinician Vaccine Integrated Platform (CVIP) application.

The new vaccine application called Clinician Vaccine Integrated Platform (CVIP) integrates with the AIR and provides prompts for assessing safety prior to administration as well as incorporating a vaccine label scanner for administrative purposes. Further details on the CVIP is available here

The COVID-19 vaccine is voluntary and free. Consumer information and privacy are strictly protected. General privacy information can be found on the Australian Government COVID-19 vaccines privacy information page and the privacy policy for the AIR can be found here.

Combined COVID-19 vaccine information and consent forms are now available for parents and guardians on the following webpages, COVID-19 vaccines for children and COVID-19 vaccination – Patient resources. The consent forms require the parent/guardian to confirm that they have the authority to provide consent on behalf of that child. The consent forms require the parent/guardian to confirm that they have the authority to provide consent on behalf of that child.

It is mandatory that all administered doses are entered into the AIR. Regardless of the method used to enter administration data into the AIR, it is expected that vaccine providers will enter in data within 24 hours from vaccine administration. Prior to vaccine administration, providers must first

check the individual's vaccine history to check for previous COVID-19 vaccinations received and other comments of note such as allergies.

Access to the AIR through My Health Record provides consumers and providers with best practice clinical workflow behaviours. It provides a view of immunisation data, allergy and medicine information.

Provider digital access (PRODA) and Health Professional Online Services (HPOS):

To access the AIR through the hosting site, Health Professional Online Services (HPOS), you will need to first sign up for a free Provider Digital Access (PRODA) account for individuals (as of 7 December 2020).

Anyone working in healthcare services can register for a PRODA account. Account logins CANNOT be shared with other users; each user must have their own account.

PRODA authenticates your login and does not require you to download or install anything. One of the following browsers is required as a minimum: Internet Explorer 9, Mozilla Firefox 30, Google Chrome 39 or Safari 5.

Visit the PRODA registration page if you don't already have one. For instructions and help with setting up a PRODA account, view the help guide. After creating an individual login, you may also need an organisational login. For assistance in setting up an organisation PRODA account view this help guide.

Once a PRODA account is opened, access to the AIR can be set-up. Medical practitioners, endorsed midwives and nurse practitioners who have a Medicare provider number are automatically recognised as vaccination providers. They can record and extract data from the AIR.

Other eligible health professionals and organisations can apply to become recognised vaccination providers and access the AIR. This may be as a delegate or as a member of a medical practice or organisation. If you are unsure of your status as a vaccination provider or need help with understanding your delegation in HPOS, first review this NCIRS guide, or alternatively you can call the AIR on 1800 653 809 for general assistance and enquires.

A PRODA authentication login can also be used to access other health provider services that you are eligible for, including but not limited to:

- Medicare online.
- Pharmaceutical Benefits Scheme (PBS) online.
- Aged Care Provider Portal.
- Practice Incentives Program (PIP).

Use your PRODA account to log in to the AIR through HPOS using this link. Confirm the person's details and check their vaccination history. After the new vaccination encounter has been entered, double-check the information.

For a full guide on how to use the AIR, including all interactions, view the help using AIR online webpage. Services Australia also has an e-learning education module that can be worked through to assist you further in signing up and using these services.

Practice management software:

Practice management software or pharmacy professional service software is the easiest way to report vaccinations given in a General Practice (GP) or community pharmacy facility. The latest version of the software must be used, or you may experience issues with the information not being reported to AIR as expected.

Before submitting each vaccination, check the individual's record again to ensure you have the correct person and have entered accurate details about the vaccine brand, batch number and serial number. Once submitted, check the transmission and exception reports to ensure vaccination records have been submitted to AIR without error.

Recognised vaccination providers can also add vaccines administered overseas if the relevant documents are in English (Services Australia, 2020).

Manual AIR entry:

As the least preferred option, AIR data can be entered through a manual paper-based form. This should only be utilised when necessary, such as a system outage, lack of power and/or internet at the vaccinating facility.

Checking immunisation history:

After receiving the COVID-19 vaccine consumers may need to have a record of their immunisation history for various reasons. My Health Record (MHR) will play a key role for the consumer in accessing their immunisation history and receiving notifications (DHAC, 2021).

There are three ways that a consumer can get their history statement. The preferred way is online through their My Health Record, or alternatively through their Medicare account, either through MyGov or their Express Plus Medicare mobile app.

Vaccination providers can provide this as a printout through My Health Record if the consumer does not have an online Medicare login or access. However, depending on where and how your clinic/facility is set up for the extraordinary roll-out of COVID-19 vaccines, this may not be possible.

The third option consumers have is to call the AIR or Medicare and they can print out a summary and send it to them through the post. Postal delivery of the immunisation history can take up to 14 days to arrive.

If a third primary dose is being considered for administration, clinicians need to ensure that this is consistent with the person's medical history, COVID-19 immunisation history and the ATAGI clinical guidance on 3rd doses.

Read through this helpful webpage and refer consumers here as needed: How to get an immunisation history statement - Services Australia or here to the Department of Health *Check Immunisation history* website.

The Department of Health COVID-19 vaccines landing page will have all related information for consumers to be able to check their eligibility, register for a vaccination, check their adverse events and access their immunisation record.

Module summary

- You are responsible for checking your scope of practice, recency and other requirements to administer the COVID-19 vaccination in your jurisdiction.
- Currently, the only known true contraindication of receiving a COVID-19 vaccination is anaphylaxis from the same vaccine or vaccine components previously.
- Some people may not be recommended to receive a COVID-19 vaccine. This includes people who:
    - Are under 6 months old.
    - Have allergies to any of the ingredients to the vaccines.
    - Are acutely unwell with a fever (≥38.5◦C).
    - Have respiratory symptoms.
- Some people may have a temporary exemption for meeting COVID-19 vaccination requirements.
- Pre-vaccination screening must be completed after determining eligibility and gaining consent at every vaccine encounter.
- All COVID-19 vaccinations administered must be entered into the AIR as soon as possible, ideally within 24 hours to ensure the information contained within AIR is up to date.
- All immunising healthcare workers need access to the AIR either through practice management software, directly through PRODA, My Health Record, the CVIP app or, as a last resort, a manual paper-based report.

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Multi-choice Questions:

1. 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

2. Under which of the following circumstances would a COVID-19 vaccine NOT be recommended?

    a. Received influenza vaccine 9 days ago
    b. Having a fever at 38.6°C
    c. Previously been diagnosed with COVID-19 and now recovered
    d. An 18 year old adolescent

3. 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

4. How can consumers obtain a copy of their immunisation history showing that they have received the COVID-19 vaccination?

    a. Online through their Medicare account or Express Plus Medicare mobile app
    b. The vaccination provider can print it out for them
    c. Through calling the AIR who can print it out and post it
    d. Through My Health Record
    e. All of the above

Module 6 – Safety, surveillance and reporting for adverse events following COVID-19 vaccination (21/09/2023)

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 30 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete and progression to Additional Modules can occur.

Learning objectives

At the end of Module 6, it is expected that you will be able to:

- Understand the potential symptoms of an adverse event following vaccination (for specific vaccines see additional modules).
- Understand the appropriate monitoring, managing and reporting of adverse events following immunisation (AEFI) for COVID-19 vaccines, including understanding the minimum observation period post-vaccination (for specific vaccines see additional modules).
- Understand and be able to advise patients how to access advice and support if they are concerned or they are experiencing an adverse event, including the appropriate digital channels they can use.
- Understand the ongoing surveillance and reporting that occurs for safety following Therapeutic Goods Administration (TGA) approval.

Topics

1. Post administration and patient education
2. Adverse events following immunisation (AEFIs)
3. Managing AEFIs
4. Monitoring and reporting AEFIs
5. Ongoing surveillance and reporting

Topic 1: Post administration and patient education

A vaccine encounter is not complete after vaccine administration.

The syringe and needle must be disposed of in an approved sharps container immediately following injection. DO NOT recap the needle.

In case of any injection site bleeding, cover with a dry cotton ball and tape. Instruct the person receiving the vaccine not to rub the site as this may encourage the vaccine to move up the needle track through to the skin and may cause an increased localised adverse event. Instead, gentle pressure can be applied for 1 to 2 minutes (Australian Technical Advisory Group on Immunisation [ATAGI], 2022q).

After a few minutes, remove the cotton wool and expose the injection site to the air (ATAGI, 2022q).

Documentation through the Australian Immunisation Register (AIR) (covered in Module 5, Topic 4) must occur after the vaccination has been administered.

The consumer must then wait for at least 15 minutes at the facility or clinic as a compulsory observation period to monitor for any signs of adverse events. Anaphylaxis and other allergic reactions normally occur within 15 minutes from the time of exposure (ATAGI, 2022q). Rapid medical care can then be given if required.

Any potential adverse events should be discussed with the consumer whilst gaining consent for the vaccination, prior to administration of the vaccine (covered in Module 3, Topic 7).

Before leaving the facility or clinic, the consumer can be given a written copy of any expected adverse events that may occur and how to manage these. This resource needs to be developed and produced by your facility or state and territory health department. Alternatively, the consumer can be directed to these online resources:

- Consumer medication information (CMI) for the Pfizer (COMIRNATY) (purple cap) vaccine
- Consumer medication information (CMI) for the Pfizer (COMIRNATY) (orange cap) vaccine
- Consumer medication information (CMI) for the Pfizer (COMIRNATY) (maroon cap) vaccine
- Consumer medication information (CMI) for Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)
- Consumer medication information (CMI) for Pfizer bivalent BA.1 (COMIRNATY) (grey cap)
- Consumer medication information (CMI) for the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine
- Consumer medication information (CMI) for the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine
- Consumer medication information (CMI) for the Novavax (NUVAXOVID) vaccine
- Healthdirect COVID-19 vaccination
- Department of Health and Aged Care – COVID-19 website
- COVID-19 vaccination – Patient resources
- COVID-19 vaccine consent form
- Pfizer information and consent form for parents and guardians of children aged 5 to 11 years

Paracetamol and ibuprofen are not routinely recommended to be taken post-COVID-19 vaccination. However, they can be taken to alleviate pain and swelling adverse events if required (ATAGI, 2021b).

Topic 2: Adverse events following immunisation (AEFIs)

All vaccines can cause side-effects. Usually, only mild effects are experienced which disappear within a few days. Common side-effects for COVID-19 vaccines are no exception as they are reactogenic so mild reactions are very common (ATAGI, 2021b).

An AEFI is any expected or unexpected negative reaction that follows an immunisation. The vaccine does not need to have specifically caused the AEFI; it may have occurred coincidentally. However, all

events are recorded as such for safety (ATAGI, 2022q; Department of Health and Aged Care [DHAC], 2019b).

An adverse event includes any of the following:

- Unfavourable or unintended sign.
- Unfavourable or unintended symptom.
- A disease.
- Abnormal laboratory finding.

AEFIs can be classified from very common to very rare, depending on the frequency of occurrences.

- Very common (>10% of people vaccinated).
- Common (1–10%).
- Uncommon (0.1 to <1%).
- Rare (0.01% to <0.1%).
- Very rare (<0.01%).

Very common and common side-effects include:

- Muscle pain.
- Joint pain.
- Chills and fever.
- Fatigue/tiredness.
- Headache.
- Pain or swelling at the injection site.
- Redness or itching at the injection site (Novavax (NUVAXOVID) vaccine only).
- Nausea (Novavax (NUVAXOVID) vaccine only).
- Pain in the extremity (Novavax (NUVAXOVID) vaccine only).

(Department of Health and Aged Care, 2021d; ATAGI, 2021c; ATAGI, 2021o; ATAGI, 2021p)

Some of the side-effects may temporarily affect the individual's ability to drive or use machines (Pfizer Australia, 2021a).

Injection techniques and risk of adverse events following COVID-19 vaccination

ATAGI is aware of scientific reports proposing that inadvertent injection of a COVID-19 vaccine into a blood vessel may be a contributing cause of serious adverse events following immunisation, such as thrombosis with thrombocytopenia syndrome (TTS) and myocarditis. ATAGI has reviewed the available evidence and considers injection technique highly unlikely to be a contributor to these adverse events, for several reasons:

- The majority of cases of TTS occur after the first dose of previously supplied AstraZeneca (VAXZEVRIA) vaccine. The majority of myocarditis cases occur after the second dose of the mRNA vaccines such as Pfizer (COMIRNATY) (purple cap) or previously supplied Moderna (SPIKEVAX) (red cap). If intravascular injection was an important contributor, there would not be this differential distribution of cases by vaccine dose.
- Direct injection into a blood vessel is unlikely in recommended injection sites.
- TTS typically occurs some days or even weeks after vaccination, which does not fit with the proposed theory of direct vascular injury which occurs early in animal models.

(DHAC, 2021j)

Based on a review of the available evidence, **ATAGI does not recommend routinely aspirating (drawing back) needles before injection**. This practice was rejected some decades ago, due to several disadvantages including prolonging the procedure, potentially associated pain, and increasing the risk of needle-syringe disconnection. Not aspirating is supported by the current advice in the Australian Immunisation Handbook (ATAGI, 2022q).

ATAGI will continue to review emerging evidence on the underlying mechanisms, prevention and treatment of TTS, myocarditis and other serious adverse events of special interest.

Other side-effects:

Less common side effects may include:

- Enlarged lymph nodes.
- Pain in the limb.
- Insomnia.
- Feeling unwell (Pfizer (COMIRNATY) vaccines only).
- Redness and itching at the injection site (Pfizer (COMIRNATY) vaccines only).
- Nausea (Pfizer (COMIRNATY) vaccines only).
- Lymphadenopathy/lymphadenitis/lymph node pain/axillary mass (Novavax (NUVAXOVID) vaccine only).
- Hypertension (Novavax (NUVAXOVID) vaccine only).
- Rash and erythema (Novavax (NUVAXOVID) vaccine only).
- Pruritus (general and injection site) and urticaria (Novavax (NUVAXOVID) vaccine only).

(Department of Health and Aged Care, 2021d; ATAGI, 2021c; ATAGI, 2021o; ATAGI, 2021p)

Allergies - A severe allergic reaction or anaphylaxis can occur with any medication. The risk is rare, but consumers and healthcare professionals must be prepared for this event. As covered in Module 4, Topic 1, a resuscitation or anaphylaxis kit must be present at every vaccination facility/clinic (ATAGI, 2022q).

The Australasian Society of Clinical Immunology and Allergy (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.

Thrombosis with thrombocytopenia syndrome (TTS) – Very rare cases of TTS were reported following administration of the previously supplied AstraZeneca (VAXZEVRIA) between 4 to 30 days after vaccination (ATAGI, 2021d).

mRNA vaccines such as Pfizer (COMIRNATY) and Moderna (SPIKEVAX), and the Novavax (NUVAXOVID) vaccines are not associated with a risk of TTS (ATAGI, 2021b).

More information about the benefits and risks regarding the AstraZeneca (VAXZEVRIA) vaccine can be found here.

Myocarditis and pericarditis - A very rare risk of myocarditis and pericarditis has been observed in people who have received mRNA COVID-19 vaccines (Pfizer (COMIRNATY) and Moderna (SPIKEVAX) vaccines) in overseas studies, particularly in males under 30 years of age after the second vaccine dose.

The risk of myocarditis or pericarditis following Moderna bivalent (SPIKEVAX) and Pfizer bivalent (COMIRNATY) vaccines have not yet been characterised, as these vaccines have not been used extensively in large populations. ATAGI states there is no reason to believe the safety of the Moderna bivalent (SPIKEVAX) and Pfizer bivalent (COMIRNATY) vaccines are any different to other Moderna (SPIKEVAX) or Pfizer (COMIRNATY) original (ancestral) vaccines (ATAGI, 2022m; ATAGI, 2022o).

Providers should be aware of warning signs of a severe condition associated with myocarditis and pericarditis. Symptoms typically appear within 1-5 days of vaccination and include chest pain, palpitations (irregular heartbeat), syncope (fainting), or shortness of breath. People who experience any of these symptoms after having an mRNA COVID-19 vaccine should seek prompt medical attention.

Minimising the risk of AEFIs:

Completing a pre-vaccination screening checklist can reduce the chances of AEFI by identifying people with contraindications or at increased risk of an AEFI before administration. The Australian Immunisation Handbook (AIH) pre-vaccinating screening checklist should be used in conjunction with any vaccine specific precautions and contraindications information. Ensure you follow all facility and state or territory requirements on pre-vaccination screening processes.

Care should be taken to follow all manufacturer's recommendations around vaccine preparation and administration as covered in Module 4, and the vaccine specific additional modules as this reduces the risk of adverse events.

COVID-19 vaccines should be administered as intramuscular injections (IM) only. Injecting these vaccines subcutaneously may increase the risk of an adverse events. A safe and effective injection technique is also important to ensure the needle reaches the muscle and is pulled out at the same angle as it was inserted.

Topic 3: Managing AEFIs

Expected and common side-effects are related to the immune system being activated by the injected antigen and from the action of injecting liquid into a muscle through a needle.

Most common AEFIs are mild and self-limiting for 1 to 2 days. To help manage pain and swelling, a cold compress or icepack wrapped in a cloth can be used on the injection site. Paracetamol and ibuprofen are not routinely recommended to be taken post COVID-19 vaccination. However, they can be taken to alleviate pain and swelling adverse events if required (ATAGI, 2021b).

It is possible that signs and symptoms following vaccination are from an illness and not related to the vaccine. Therefore, medical advice should be sought if unexpected, serious or prolonged AEFIs occur (ATAGI, 2022q). Consumers should be advised to monitor any symptoms they may have post vaccination and seek medical advice if they arise. Consumers can contact the Healthdirect hotline on 1800 022 222 or contact their local health service.

Clinical management and advice may be required for some individuals who present with AEFIs. If expert advice is needed, then contact medical specialists who are experienced in managing patients with AEFIs. Individual State and Territory immunisation contacts and immunisation specialists can be found here.

The National Centre for Immunisation Research and Surveillance (NCIRS) have a *Vaccine Safety* page outlining passive and active surveillance and presenting a brief overall guide to different types of AEFI.

Anaphylaxis:

Anaphylaxis is a medical emergency and while rare, all immunising healthcare professionals must be able to recognise the signs and symptoms. It is also vital to be able to distinguish anaphylaxis from convulsions or a vasovagal episode (DHAC, 2019b).

A vasovagal episode may occur following administration and can be a similar presentation to anaphylaxis. During a vasovagal or syncope episode the person may have bradycardia with a good carotid pulse, sweating, generalised pallor, normal breathing and no signs of a rash (ATAGI, 2022q).

Anaphylaxis is characterised by sudden respiratory compromise and/or circulatory collapse (ATAGI, 2022q).

While anaphylaxis has been reported up to 6 hours after vaccination, it usually occurs rapidly and within the first 15 minutes after administration.

Early signs and symptoms of anaphylaxis include:

- Generalised erythema (skin).
- Urticaria (skin).
- Angioedema (skin).
- Diarrhoea (gastrointestinal).
- Nausea and vomiting (gastrointestinal).

(ATAGI, 2022q)

Severe cases include:

- Circulatory collapse (cardiovascular).
- Hypotension (cardiovascular).
- Weak or absent pulse (cardiovascular).
- Altered consciousness (neurological).
- Marked respiratory compromise from airway oedema or bronchospasm (respiratory).

(ATAGI, 2022q)

Prompt identification, management and treatment with intramuscular (IM) adrenaline is required. Adrenaline from a 1:1000 vial should be administered based on the equation of 0.01mL/kg of body weight up to a maximum of 0.5mL or 0.5mg.

If the person requiring adrenaline is ≥50kgs (age ≥14 years on average), 0.5mL will be recommended (ATAGI, 2022q).

If treating a person who is <50kgs you will need to calculate their dose based on the recommendation of 0.01mL/kg. For assistance with calculating the adrenaline dosage the doses of intramuscular 1:1000 adrenaline for anaphylaxis page in the Australian Immunisation Handbook (AIH).

The *Table. Recognition and treatment of anaphylaxis* in the AIH can be used for further assistance in treating and managing anaphylaxis (ATAGI, 2022q).

Managing anaphylaxis protocol:

- If the individual is unconscious, lie them in the recovery position on their left and keep their airway clear.
- If the individual is conscious, lie them on their back with their feet elevated and head down (unless this results in breathing difficulties).
- If the individual has respiratory or cardiovascular symptoms or other signs of anaphylaxis, give a deep IM injection of adrenaline into the **anterolateral thigh** using a 1mL syringe and 25mm needle (22 or 23 gauge) unless the person is very large or obese, in which case a 38mm long needle is recommended.
- Call for help, but never leave the person alone.
- Give oxygen via a face mask at a high flow rate, if available.
- IM adrenaline should be given every 5 minutes if their condition does not improve.
- Monitor airway, breathing and circulation (ABC). If the individual is not breathing, start CPR as per the Australian Resuscitation Council Guidelines.
- Transfer the individual to a hospital for observation and treatment, even if they recover following adrenaline administration.
- Document all events and actions taken, including the time of all adrenaline given.

(ATAGI, 2022q)

It is **NOT** recommended to use antihistamines or hydrocortisone to treat anaphylaxis as this is a medical emergency. IM adrenaline is required (do not give IV) (ATAGI, 2022q).

The Australasian Society of Clinical Immunology and Allergies has an e-learning module on anaphylaxis management for health professionals. If you have any doubts or concerns regarding managing suspected anaphylaxis, you would be recommended to complete this module.

Generalised reactions such as a skin rash and angioedema without cardiovascular or respiratory compromise do not need to be treated with adrenaline. However, if in doubt give adrenaline as no serious or permanent harm is likely to occur from administering adrenaline when not required (ATAGI, 2022q).

To view more details, view the *Table. Recognition and treatment of anaphylaxis* in the AIH. A printable infographic may also be helpful to have printed at your facility; this can be found in the AIH under Managing anaphylaxis.

If a person has their own autoinjector with them, it is appropriate to use this as required to administer the adrenaline. The autoinjector should be administered in the mid-outer thigh (ATAGI, 2022q).

Figure 1. *How to give EpiPen* (ASCIA, 2018).

Vasovagal episode:

A vasovagal episode (fainting) is the most common immediate AEFI. Fainting after vaccination can be serious. Instruct the person to lie down somewhere safe if they are feeling dizzy or light-headed until they feel better (ATAGI, 2022q). Help them to loosen tight clothing and elevate their legs to promote venous return (DHAC, 2019b).

The key differentiating sign between anaphylaxis and a vasovagal episode is that the central (carotid) pulse is weak or absent during anaphylaxis but is strong during a vasovagal episode or convulsions. For more information about distinguishing between anaphylaxis and a vasovagal episode, view this *Table. Clinical features that may help differentiate between a vasovagal episode and anaphylaxis* in the AIH (ATAGI, 2022q).

If a person is going to faint, this normally happens within 5 minutes of administration. 98% of people who faint following vaccination have done so within 30 minutes (DHAC, 2019b).

No specific treatment is required for a vasovagal episode other than to lie the person down until they feel better and monitor closely.

Thrombosis with thrombocytopenia syndrome (TTS)

Healthcare professionals should be alert to the signs and symptoms of TTS as well as coagulopathies. Vaccinated individuals should be instructed to seek immediate medical attention if they develop symptoms of thrombosis such as:

- New onset of a severe persistent headache which does not improve with simple analgesia.
- Signs and symptoms of raised intracranial pressure or focal neurological deficits including blurred vision, or seizures.
- Signs or symptoms suggestive of thrombosis in other anatomical locations, eg:
    - Shortness of breath or chest pain suggestive of pulmonary embolism.
    - Leg swelling suggestive of lower limb embolism.

    - Persistent abdominal pain suggestive of thrombosis in the splanchnic circulation.
- Signs suggestive of clinically significant thrombocytopenia, such as petechial rash or bleeding, or bruising not at the vaccination site that cannot be explained.

(ATAGI, 2021f; ATAGI, 2021h)

Although the COVID-19 vaccine AstraZeneca (VAXZEVRIA) is no longer supplied, any patient with concerning signs or symptoms potentially relating to TTS following receipt of the AstraZeneca (VAXZEVRIA) vaccine should be referred to an emergency department for assessment and investigation, including consultation with a haematologist (ATAGI, 2021h).

DO NOT give a person with suspected or confirmed TTS heparin or platelet transfusions (ATAGI, 2021h). These treatments can potentially worsen the clinical course.

There has not been a higher overall rate of relatively common types of blood clots (including deep vein thrombosis (DVT) and pulmonary embolism (PE) reported after COVID-19 vaccination (ATAGI, 2021f). Additionally, the overall rate of blood clots (1 per 1000) has not risen in countries that have extensively used the AstraZeneca (VAXZEVRIA) vaccine (DHAC, 2021h). Some of the blood clots that occur after administration of the AstraZeneca (VAXZEVRIA) vaccine will be coincidental and not causally related to the vaccine (ATAGI, 2021h).

Myocarditis and pericarditis – People presenting with any myocarditis or pericarditis symptoms within the first 2 weeks of receiving either a Pfizer (COMIRNATY) or Moderna (SPIKEVAX) vaccine should be assessed by a healthcare professional, and those who appear unwell should be referred immediately to an emergency department.

People who are diagnosed with myocarditis and/or pericarditis after an mRNA COVID-19 vaccine should be referred to a cardiologist for further assessment and management, to investigate for possible causes other than vaccination, and for follow-up. People who already have underlying heart dysfunction should seek medical attention for new-onset or worsening of pre-existing symptoms following vaccination.

For more information and detailed assessment and management please review the COVID-19 vaccination – Guidance on myocarditis and pericarditis after COVID-19 vaccines publication.

Topic 4: Monitoring and reporting of AEFIs

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 (Offit, Davis & Gust, 2017).

Normally, mild, common and very common AEFIs which are expected are not reported (ATAGI, 2022q; DHAC, 2019b). However, as these COVID-19 vaccines are new medicines, they are subject to additional monitoring. Health professionals are strongly encouraged to report all side-effects for analysis and ongoing surveillance (DHAC, 2021d; Pfizer Australia, 2021a;).

The Black Triangle Scheme is the identification system the TGA use for new medicines to provide a simple means for health professionals and consumers to identify a new medicine. A upside down black triangle is located at the top of the consumer information and product information sheets to easily identify these medicines. Next to the black triangle, text will state that the product is subject to additional monitoring which will be in place for 5 years (TGA, 2018).

Once a COVID-19 vaccine is approved, the Therapeutic Goods Administration (TGA) continues to monitor its safety and effectiveness. Australia has robust procedures to quickly detect and respond to vaccine safety concerns.

State and territory reporting:

Information about how to report suspected adverse events associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side-effects directly to the TGA

In New South Wales, Western Australia, Queensland, Northern Territory, South Australia and the Australian Capital Territory, health professionals are required under public health legislation to notify AEFIs to the relevant health department. AEFI reporting is not currently mandated in Victoria or Tasmania but is strongly encouraged. These reports are then submitted to the TGA and entered into the Adverse Event Management System (AEMS).

All immunisers are strongly encouraged to report ALL adverse events following COVID-19 vaccination that are serious, unexpected or require medical attendance through the available channels, which are the same as used for reporting on other National Immunisation Program (NIP) vaccines, shown in the table below (ATAGI, 2021b).

Please refer to the TGA website for more information.

Where to report in each state /territory	
NSW	NSW Health website Additional COVID-19 AEFI reporting information.
Victoria	Victorian COVID-19 Vaccination Guidelines – for clinics using CVMS. Safevac – for clinics not using CVMS
Queensland	Queensland Health website
Western Australia	WA Department of Health website (WAVSS) SAFEVAC Reporting
ACT	ACT Health website Factsheet: COVID-19 vaccine enhanced surveillance and AEFI reporting for healthcare professionals COVID-19 Vaccine AEFI reporting form
South Australia	SA Health website
Northern Territory	Recording and reports on immunisations – NT Department of Health
Tasmania	To Public Health Services, Department of Health Tasmania or Directly to the TGA

Sharing information

To make sure that stakeholders have the most up-to-date information on AEFIs occurring in Australia, the TGA meets weekly with Jurisdictional Immunisation Coordinators (JICs) from each state and territory, as well as representatives from the National Centre for Immunisation Research and Surveillance (NCIRS) and Surveillance of Adverse Events Following Vaccination In the Community (SAEFVIC).

During these meetings, the group discusses particularly serious or clinically significant AEFI reports and related information (such as the state or territory where the AEFI occurred and the age and gender of the patient).

Topic 5: Ongoing surveillance and reporting

Vaccine preventable disease surveillance, as well as surveillance of other communicable diseases, is well established in Australia. The National Notifiable Diseases Surveillance System (NNDSS) co-ordinates that national surveillance of more than 50 communicable diseases or disease groups that are that are listed on the National Notifiable Disease List. The NNDSS is overseen by the Australian Government Department of Health in coordination with the Communicable Diseases Network Australia (CDNA) (DHAC, 2015).

Under this scheme, notifications are made to the States or Territory health authority under the provisions of the public health legislation in their jurisdiction. De-identified data on notifications of notifiable diseases are collated and analysed by the Department of Health, with summary data tables published daily to the internet here (DHAC, 2015).

For COVID-19, a weekly summary of the situation is published on the Australian Government, Department of Health and Aged Care website and an epidemiological summary of the situation is published fortnightly in the *Communicable Diseases Intelligence* journal.

Therapeutic Goods Administration (TGA):

The TGA is responsible for monitoring the safety of all vaccines approved for use in Australia. The TGA closely assess safety data prior to approval and continues to monitor the safety of vaccines after they are registered in Australia so that the TGA can detect and respond to any safety concerns. This is known as 'pharmacovigilance'.

The TGA's safety monitoring processes for vaccines are robust and well established. They include collaboration with Australian stakeholders, including state and territory health departments and professional bodies, and international regulators. This enables the TGA to rapidly detect, investigate and respond to any emerging safety issues.

The TGA has developed a COVID-19 Vaccine Hub. The Hub is a repository for consumers, health professionals and sponsors to easily access information about COVID-19 vaccine regulation activities.

Vaccine safety monitoring

The TGA, like other regulatory agencies around the world, continues to monitor the safety of vaccines and medicines after they are approved to contribute to a better understanding of their safety profile.

The TGA is the Government body responsible for ensuring that medicines and vaccines supplied in Australia continue to meet the required standards of safety, effectiveness and quality for their intended use. The TGA also has oversight of sponsors of vaccines and medicines who are legally responsible for monitoring the safety, quality and effectiveness of their products.

The existing safety monitoring system for vaccines involves:

- reviewing and analysing reports of suspected side effects (also known as adverse events) submitted by health professionals and consumers
- requiring pharmaceutical companies to have risk management plans for the vaccines they supply
- proactively reviewing medical literature and other potential sources of new safety information
- working with international regulators to assess significant side effects detected overseas
- working with state and territory health departments and clinical experts to ensure a coordinated approach.

Pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data, known collectively as their 'pharmacovigilance responsibilities'.

AusVaxSafety:

AusVaxSafety is the national safety surveillance initiative led by the NCIRS and funded by the Department of Health and Aged Care. AusVaxSafety is currently linked into medical software programs within General Practices, community immunisation clinics, hospitals and other vaccination clinics. This link generates an automatic text message to people who have received a COVID 19 vaccine to invite them to participate in a AUSVaxSafety survey and share their experience of receiving the vaccine.

AusVaxSafety covers three main areas:

- Active vaccine safety surveillance.
- AEFI Clinical Assessment Network.
- Vaccine safety in primary healthcare data.

AusVaxSafety generates weekly summaries detailing the rates of AEFI within days of COVID-19 vaccination by age, jurisdiction and vaccine brand. For more information about AusVaxSafety visit their FAQ page.

COVID-19 vaccine surveillance differences:

As part of the 2-year provisional approval which will be granted to successful vaccine candidates in Australia, strict conditions must be met for safety. The vaccine companies must continue providing

the TGA with long-term efficacy and safety reports from further clinical trials and post-market assessment (DHAC, 2021d).

The TGA has a comprehensive system is in place to capture reports of adverse events following COVID-19 vaccination, through:

- Australia's well-established safety monitoring processes for vaccines.
- Enhancements to vaccine safety monitoring as described in *the COVID-19 Vaccine Safety Monitoring Plan*.
- Active surveillance by SMS or email through AusVaxSafety.

Surveillance is particularly important for the new COVID-19 vaccines, and the specific safety profiles for each brand. This is important because vaccine confidence and uptake is closely related to vaccine safety.

The TGA will carry out a batch assessment as an extra safety measure. Each batch will be checked by the TGA before it can be distributed in Australia. Monitoring will occur in Australia and internationally. If the TGA have safety concerns following a batch assessment, the Australian Government, Department of Health will not hesitate to take action as safety is the most important factor (DHAC, 2021d)

Module Summary

- The minimum observation time following a COVID-19 vaccination is 15 minutes.
- AEFIs include all negative events that occur following an immunisation. Some are common, mild and expected. Some are rare and severe. Others may happen coincidentally but must still be reported for safety reasons.
- AEFIs are classified based on their prevalence, ranging from very common if they occur in >10% of vaccine recipients to very rare if they occur in <0.01% of vaccine recipients.
- AEFIs can be reduced by following best practice vaccination preparation and administration guidelines.
- Anaphylaxis is a medical emergency and should be treated with 0.5mL (assuming the person weighs ≥50kgs) of adrenaline 1:1000 IM injection in the anterolateral thigh every 5 minutes until improvement is seen.
- A vasovagal episode should be distinguished from anaphylaxis.
- AEFIs must be reported through your established state or territory reporting network. AEFIs can also be reported directly through the TGA.
- The TGA, AusVaxSafety and state and territory departments work closely to review and analyse surveillance data frequently.

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Multi-choice Questions:

1. What is the minimum observation time that an individual must remain at the clinic/facility after receiving a COVID-19 vaccination?

    a. 10 minutes
    b. 15 minutes
    c. 20 minutes
    d. 30 minutes

2. Most AEFI experienced are mild and self-limiting. Which of these adverse events are NOT considered as either common or very common?

    a. Headache
    b. Pain, redness and swelling at the injection site
    c. Chills and fever
    d. Enlarged Lymph nodes

3. Anaphylaxis is a very rare but serious medical emergency. Which of these statements is correct regarding all aspects of adrenaline administration?

    a. Adrenaline from a **1:1000 vial** should be used. The dose is **0.01mL/kg** body weight up to a maximum of **0.5mL or 0.5mg** in a person ≥50 kgs. Adrenaline is given **IM** into the **anterolateral thigh** every **5 minutes** as needed until the condition starts to improve.
    b. Adrenaline from a **1:1000 vial** should be used. The dose **is 0.1mL/kg** body weight up to a maximum of **0.5mL or 0.5mg** in a person ≥50 kgs. Adrenaline is given **IM** into the **deltoid** every **3 minutes** as needed until the condition starts to improve.

c. Adrenaline from a **1:1000 vial** should be used. The dose **is 0.1mL/kg** body weight up to a maximum of **0.5mL or 0.5mg** in a person ≥50 kgs. Adrenaline is given **IV** into the **anterolateral thigh** every **5 minutes** as needed until the condition starts to improve.
d. Adrenaline from a **1:1000** vial should be used. The dose **is 0.01mL/kg** body weight up to a maximum **of 0.5mL or 0.5mg** in a person ≥50 kgs. Adrenaline is given **IM** into the **deltoid** every **3 minutes** as needed until the condition starts to improve.

4. Anaphylaxis signs 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

5. 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

Additional Module 1a: Pfizer (BIVALENT) BA.1 COVID-19 Booster Vaccine

(21/09/2023)

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 15 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete.

Learning objectives

At the end of Additional Module 1a: Pfizer bivalent BA.1 (COMIRNATY) (grey cap) for individuals aged 18 years and older, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine for individuals aged 18 years and older.
- Understand the contraindications, warnings, adverse reactions, and recommendations for co-administration with other vaccines for the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine for individuals aged 18 years and older.
- Demonstrate appropriate dose preparation and verification before administration of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine for individuals aged 18 years and older.
- Understand the appropriate administration of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine for individuals aged 18 years and older.

Topics

1. Introduction and summary
2. Cold chain and storage
3. Preparation and administration
4. Precautions
5. Adverse events

Topic 1: Introduction and summary

This module builds on the Additional Module 1 (pre-requisite) and this module will not repeat the information covered in that module. As required, please review Additional Module 1.

The Pfizer/BioNTech (COMIRNATY) Original/Omicron BA.1 vaccine is also known as the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine (which term will be used in this module).

On 27 October 2022, the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine was provisionally approved by the Therapeutic Goods Administration (TGA) for use in individuals aged 18 years and older (TGA, 2022d).

This vaccine uses similar technology to the Pfizer (COMIRNATY) and Moderna (SPIKEVAX) vaccines to induce immunity.

The Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine contains 30mcg of mRNA, comprising equal quantities encoding the spike protein from the original SARS-CoV-2 virus and the Omicron BA.1 variant (i.e., one dose of 0.3mL contains 15 micrograms of tozinameran and 15 micrograms of riltozinameran) (TGA, 2022d).

Further information can be found on the Product information sheet and the Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance for COVID-19 vaccine providers. The Consumer Medicine Information (CMI) summary can also be given to individuals receiving the vaccine.

Vaccine recommendations

For people aged 18 years and older, ATAGI recommends to receiving either a BA.1-containing bivalent vaccine (e.g. Pfizer bivalent BA.1 (COMIRNATY) (grey cap)) or a BA.4-5-containing bivalent vaccine **for both the primary course and booster doses**.

Bivalent vaccines are designed to broaden cross-protection from vaccination against Omicron and its subvariants by including an Omicron strain in the vaccine. Circulating strains since 2022 have all evolved as subvariants from the first Omicron variant. Pre-Omicron variants no longer circulate, and reversion to a pre-Omicron variant by a future strain is considered unlikely.

ATAGI, therefore, considers the bivalent vaccines (which protect against either Omicron subvariants BA.1 or BA.4-5) preferable for use in a primary series. ATAGI notes that use of bivalent vaccines for primary vaccination is consistent with evolving advice from the World Health Organization's Strategic Advisory Group of Experts on Immunization (SAGE) and the European Medicines Agency's Emergency Task Force, and that off-label use has been permitted in the United Kingdom.

The safety of bivalent vaccines is similar to monovalent original vaccines when used as a booster dose. ATAGI has no additional concerns regarding the safety or effectiveness of bivalent vaccines compared with monovalent vaccines when used for a primary course.

The ATAGI COVID-19 2023 Booster Advice provides guidance on which individuals are recommended, or can consider, a COVID-19 vaccine booster dose for additional protection against severe COVID-19.

Booster doses of the COVID-19 vaccine should be given at least 6 months after the most recent COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (whichever is the most recent) (ATAGI 2022o; ATAGI, 2023a).

ATAGI **does not** currently recommend use of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) in anyone under 18 years as it is not registered for this age group.

The Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine is presented as a **grey-capped** multidose vial (MDV) (30 mcg/0.3mL). Each pack contains 10 MDVs:

- Six (6) doses (of 0.3mL volume each) can be withdrawn from each 2.25mL vial

When frozen the vaccine is a white to off-white suspension with a total volume of 2.25mL.

This product is a ready-to-use formulation and does not require dilution (TGA, 2022d).

The vial is made of glass with a synthetic bromobutyl rubber stopper and a **grey** flip-off plastic cap with an aluminium seal (TGA, 2022d).

Refer to *Table 1. Dose types and dose volume for Pfizer (COMIRNATY) vaccines for different age groups*.

Category	Pfizer (COMIRNATY) 10mcg/0.2mL concentrated suspension for injection vial	Pfizer (COMIRNATY) 30mcg/0.3mL concentrated suspension for injection vial	Pfizer bivalent **BA.1** 15/15mcg/0.3mL suspension for injection vial	Pfizer bivalent **BA.4-5** 15/15mcg/0.3mL suspension for injection vial
Approved age	5 to 11 years	≥ 12 years	**≥ 18 years**	**≥ 12 years**
Cap colour	Orange cap	Purple cap	Grey cap	Grey cap
ATAGI recommended indications	**Primary** and **booster** doses	**Primary** and **booster** doses	Preferred for **Primary** and **booster** doses	Preferred for **Primary** and **booster** doses
Dilution	Requires dilution	Requires dilution	**Do not dilute**	**Do not dilute**
Dose	10 micrograms	30 micrograms	30 micrograms	30 micrograms
Dose volume	0.2mL	0.3mL	0.3mL	0.3mL

Table 1. Dose types and dose volume for Pfizer (COMIRNATY) vaccines for different age groups.

Refer to *Table 2. Vial presentation differences for* P*fizer bivalent BA.1 (COMIRNATY) (grey cap) and Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) for different age groups.*

Category	**Pfizer bivalent BA.1 (COMIRNATY) (grey cap)** 15/15mcg/0.3mL suspension for injection vial	**Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)** 15/15mcg/0.3mL suspension for injection vial
Vial presentation	 © 2023 Pfizer Inc. All rights reserved.	 © 2023 Pfizer Inc. All rights reserved.
Approved age	≥ 18 years	≥ 12 years
Cap and label colour	Grey cap and grey border label	Grey cap and grey border label
ATAGI recommended indication	Preferred for **Primary** and **booster** doses	Preferred for **Primary** and **booster** doses
Dilution	**Do not dilute**	**Do not dilute**
Dose	30 micrograms	30 micrograms
Dose volume	0.3mL	0.3mL

Table 2. Vial presentation differences for Pfizer bivalent BA.1 (COMIRNATY) (grey cap) *and Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) for different age groups.*

Immunisation providers should be vigilant and note the subtle differences with the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine and the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine vials. Both these bivalent vaccines have a grey cap and grey border around the label; however, the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine is registered for people aged 18 years and over and has the naming convention as Tozinameran/Riltozinameran. Conversely, the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine has the naming convention as Original/Omicron BA.4-5 and is registered for people aged 12 years and older (ATAGI, 2023a).

Protection

In clinical trials conducted, all mRNA COVID-19 booster vaccine doses (bivalent and original) result in an improvement in the immune response against Omicron subvariants BA.1 and BA.4-5. The inclusion of BA.1 in bivalent vaccines is expected to provide a greater breadth of protection compared with ancestral vaccines against current and future Omicron sub-variants such as BQ.1 and XBB, though there are no published data yet to demonstrate this (ATAGI, 2022o).

In a clinical trial among people not immunosuppressed, aged over 55 years, the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine was administered as a second booster dose. The results of the trial have indicated that the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine induces a reasonably higher level of antibody response against the Omicron subvariants BA.1 and BA.4-5 compared to the Pfizer (COMIRNATY) (purple cap) vaccine (ATAGI 2022o).

Safety, reactogenicity and immunogenicity data are available from substudy E in participants 55 years of age and older (C4591031 trial). Evidence supporting the use of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine is limited to immunogenicity and safety data at 4 weeks after a second booster dose (fourth dose). In this study 305 people received the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine and 305 people received the Pfizer (COMIRNATY) (purple cap) vaccine as a second booster dose.

In people without prior infection, the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine provided 1.6 times (95% CI: 1.17, 2.08) higher neutralising antibodies compared to the Pfizer (COMIRNATY) (purple cap) vaccine against the Omicron BA.1 variant. Neutralising antibody titres were similar for the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) and Pfizer (COMIRNATY) (purple cap) vaccine against the original virus (geometric mean ratio 0.99 [95% CI: 0.82, 1.20]).

Provisional results from the clinical trials suggest that differences in the additional protection against COVID-19 from a bivalent booster over an original booster are relatively small compared to the difference in protection obtained from the original booster over receiving no booster at all.

There is no data available on the use of Pfizer bivalent BA.1 (COMIRNATY) (grey cap) in people aged < 18 years old and there are no studies currently that compare the Pfizer Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine with the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine.

Early immunogenicity and safety data on bivalent vaccines used as primary vaccination are limited. The safety of bivalent vaccines is similar to monovalent original vaccines when used as a booster dose. ATAGI has no additional concerns regarding the safety or effectiveness of bivalent vaccines compared with monovalent vaccines when used for a primary course (ATAGI, 2023d).

While there are currently no efficacy or effectiveness studies of bivalent vaccines when used for the primary vaccination course, early effectiveness studies of bivalent vaccines used as a booster dose suggest equivalent or better protection than original vaccines. There is no reason to expect that using bivalent vaccines for a primary vaccination course would differ (ATAGI, 2023d).

Protection against different variants

Pre-print studies have found that BA.4/5 bivalent vaccines induce an immune response against emerging sub-variants BQ.1.1 and XBB. These studies, however, have not yet been peer-reviewed. There are no published data on the immunogenicity of BA.1 bivalent vaccines against these newer sublineages (ATAGI 2022o).

Topic 2: Cold chain and thawing

Ultra-cold chain (UCC) storage for frozen vials

Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccines may be received frozen at **-90°C to -60°C.** Frozen vaccines can be stored either at **-90°C to -60°C for up to 18 months** or **+2°C to +8°C** for **up to 10 weeks** (TGA, 2022d).

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 **10 weeks** within the **18-month** shelf life. If the vaccine is received at +**2°C to +8°C** it should be stored at +**2°C to +8°C**. Upon moving the product to +2°C to +8°C storage, the use-by date must be written on the outer carton and the vaccine should be used or discarded by the earliest of both the thaw and manufacturer use-by dates.

All vials must be stored in their original carton to protect them from exposure to light including room and sun light (TGA, 2022d).

Thermal shippers will be used to deliver the vaccines. Thermal shippers are boxes that contain a freezer carton of 60 packs. The carton is submerged in dry ice pellets and can maintain UCC (-75^{o}C ± 15^{o}C) during transport.

Once empty of vials and before sending back, the thermal shipper should be left open in a well-ventilated area where the dry ice will readily sublime (melt from solid to gas) into carbon dioxide gas and dissipate. Dry ice should not be left unattended.

Cold chain breach

As per Additional Module 1.

Thawing

Pfizer bivalent BA.1 (COMIRNATY) (grey cap) MDV vaccines need to be thawed before use. An **unopened thawed** vial may be stored refrigerated at +2°C to +8°C for a single period of up to 10 weeks within the 18-month shelf life.

Thawing can occur by one of two methods:

- 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.
- Place the individual vials on a workbench for 30 minutes at temperatures **up to +30°C**. The vials must then be used immediately.

(Pfizer Australia, 2021b; TGA, 2022d)

By following one of the thawing methods above, the vial will be thawed. **DO NOT** shake the vial to confirm that vial has thawed.

Once thawed, Pfizer bivalent BA.1 (COMIRNATY) (grey cap) **CANNOT** be re-frozen (Pfizer, Australia, 2021b; TGA, 2022d).

Topic 3: Preparation and administration

Dose preparation

Prior to each vaccination, ensure **all** relevant expiry dates and times are checked.

Some providers will receive the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine thawed. **Unopened thawed vials** can be stored at **+2°C to +8°C** for a maximum of **10 weeks**.

Expiry dates must be followed precisely to prevent expired stock being administered. There are two expiry dates that must be observed on Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccines: the manufacturer expiry date and the thaw use-by date. Both must be checked prior to every vaccine administration.

The manufacture expiry date indicates the expiry for the vaccine when stored frozen. The thaw use-by date commences when the vials are removed from the freezer or UCC storage to commence thawing and may be written on either 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**.

To prevent administrative errors, all sites should clearly label the use by 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 (VAEs).

If vaccines are administered outside the revised expiry date, it is considered a VAE. The Vaccines Operations Centre (VOC) on **1800 318 208** is available to provide advice and guidance to clinicians regarding the management of VAEs. Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information (ATAGI, 2022a).

Before beginning any dose preparation or administration, double-check you have the correct vaccine brand and formulation: Pfizer bivalent BA.1 (COMIRNATY) (grey cap) **(i.e., Tozinameran/Riltozinameran 15/15mcg) and confirm the expiry date.**

The storage requirements, dosage and expiry for each vial type are different and great care must be taken to avoid any incorrect administration. It is recommended that facilities store the vaccines and supplies in dedicated containers in separate spaces, such as in clearly labelled shelves (or fridges, if possible) and use colour coding to differentiate between prepared doses of Pfizer bivalent BA.1 (COMIRNATY) (grey cap), Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), Pfizer (COMIRNATY) (maroon cap), Pfizer (COMIRNATY) (orange cap) and Pfizer (COMIRNATY) (purple cap) vaccines. Where possible, separate drawing-up spaces may be designated, with separate staff preparing each formulation.

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Pfizer bivalent BA.1 (COMIRNATY) (grey cap) **is a ready-to-use formulation and does not require dilution (TGA, 2022d).**

Only thawed vials can be opened in preparation for administration. The vial should contain white to off-white opaque amorphous particles prior to mixing (TGA, 2022d).

Gathering and preparing the vial for use:

1. Perform hand hygiene with either soap and water or an alcohol-based rub.
2. Clean and disinfect the separate area for preparation and procedure dish or tray.

3. Collect the required equipment (as outlined earlier in Module 4, Topic 2 in the 'vaccine administration checklist per person').
4. Remove the required vaccine vial (only 1 at a time) from the cold chain storage system used and check the temperature while doing so.
5. **Double check you have the correct vaccine** before opening the vial, ideally with another health professional if available, and as per your facility and jurisdictional policies.
6. Check the manufacturer expiry date, the thaw use-by date and the date and time that the vial was opened. **DISCARD** the vaccine if it exceeds any expiry date and time. If you are opening the vial for the first time, record the current date and time on the vial, before opening it.
7. Examine the vaccine vial gently and ensure there is no discolouration, turbidity or particulate matter as per the product information by **inverting it gently 10 times**. If you are unsure of its appearance, **DO NOT** use and seek advice from the VOC on **1800 318 208**.
8. Perform hand hygiene.
9. Open the vial (if applicable) and check the bung (also known as the septum/stopper/diaphragm) integrity.
10. Disinfect the bung using a 70% isopropyl alcohol wipe.
11. Allow to fully dry for 30 seconds.

DO NOT use if the vial has been opened without a date and time of opening.

To extract the full 6 doses from the MDV, low dead-volume syringes and/or needles are recommended when available. Care should be taken to draw up the dose volume exactly. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL, the vial and any remaining excess volume must be discarded as doses cannot be drawn from multiple MDVs (Pfizer Australia, 2021b; TGA, 2022d).

Storing vials and vaccine doses

After initial puncture, vials can be stored **up to 12 hours** at **+2°C +30 °C** and must be used within the 12 hours (Pfizer, Australia, 2021c). 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 from the time of initial puncture. **Do not re-freeze the 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.

Administration

As per Additional Module 1.

Dosing and schedule

For people aged 18 years and older, ATAGI recommends receiving either a BA.1-containing bivalent vaccine (e.g. Pfizer bivalent BA.1-5 (COMIRNATY) (grey cap)) or a BA.4-5-containing bivalent vaccine **for both the primary course and booster doses**.

Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine is administered as an intramuscular (IM) injection containing 0.3mL vaccine. The Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine contains 30mcg of mRNA (15 micrograms of tozinameran and 15 micrograms of riltozinameran).

A total of two primary course doses are required for most people. The recommended interval between two doses of Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine is 8 weeks (ATAGI, 2022f).

The extended dose interval of 8 weeks has been shown to improve the immune response to vaccination and therefore may improve effectiveness. A longer dose interval may also reduce the risk of myocarditis and pericarditis. The longer dose interval is particularly recommended for groups at higher risk of this side effect (those under the age of 40 years) (ATAGI, 2022f).

The dose interval can be reduced to a minimum of 3 weeks for people at higher risk of severe COVID-19 (including older adults and people with underlying medical conditions), in an outbreak setting, or prior to international travel (ATAGI, 2022f).

Severely immunocompromised individuals

A third primary dose of COVID-19 vaccine is recommended for all people aged 6 months or older with severe immunocompromise who are receiving a 2-dose primary course. The third dose should be given from 2 months after the second vaccine dose. A minimum interval of 4 weeks may be considered in exceptional circumstances (e.g., anticipated intensification of immunosuppression; outbreaks). People who have received a second dose more than 6 months ago should receive a third dose as soon as feasible (ATAGI, 2021w).

The third dose is intended to address the risk of lowered response or non-response to the standard 2-dose schedule. For more details on vaccine effectiveness in people who are immunocompromised, see COVID-19 vaccine information.

Individuals who currently are not severely immunocompromised but who will commence significant immunosuppressive therapy 2 or more weeks after their second dose do not require a third dose, as it can be expected that an adequate response to 2 primary doses will be achieved (ATAGI, 2021w).

For a comprehensive list of immunocompromising conditions and therapies for which a third primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Booster dose recommendations

ATAGI **recommends** 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 (ATAGI, 2023d):

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.

ATAGI advises the following groups should **consider** a 2023 booster dose 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 (ATAGI, 2023d).

- 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.

Booster doses are **not currently recommended** for children aged under 5 years, or for children and adolescents aged 5 to 17 years who are not at increased risk of severe disease as defined above. Severe COVID-19 in children is uncommon and the primary course of COVID-19 vaccines generates a strong immune response. The benefit from additional doses of vaccine is likely to be small. Current evidence does not suggest that booster doses are needed at this time.

Development of a seasonal immunisation policy to manage COVID-19 is limited, as the evolution, duration and strength of protection against serious SARS-CoV-2 illness are uncertain at this time (ATAGI, 2023a).

Vaccine preference recommendations

Any age-appropriate COVID-19 vaccine, including original (ancestral virus-based) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer-lasting protection against severe disease.

However, bivalent mRNA vaccines are preferred over other vaccines for people aged 12 years and older. These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), for people aged 12 years and over.
- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS), for people aged 12 years and over.
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap), for people aged 18 years and over.
- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label), for people aged 18 years and over.

ATAGI **does not** currently recommend use of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine in anyone under 18 years as it is not registered for this age group (ATAGI, 2022o).

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Topic 4: Precautions

ATAGI continues to monitor evidence on vaccine effectiveness, the epidemiology of SARS-CoV-2 including its seasonality and emerging subvariants. ATAGI will add to its recommendations as further evidence on the bivalent vaccine(s) and knowledge about other uncertainties accumulates.

Vaccine administration errors (VAEs)

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training is undertaken to minimise the risk of VAEs occurring (ATAGI, 2022a).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible VAEs, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022a). The Vaccine Operations Centre (VOC) on 1800 318 208 is available to provide advice to clinicians regarding VAEs.

Please see Appendix 4 for the steps to be followed if a Vaccine administration error occurs.

For more information, see Additional Module 1 – Topic 3.

Pre-screening – Pre-screening is covered in detail in Module 5, Topic 3. This topic reviews a few special population groups with manufacturer's recommendations on administering the Pfizer (COMIRNATY) vaccines to members of these groups.

Contraindications – As per Additional Module 1.

Precautions – The precautions relating to Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine are the same as the ones outlined in Module 5, Topic 2. Please review these again as required.

Children and adolescents – The safety and efficacy of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine in children and adolescents aged less than 18 years of age have not been established. ATAGI **does not** currently recommend use of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine in anyone under 18 years as it is not registered for this age group (ATAGI, 2022o).

Immunocompromised individuals – As per Additional Module 1.

Myocarditis and Pericarditis – The risk of myocarditis or pericarditis, very rare adverse effects following the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine has not yet been characterised, as this vaccine has not been used extensively in large populations. ATAGI states there is no reason to believe the safety of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine is any different to other Pfizer (COMIRNATY) mRNA vaccines (ATAGI, 2022o).

For more information, see Additional Module 1.

Past infection with SARS-CoV-2 – Past infection with SARS-CoV-2 is not a contraindication to vaccination. ATAGI recommends that vaccination should be deferred for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19 (ATAGI, 2023a).

For more information, see Additional Module 1.

Pregnancy, breastfeeding and fertility recommendations – As per Additional Module 1.

Co-administration of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine with other non-COVID vaccines is acceptable, as per the current ATAGI Clinical recommendations for COVID-19 vaccines (ATAGI, 2023a).

For more information, see Additional Module 1.

Topic 5: Adverse events

General adverse events have been discussed in Module 6, Topic 2. All adverse events following immunisation (AEFI) from the administration of Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine must be reported.

Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website. For more information, please refer to Core Module 6. For more information, please refer to Core Module 6.

The consumer resource, COVID-19 vaccination – Side effects you might have after your vaccination can be given to people following their vaccination.

The Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) trial and the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) trial suggests that the safety profile of these vaccines are similar to the Pfizer (COMIRNATY) (purple cap) vaccine.

The most commonly reported local adverse reactions following a second booster dose of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine were:

- Injection site pain - 58% of individuals,
- Fatigue - 49% of individuals,
- Headache - 34% of individuals and
- Myalgia - 22% of individuals.

(ATAGI 2022o)

Rare side-effects – As per Additional Module 1.

Consumer medicine information can be given to individuals receiving the vaccine which details what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for your state or territory, please review this website.

Module Summary

- The Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine uses mRNA technology.
- The multidose vial (MDV) must be thawed before administration.
- Do **NOT** dilute the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine.
- The Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine can be given to people 18 years and older for primary course and booster doses.
- Each dose of Pfizer bivalent BA.1 (COMIRNATY) (grey cap) is **30 micrograms/0.3mL.**
- ATAGI **does not** currently recommend use of the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine in anyone under 18 years as it is not registered for this age group.
- All adverse events must be reported as this is a novel vaccine.
- Thawed vaccine can be used for a maximum of 10 weeks (70 days) within the **18-month** shelf-life when stored refrigerated between +**2°C to +8°C**.
- Prior to each vaccination, ensure all relevant expiry dates and times are checked

References:

Australian Technical Advisory Group on Immunisation [ATAGI]. (2021b, October). *Clinical Guidance for COVID-19 vaccine providers*. https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/clinical-guidance.

Australian Technical Advisory Group on Immunisation [ATAGI]. (2022a, September). *ATAGI clinical guidance on COVID-19 vaccination administration errors.* https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-covid-19-vaccine-administration-errors.

Australian Technical Advisory Group on Immunisation [ATAGI]. (2022o, November) *ATAGI recommendations on use of the Pfizer bivalent (Original/Omicron BA.1) COVID-19 vaccine.* https://www.health.gov.au/news/atagi-recommendations-on-use-of-the-pfizer-bivalent-originalomicron-ba1-covid-19-vaccine.

Australian Technical Advisory Group on Immunisation [ATAGI] (2023a, February). *ATAGI 2023 booster advice.* https://www.health.gov.au/news/atagi-2023-booster-advice.

Australian Technical Advisory Group on Immunisation [ATAGI] (2023d, May). *ATAGI advice on the preferential use of bivalent COVID-19 vaccines for primary vaccination of people aged ≥ 12 years*. https://www.health.gov.au/news/atagi-advice-on-the-preferential-use-of-bivalent-covid-19-vaccines-for-primary-vaccination-of-people-aged-12-years-or-older?language=en.

Pfizer, Australia. (2021b). *Australian product information – Comirnaty™ (BNT162b2 [mRNA]) COVID-19 vaccine*. TGA. https://www.tga.gov.au/sites/default/files/comirnaty-pi.pdf.

Therapeutic Goods Administration [TGA]. (2022d). *Australian Product information: COMIRNATY Original/Omicron BA.1 COVID-19 vaccine.* https://www.tga.gov.au/sites/default/files/2022-11/auspar-comirnaty-original-omicron-ba1-covid-19-vaccine-20221110-pi.pdf.

Multi-choice Questions:

1. Which of these statements about storage for the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine is CORRECT?

    a. The thawed vials can be stored in cold chain storage (+2°C to +8°C) for a maximum of 3 months.
    b. Pfizer bivalent BA.1 (COMIRNATY) (grey cap) received at +2°C to +8°C should be stored at +2°C to +8°C
    c. If vials are thawed, unopened and maintained at +2°C to +8°C they can be re-frozen if needed but only once.
    d. The thawed vials can be stored at room temperature for a maximum of 48 hours

2. The Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine is recommended for use as:

    a. Primary course and booster doses in people aged 18 years and older
    b. Primary course and booster doses in people aged 12 years and older
    c. Booster doses for immunocompromised individuals 6 months and older
    d. Booster doses for people aged 12 to 17 years old

3. How is the correct Pfizer bivalent BA.1 (COMIRNATY) (grey cap) multi-dose vial for individuals aged 18 years and older identified?

    a. 10mcg/0.2mL multi-dose vials WITH AN ORANGE cap
    b. 3mcg/0.2mL multi-dose vial WITH A MAROON cap
    c. 30mcg/0.3mL multi-dose vials WITH A PURPLE cap
    d. 30mcg/0.3mL multi-dose vial WITH A GREY cap

4. The dose for Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine, for people 18 years and over is:

    a. 0.3mL/30 micrograms given intramuscularly
    b. 0.2mL/10 micrograms given intramuscularly
    c. 0.2mL/3 micrograms given subcutaneously
    d. 0.3mL/30 micrograms given intradermally

5. What are the correct steps for Pfizer bivalent BA.1 (COMIRNATY) (grey cap) dilution?

    a. Inject 1.8mL of sodium chloride (0.9%) for injection into the MDV after cleaning the bung and allowing it to fully dry. Remove 1.8mL of air before withdrawing the needle to equalize the vial pressure. Gently invert the vial 10 times.
    b. Inject 1.5mL of sodium chloride (0.9%) for injection into the MDV after cleaning the bung and allowing it to fully dry. Remove 1.5mL of air before withdrawing the needle to equalize the vial pressure. Gently invert the vial 10 times.
    c. Inject 10mL of sodium chloride (0.9%) for injection into the MDV after cleaning the bung and allowing it to fully dry. Remove 10mL of air before withdrawing the needle to equalize the vial pressure. Gently invert the vial 5 times.
    d. Do not dilute the vaccine. Each dose must contain 0.3mL of vaccine. Gently invert the vial 10 times prior to use.

Additional Module 1b: Pfizer Bivalent BA.4-5 COVID-19 Booster Vaccine

(21/09/2023)

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 25 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete.

Learning objectives

At the end of Additional Module 1b: Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine for individuals aged 12 years and older, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine for individuals aged 12 years and older.
- Understand the contraindications, warnings, adverse reactions, and recommendations for co-administration with other vaccines for the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine for individuals aged 12 years and older.
- Demonstrate appropriate dose preparation and verification before administration of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine for individuals aged 12 years and older.
- Understand the appropriate administration of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine for individuals aged 12 years and older.

Topics

1. Introduction and summary
2. Cold chain and storage
3. Preparation and administration
4. Precautions
5. Adverse events

Topic 1: Introduction and summary

This module builds on the Additional Module 1 (pre-requisite) and will not repeat the information covered in that module. As required, please review Additional Module 1.

The COMIRNATY BIVALENT Omicron BA.4/BA.5 COVID-19 vaccine is also known as the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine (the term which will be used in this module).

On 20 January 2023, the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine was provisionally approved by the Therapeutic Goods Administration (TGA) for use in individuals aged 12 years and older (Australian Technical Advisory Group on Immunisation [ATAGI], 2023b; TGA, 2023a).

This vaccine uses similar technology to the Pfizer (COMIRNATY) and Moderna (SPIKEVAX) vaccines to induce immunity.

The Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine contains 30mcg of mRNA, comprising equal quantities encoding the spike protein from the original SARS-CoV-2 virus and the Omicron BA.4-5 variant (i.e. one dose of 0.3mL contains 15 micrograms of tozinameran and 15 micrograms of famtozinameran).

Further information can be found in the Product Information and ATAGI Clinical recommendations for COVID-19 vaccines. The Consumer Medicine Information (CMI) can also be given to individuals receiving the vaccine.

For people aged 12 years or older, ATAGI advises bivalent mRNA vaccine (e.g. Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)) is preferred over original (ancestral) vaccines **for both primary course and booster doses** (ATAGI, 2023d).

Bivalent vaccines are designed to broaden cross-protection from vaccination against Omicron and its subvariants by including an Omicron strain in the vaccine. Circulating strains since 2022 have all evolved as subvariants from the first Omicron variant. Pre-Omicron variants no longer circulate, and reversion to a pre-Omicron variant by a future strain is considered unlikely (ATAGI, 2023d).

ATAGI, therefore, considers the bivalent vaccines (which protect against either Omicron subvariants BA.1 or BA.4-5) preferable for use in a primary series. ATAGI notes that use of bivalent vaccines for primary vaccination is consistent with evolving advice from the World Health Organization's Strategic Advisory Group of Experts on Immunization (SAGE) and the European Medicines Agency's Emergency Task Force, and that off-label use has been permitted in the United Kingdom (ATAGI, 2023d).

The safety of bivalent vaccines is similar to monovalent original vaccines when used as a booster dose. ATAGI has no additional concerns regarding the safety or effectiveness of bivalent vaccines compared with monovalent vaccines when used for a primary course (ATAGI, 2023d).

The ATAGI COVID-19 2023 Booster Advice provides guidance on which individuals are recommended, or can consider, a COVID-19 vaccine booster dose for additional protection against severe COVID-19 (ATAGI, 2023b).

Booster doses of the COVID-19 vaccine should be given at least **6 months** after the most recent COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (**whichever is the most recent**) (ATAGI 2023b).

ATAGI **does not** currently recommend use of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine in anyone under 12 years as it is not registered for this age group. An approved alternative COVID-19 vaccine, i.e. Pfizer (COMIRNATY) (orange cap) vaccine, should be used for primary course and booster doses in children aged 5-11 years (ATAGI, 2023b).

The Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine is presented as a **grey-capped** multidose vial (MDV) (15/15mcg). Each carton pack contains 10 MDVs:

- Six (6) doses (of 0.3mL volume each) can be withdrawn from each 2.25mL vial.

When frozen the vaccine is a white to off-white suspension with a total volume of 2.25mL.

This product is a ready-to-use formulation and does not require dilution (TGA, 2023a).

The vial is made of type I glass with a synthetic bromobutyl rubber stopper and a **grey** flip-off plastic cap with an aluminium seal (TGA, 2023a).

Figure 1. *Example of Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine outer packaging*.

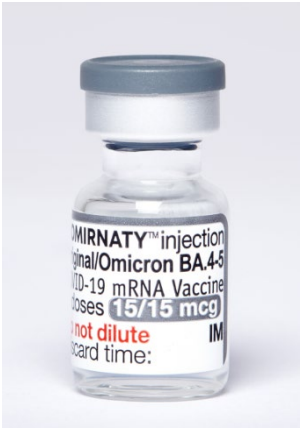

Figure 2. *Example of Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) 2.25mL vial*.

Refer to *Table 1. Dose types and dose volume for Pfizer (COMIRNATY) vaccines for different age groups*.

Category	Pfizer (COMIRNATY) 10mcg/0.2mL concentrated suspension for injection vial	Pfizer (COMIRNATY) 30mcg/0.3mL concentrated suspension for injection vial	Pfizer bivalent **BA.1** (COMIRNATY) 15/15mcg/0.3mL suspension for injection vial	Pfizer bivalent **BA.4-5** (COMIRNATY) 15/15mcg/0.3mL suspension for injection vial
Approved age	5 to 11 years	≥ 12 years	**≥ 18 years**	**≥ 12 years**
Cap colour	Orange cap	Purple cap	Grey cap	Grey cap
ATAGI recommended indication	**Primary** and **booster** doses	**Primary** and **booster** doses	Preferred for **Primary** and **booster** doses	Preferred for **Primary** and **booster** doses
Dilution	Requires dilution	Requires dilution	**Do not dilute**	**Do not dilute**
Dose	10 micrograms	30 micrograms	30 micrograms	30 micrograms
Dose volume	0.2mL	0.3mL	0.3mL	0.3mL

Table 1. Dose types and dose volume for Pfizer (COMIRNATY) vaccines for different age groups.

Refer to *Table 2. Vial presentation differences for Pfizer bivalent (COMIRNATY) vaccines for different age groups*.

Category	**Pfizer bivalent BA.1 (COMIRNATY) (grey cap)** 15/15mcg/0.3mL suspension for injection vial	**Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)** 15/15mcg/0.3mL suspension for injection vial
Vial presentation		
Approved age	≥ 18 years	≥ 12 years
Cap and label colour	Grey cap and grey border label	Grey cap and grey border label

ATAGI recommended indication	Preferred for **Primary course** and **booster** doses	Preferred for **Primary course** and **booster** doses
Dilution	**Do not dilute**	**Do not dilute**
Dose	30 micrograms	30 micrograms
Dose volume	0.3mL	0.3mL

Table 2. Vial presentation differences for Pfizer bivalent (COMIRNATY) (grey cap) vaccines for different age groups.

Immunisation providers should be vigilant and note the subtle differences between the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) and the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine vials. Both these bivalent vaccines have a grey cap and grey border around the label; however, the Pfizer bivalent BA.1 (COMIRNATY) (grey cap) vaccine is registered for people aged 18 years and over with the naming convention Tozinameran/Riltozinameran. Conversely, the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine has the naming convention Original/Omicron BA.4-5 and is registered for people aged 12 years and older (ATAGI, 2023a).

Protection

In clinical trials conducted, all mRNA COVID-19 booster vaccine doses (bivalent and original) resulted in improved immune response against Omicron subvariants BA.1 and BA.4-5. Two Pfizer immunogenicity studies in adolescents and adults aged ≥12 years who had received a primary series and first booster of Pfizer (COMIRNATY) (purple cap) vaccine provide a comparison between neutralising antibody levels after a second booster of 30 mcg of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine and after a second booster of the Pfizer (COMIRNATY) (purple cap) (ATAGI, 2023b).

Adults aged >55 years who received the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine developed higher neutralising antibody titres to the BA.4-5 Omicron subvariant (geometric mean ratio 2.91, 95% CI 2.45-3.44) than those who received the Pfizer (COMIRNATY) (purple cap) vaccine. Neutralisation of newer BQ.1.1 and XBB.1 subvariants was also higher with the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine than with the Pfizer (COMIRNATY) (purple cap) vaccine. The bivalent vaccine had non-inferior and modestly higher titres for ancestral strain neutralisation (GMR 1.38, 95% CI 1.22-1.56). Similar trends were seen in the 12 to 17-year and 18 to 55-year age groups (ATAGI, 2023b).

An additional four studies conducted reported higher neutralisation titres following a booster dose of Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine for BA.4-5 and other sub-variants (e.g. BQ.1, XBB) compared to the Pfizer (COMIRNATY) (purple cap) vaccine. Two studies have found the neutralisation response to be similar between bivalent BA.4-5 and original vaccines (ATAGI, 2023b).

A US study showed vaccine effectiveness (VE) against hospitalisation or death with a bivalent BA.4-5 booster (either Pfizer or Moderna) was 61.8% (95% CI 48.2% to 71.8%) compared with an original booster VE of 24.9% (95% CI 1.4% to 42.8%). A nationwide cohort study conducted in Nordic countries from July to December 2022 found VE against hospitalisation for a second booster of bivalent BA.4-5 vaccine of 80.5% (95% CI 69.5% to 91.5%) and for an original vaccine second booster of 64.9% (95% CI 57.7% to 72.2%), both relative to not receiving a second booster. The short-term safety of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine was shown to be similar to the

previous Pfizer bivalent BA.1 (COMIRNATY) (grey cap) and Pfizer (COMIRNATY) (purple cap) vaccines when used as a booster (ATAGI, 2023b).

Early immunogenicity and safety data on bivalent vaccines used as primary vaccination are limited. The safety of bivalent vaccines is similar to monovalent original vaccines when used as a booster dose. ATAGI has no additional concerns regarding the safety or effectiveness of bivalent vaccines compared with monovalent vaccines when used for a primary course (ATAGI, 2023d).

While there are currently no efficacy or effectiveness studies of bivalent vaccines when used for the primary vaccination course, early effectiveness studies of bivalent vaccines used as a booster dose suggest equivalent or better protection than original vaccines. There is no reason to expect that using bivalent vaccines for a primary vaccination course would differ (ATAGI, 2023d).

Topic 2: Cold chain and thawing

Ultra-cold chain (UCC) storage for frozen vials

The Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine may be received frozen at **-90°C to -60°C.** Frozen vaccines can be stored either at **-90°C to -60°C for up to 18 months** or **+2°C to +8°C** for up to 10 weeks (TGA, 2023a).

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 **10 weeks** within the **18-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 the use-by date on the outer carton which has been updated to reflect the earliest date of the thawed use-by date and batch expiry date (TGA, 2023a).

Cold chain breach (CCB)

If you suspect your vaccines may have been involved in a CCB, either 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 Vaccine Operations Centre (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.

Thawing

Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine MDVs must be thawed before use. An **unopened thawed** vial may be stored refrigerated at +2°C to +8°C for a single period of up to 10 weeks within the 18-month shelf life.

Thawing can occur by one of two methods:

- 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.
- Place the individual vials on a workbench for 30 minutes at temperatures up to +30°C. The vials must then be used immediately.

(TGA, 2023a)

By following one of the thawing methods above, the vial will be thawed. **DO NOT** shake the vial.

Once thawed, the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine **CANNOT** be re-frozen (TGA, 2023a).

Topic 3: Preparation and administration

Dose preparation

Prior to each vaccination, ensure **all** relevant expiry dates and times are checked.

To prevent administrative errors, all sites should clearly label the use by 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 (VAEs). If vaccines are administered outside the revised expiry date, it is considered a VAE. The Vaccines Operations Centre (VOC) is available on **1800 318 208** to provide advice and guidance to clinicians regarding the management of VAEs. Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information (ATAGI, 2022a).

Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine is a ready-to-use formulation and does not require dilution (TGA, 2023a).

Gathering and preparing the vial for use:

1. Perform hand hygiene with either soap and water or an alcohol-based rub.
2. Clean and disinfect the separate area for preparation and procedure dish or tray.
3. Collect the required equipment (as outlined earlier in Module 4, Topic 2 in the 'vaccine administration checklist per person').
4. Remove the required vaccine vial (only 1 at a time) from the cold chain storage system used and check the temperature while doing so.
5. **Double check you have the correct vaccine** before opening the vial, ideally with another health professional if available, and as per your facility and jurisdictional policies.
6. Check the manufacturer expiry date, the thaw use-by date and the date and time that the vial was opened. **DISCARD** the vaccine if it exceeds any expiry date and time. If you are opening the vial for the first time, record the current date and time on the vial, before opening it.
7. Examine the vaccine vial gently and ensure there is no discolouration, turbidity or particulate matter as per the product information by inverting it gently 10 times. If you are unsure of its appearance, **DO NOT** use and seek advice from the VOC on **1800 318 208**.
8. Perform hand hygiene.
9. Open the vial (if applicable) and check the bung (also known as the septum/stopper/diaphragm) integrity.
10. Disinfect the bung using a 70% isopropyl alcohol wipe.
11. Allow to fully dry for 30 seconds.

DO NOT use if the vial has been opened without a date and time of opening.

To extract the full 6 doses from the MDV, low dead-volume syringes and/or needles are recommended when available. Care should be taken to draw up the dose volume exactly. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL, the vial and any remaining excess volume must be discarded as doses cannot be drawn from multiple MDVs (TGA, 2023a).

After initial puncture, vials can be stored **up to 12 hours** in room temperature **up to +30°C** and must be used within the 12 hours (TGA, 2023a). **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** from the time of initial puncture (ATAGI, 2022r).

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 (ATAGI, 2022r).

Administration

As per Additional Module 1.

Dosing and schedule

For people aged 12 years or older, a bivalent mRNA vaccine i.e. Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine is preferred for primary vaccination.

Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine is administered as an intramuscular (IM) injection containing 0.3mL vaccine. The Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine contains 30mcg of mRNA (15 micrograms of tozinameran and 15 micrograms of famtozinameran).

A total of two primary course doses are required for most people. The recommended interval between two doses of Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine is 8 weeks (ATAGI, 2022f).

The extended dose interval of 8 weeks has been shown to improve the immune response to vaccination and therefore may improve effectiveness. A longer dose interval may also reduce the risk of myocarditis and pericarditis. The longer dose interval is particularly recommended for groups at higher risk of this side effect (those under the age of 40 years) (ATAGI, 2022f).

The dose interval can be reduced to a minimum of 3 weeks for people at higher risk of severe COVID-19 (including older adults and people with underlying medical conditions), in an outbreak setting, or prior to international travel (ATAGI, 2022f).

Severely immunocompromised individuals

A third primary dose of COVID-19 vaccine is recommended for all people aged 6 months or older with severe immunocompromise who are receiving a 2-dose primary course. The third dose should be given from 2 months after the second vaccine dose. A minimum interval of 4 weeks may be considered in exceptional circumstances (e.g., anticipated intensification of immunosuppression; outbreaks). People who received a second dose more than 6 months ago should receive a third dose as soon as feasible (ATAGI, 2021w).

The third dose is intended to address the risk of lowered response or non-response to the standard 2-dose schedule. For more details on vaccine effectiveness in people who are immunocompromised, see COVID-19 vaccine information.

Individuals who currently are not severely immunocompromised but who will commence significant immunosuppressive therapy 2 or more weeks after their second dose do not require a third dose, as it can be expected that an adequate response to 2 primary doses will be achieved (ATAGI, 2021w).

For a comprehensive list of immunocompromising conditions and therapies for which a third primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Booster dose recommendations

ATAGI **recommends** 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 (ATAGI, 2021b):

- 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.

ATAGI advises the following groups should **consider** a 2023 booster dose 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 (ATAGI, 2021b).

- 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.

ATAGI advises that a booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19.

Development of a seasonal immunisation policy to manage COVID-19 is limited, as the evolution, duration and strength of protection against serious SARS-CoV-2 illness are uncertain at this time (ATAGI, 2023a).

Booster doses are not currently recommended for children aged under 5 years, or for children and adolescents aged 5 to 17 years who are not at increased risk of severe disease as defined above. Severe COVID-19 in children is uncommon and the primary course of COVID-19 vaccines generates a strong immune response. The benefit from additional doses of vaccine is likely to be small. Current evidence does not suggest that booster doses are needed at this time (ATAGI, 2023b).

Booster dose: vaccine preference recommendations

Any age-appropriate COVID-19 vaccine, including original (ancestral virus-based) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer-lasting protection against severe disease.

However, bivalent mRNA vaccines are preferred over other vaccines for people aged 12 years and older. These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), for people aged 12 years and over.
- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS), for people aged 12 years and over.
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap), for people aged 18 years and over.

- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label), for people aged 18 years and over.

ATAGI **does not** currently recommend use of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine in anyone under 12 years as it is not registered for this age group (ATAGI, 2023a).

Refer to and download the COVID-19 Vaccines in Australia poster for further information.

Topic 4: Precautions

ATAGI continues to monitor evidence on vaccine effectiveness, the epidemiology of SARS-CoV-2 including its seasonality and emerging subvariants, and other candidate bivalent COVID-19 vaccines. ATAGI will add to its recommendations as further evidence on the bivalent vaccine(s) and knowledge about other uncertainties accumulates.

Vaccine administration errors (VAEs)

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training is undertaken to minimise the risk of VAEs occurring (ATAGI, 2022a).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible VAEs, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022a). The Vaccine Operations Centre (VOC) is available on **1800 318 208** to provide advice to clinicians regarding VAEs.

Please see Appendix 4 the steps to be followed if a vaccine administration error occurs.

For more information, see Additional Module 1 – Topic 3.

Pre-screening – Pre-screening is covered in detail in Module 5, Topic 3. This topic reviews a few special population groups with manufacturer's recommendations on administering the Pfizer (COMIRNATY) vaccine to members of these groups.

Contraindications – As per Additional Module 1.

Precautions – The precautions relating to Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine are the same as the ones outlined in Module 5, Topic 2. Please review these again as required.

Children and adolescents – The safety and efficacy of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine in children aged less than 12 years of age have not been established. ATAGI **does not** currently recommend use of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine in anyone under 12 years as it is not registered for this age group (ATAGI, 2023a).

Immunocompromised individuals – As per Additional Module 1.

Myocarditis and pericarditis – As per Additional Module 1.

Past infection with SARS-CoV-2 – Past infection is not a contraindication to a booster dose. ATAGI recommends that vaccination should be deferred for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19 (ATAGI, 2023a). For more information, see Additional Module 1.

Pregnancy, breastfeeding and fertility recommendations – As per Additional Module 1.

Co-administration of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine with other non-COVID vaccines is acceptable, as per current ATAGI 2023 booster advice (ATAGI, 2023a).

For more information, see Additional Module 1.

Topic 5: Adverse events

General adverse events have been discussed in Module 6, Topic 2. All adverse events following immunisation (AEFI) from the administration of either of the two Pfizer bivalent vaccines must be reported.

Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website.

For more information, please refer to Core Module 6.

The consumer resource, COVID-19 vaccination – Side effects you might have after your vaccination can be given to people following their vaccination.

The short-term safety of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine was shown to be similar to the previous Pfizer bivalent BA.1 (COMIRNATY) (grey cap) and original Pfizer (COMIRNATY) vaccines. ATAGI has no additional concerns regarding the safety of bivalent vaccines compared with original vaccines when used for a primary course.

The most commonly reported local adverse reactions following a second booster dose of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine were:

- Injection site pain – 68.5% of individuals,
- Injection site swelling – 5.4% of individuals,
- Injection site redness – 4.8% of individuals,
- Fatigue – 56.4% of individuals,
- Headache – 41.4% of individuals,
- Myalgia – 25.8% of individuals,
- Chills – 16.9% of individuals,
- Joint pain – 13.4% of individuals,
- Fever – 7.3% of individuals and
- Lymphadenopathy – 0.3% of individuals

(ATAGI 2023b)

Rare side-effects – As per Additional Module 1.

Consumer Medicine Information can be given to people after receiving the vaccine which detail what to expect and monitoring of adverse effects.

Module Summary

- The Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine uses mRNA technology.

- The multidose vial (MDV) must be thawed before administration.
- Do **NOT** dilute the Pfizer bivalent BA.4-5 COVID-19 booster vaccine.
- The Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine can be given to people 12 years and older for primary course and booster doses.
- Each dose of Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine is **30 microgram/0.3mL.**
- ATAGI **does not** currently recommend use of the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine in anyone under 12 years as it is not registered for this age group.
- All adverse events must be reported as this is a novel vaccine.
- Thawed vaccine can be used for a maximum of 10 weeks (70 days) within the 18-month shelf-life when stored refrigerated between +**2°C to +8°C**.
- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

References:

Australian Technical Advisory Group on Immunisation [ATAGI]. (2022a, September). *ATAGI clinical guidance on COVID-19 vaccination administration errors.* https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-covid-19-vaccine-administration-errors.

Australian Technical Advisory Group on Immunisation [ATAGI]. (2022r December). *Transporting, storing and handling of COVID-19 vaccines.* https://www.health.gov.au/our-work/covid-19-vaccines/advice-for-providers/clinical-guidance/transporting-storing-and-handling.

Australian Technical Advisory Group on Immunisation [ATAGI] (2023a, February). *ATAGI 2023 booster advice.* https://www.health.gov.au/news/atagi-2023-booster-advice?language=en.

Australian Technical Advisory Group on Immunisation [ATAGI]. (2023b, February) *ATAGI recommendations on use of the Pfizer bivalent (Original/Omicron BA.4-5) COVID-19 vaccine.* https://www.health.gov.au/news/atagi-recommendations-on-use-of-the-pfizer-bivalent-originalomicron-ba45-covid-19-vaccine?language=en.

Australian Technical Advisory Group on Immunisation [ATAGI] (2023d, May). *ATAGI advice on the preferential use of bivalent COVID-19 vaccines for primary vaccination of people aged ≥ 12 years*. https://www.health.gov.au/news/atagi-advice-on-the-preferential-use-of-bivalent-covid-19-vaccines-for-primary-vaccination-of-people-aged-12-years-or-older?language=en

Therapeutic Goods Administration [TGA]. (2023a). *Australian Product information: COMIRNATY Original/Omicron BA.4-5 COVID-19 vaccine.* https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2023-PI-01101-1&d=202104131016933.

Multi-choice Questions:

1. Which of these statements about storage for the Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine is CORRECT?

    a. The thawed vials can be stored in cold chain storage (+2°C to +8°C) for a maximum of 3 months.
    b. Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine received at +2°C to +8°C should be stored at +2°C to +8°C

c. If vials are thawed, unopened and maintained at +2°C to +8°C they can be re-frozen if needed but only once.
d. The thawed vials can be stored at room temperature for a maximum of 48 hours.

2. The Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine is recommended for use as:

a. Primary course and booster doses in people aged 12 years and older
b. Primary course for people aged 5 to 11 years
c. Primary course for immunocompromised individuals aged 6 months and older
d. Booster doses for people aged 5 to 11 years old

3. The dose for Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine for people 12 years and over is:

a. 0.3mL/30 micrograms given intramuscularly
b. 0.2mL/10 micrograms given intramuscularly
c. 0.2mL/3 micrograms given subcutaneously
d. 0.3mL/30 micrograms given intradermally

4. What are the correct steps for Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) vaccine dilution?

a. After cleaning the bung and allowing it to fully dry, inject 1.8mL of sodium chloride (0.9%) for injection into the MDV. Remove 1.8mL of air before withdrawing the needle to equalize the vial pressure. Gently invert the vial 10 times.
b. After cleaning the bung and allowing it to fully dry, inject 1.5mL of sodium chloride (0.9%) for injection into the MDV. Remove 1.5mL of air before withdrawing the needle to equalize the vial pressure. Gently invert the vial 10 times.
c. After cleaning the bung and allowing it to fully dry, inject 10mL of sodium chloride (0.9%) for injection into the MDV. Remove 10mL of air before withdrawing the needle to equalize the vial pressure. Gently invert the vial 5 times.
d. Do not dilute the vaccine. Each dose must contain 0.3mL of vaccine. Gently invert the vial 10 times prior to use.

Additional Module 2: COVID-19 Vaccine AstraZeneca (Decommissioned) (21/09/2023)

MODULE DECOMMISSIONED - Effective March 2023, AstraZeneca (VAXZEVRIA) COVID-19 vaccine is no longer being supplied in Australia. Therefore, *no further content updates will be made to this module from May 2023.*

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 30 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete.

Learning objectives

At the end of this module, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of the AstraZeneca (VAXZEVRIA) vaccine.
- Understand the appropriate dose preparation and administration of the AstraZeneca (VAXZEVRIA) vaccine.
- Understand the contraindications, warnings, adverse reactions, and recommendations for co-administration with other vaccines for the AstraZeneca (VAXZEVRIA) vaccine.
- Understand the appropriate storage and handling of the AstraZeneca (VAXZEVRIA) vaccine.

Topics

1. Introduction and summary
2. Cold chain storage and disposal
3. Preparation and administration
4. Precautions and contraindications
5. Adverse events

Topic 1: Introduction and summary

MODULE DECOMMISSIONED - Effective March 2023, AstraZeneca (VAXZEVRIA) COVID-19 vaccine is no longer being supplied in Australia. Therefore, *no further content updates will be made to this module from May 2023.*

THE FOLLOWING INFORMATION REMAINS FOR REFERENCE PURPOSES ONLY.

The AstraZeneca (VAXZEVRIA) vaccine has been provisionally approved by the Therapeutic Goods Administration (TGA) in Australia. The vaccine is registered for use in people aged 18 years of age and over (TGA, 2021a).

The previously supplied AstraZeneca (VAXZEVRIA) could have been used in adults aged between 18 to 59 years if the benefits were likely to outweigh the risks for that individual and the person made an informed decision based on an understanding of the risks and benefits (ATAGI, 2021n).

The vaccine name is VAXZEVRIA **(ChAdOx1-S)** (AstraZeneca, 2021a).

This vaccine uses existing vaccine technology to genetically modify an organism, specifically an adenovirus or common cold causing virus. This vaccine technology has been tested and successfully used in a vaccine for Ebola virus. The vaccine contains a single recombinant, non-replicating viral vector vaccine.

The adenovirus has been genetically modified in two ways:

- The genetic code needed for replication has been removed and,
- The genetic code for the SARS-CoV-2 spike protein has been added.

The AstraZeneca (VAXZEVRIA) **CANNOT** cause COVID-19 or colds.

The modified adenovirus can enter human host cells but is not able to replicate inside. Instead it delivers genetic code instructions to produce the SARS-CoV-2 spike protein only which is recognised by the immune system. There are **no changes to the human DNA** through this process. These are the same steps which occur when a virus invades normally, except that the spike proteins are reproduced instead of more viruses.

This vaccine is NOT a live-attenuated vaccine and therefore live vaccine precautions are NOT required for this vaccine.

Vaccination with AstraZeneca (VAXZEVRIA) will not affect a polymerase chain reaction (PCR) swab test used to detect COVID-19. Results may be altered for serum antibody tests if they detect the spike protein antibodies (AstraZeneca, 2021a).

Each 5 ml multi-dose vial (MDV) contains **ten 0.5mL doses.** There are 10 MDVs in a carton (outer packaging) (AstraZeneca, 2021a).

Figure 1. *Example only of previously supplied AstraZeneca (VAXZEVRIA) 5mL MDV and outer packaging*.

The MDV contains liquid which appears as clear to slightly opaque and colourless to slightly brown. There are no visible particles within the MDV (AstraZeneca, 2021a).

The active ingredient is the modified adenovirus (ChAdOx1) containing spike protein genetic code, a genetically modified organism (GMO) (AstraZeneca, 2021a). Other non-active ingredients are included to stabilise the vaccine (listed below). No preservatives are used:

- L-Histidine (an amino acid).
- L-Histidine hydrochloride monohydrate (an amino acid).
- Magnesium chloride hexahydrate (supports many activities inside cells).
- Polysorbate 80 (a stabiliser).
- Ethanol.
- Sucrose.
- Sodium chloride.
- Disodium edetate dihydrate (EDTA, a binding agent)
- Water for injection.

(AstraZeneca, 2021a)

None of the vaccine ingredients are of human or animal origin and there are no food, latex or gelatin in the COVID-19 vaccines that are currently available. If individuals have had an allergic reaction to other vaccines in the past, it does not mean that they will also be allergic to the COVID-19 vaccines (Australasian Society of Clinical Immunology and Allergy [ASCIA], 2021)

Protection:

It is essential to follow Department of Health and Aged Care and jurisdictional infection control and prevention requirements for COVID-19 regardless of vaccination status (AstraZeneca, 2021a).

As with all vaccines, immunity is not guaranteed for all individuals (AstraZeneca, 2021a). Complete protection from severe disease and hospitalisation related to COVID-19 was shown at ≥ 22 days following the first dose in 71% of people (95% Confidence Interval [CI]: 51.11% - 84.08%) (AstraZeneca, 2021a).

No cases of hospitalisation occurred for COVID-19 in trials of individuals who received the full two (2) dose course of the vaccine compared to 14 in the control group (AstraZeneca, 2021a).

The overall efficacy is based on an interim analysis of pooled data from the United Kingdom and Brazil. Over 12,000 participants were followed through a randomised controlled trial over a median of 19 weeks (after dose 1), and 9 weeks (after dose 2). These participants are planned to be followed for at least 12 months for the safety and efficacy against COVID-19.

Following two (2) doses of the AstraZeneca (VAXZEVRIA) vaccine, the efficacy against COVID-19 is 62% (95% CI: 39.96% - 76.08%) (AstraZeneca, 2021a). The efficacy increases to 73% when a longer dose interval of 12 weeks is used. Short term efficacy from 22 days until 90 days after a single dose was 76% (95% CI: 59·3–85·9). The duration of protection after a single dose has not yet been established, and a second dose is recommended for optimal protection (ATAGI, 2021b).

Limited data is available on the impact of emerging SARS-CoV-2 variants on the AstraZeneca (VAXZEVRIA) vaccine efficacy. However, so far, no naturally occurring mutations have been identified that affect how well the vaccine works. Clinical trials will continue to evaluate all new mutations and any impact this has on vaccine efficacy.

More information can be found in the:

- Product Information for COVID-19 vaccine AstraZeneca,
- COVID-19 vaccine information,
- ATAGI Clinical guidance for COVID-19 vaccine providers,
- COVID-19 Vaccination: How COVID-19 vaccines work, and
- COVID-19 vaccination – Patient resources.

Protection against different variants

A cohort study in Scotland with more than 19,000 sequenced cases including 7,723 Delta cases, showed effectiveness against PCR-positive SARS-CoV-2 infection irrespective of symptoms at the swab test was 18% (95% CI: 9 - 25) ≥28 days after dose 1 and 60% (95% CI: 53 - 66) ≥14 days after dose 2. When assessed against symptomatic infection, effectiveness estimates were 33% (95% CI: 23 to 41) and 61% (95% CI: 51 to 70) respectively (ATAGI, 2021b).

A test-negative case–control study in the UK, with more than 19,000 sequenced cases (>4,000 Delta cases), showed that effectiveness against PCR-positive symptomatic disease after 2 doses was 67.0% (95% CI: 61.3 - 71.8) for Delta variant cases compared to 74.5% (95% CI: 68.4 - 79.4) for Alpha variant cases. After 1 dose, it was 30.0 (95% CI: 24.3 - 35.3) and 48.7 (95% CI: 45.2 - 51.9), respectively (ATAGI, 2021b).

Another UK study, with 14,019 symptomatic cases with Delta showed that effectiveness against hospitalisation after 2 doses was 92% (95% CI:75 - 97) for Delta variant cases compared to 86% (95% CI: 53 - 96) for Alpha variant cases. After 1 dose, it was 71% (95% CI 51 - 83) and 76% (95% CI 61 - 85), respectively (ATAGI, 2021b).

Studies in the UK, India and Canada reinforce these results. Effectiveness against PCR-confirmed infection ranges from 60-67%, against symptomatic disease ranges from 61-71% and against severe disease ranges from 77-92% after dose 2. Regional differences in the vaccine roll out may have confounded the estimates of vaccine effectiveness (e.g., different vaccine intervals used over time and/or across different countries the world). Emerging data is constantly being monitored to inform future recommendations (ATAGI, 2021b).

In November 2021, the World Health Organisation (WHO) declared the Omicron variant as a Variant of Concern and a dominant strain globally.

Benefits of doses

Evolving evidence based on early vaccine effectiveness data and analysis of antibody levels after the first booster dose suggest there is gradual waning of immunity against the Omicron variant. This is most prominent for vaccine effectiveness against symptomatic infection (ATAGI, 2022d). The reduction in protection is similar for Delta and other virus variants. However, protection against severe disease has been shown to remain high and wane to a lesser degree than against infection or non-severe disease in many studies, including for the Delta variant. Protection against transmission from vaccinated individuals who are infected also appears to wane over time (ATAGI, 2021x).

ATAGI advises that an additional COVID-19 2023 booster dose is anticipated to address waning of protection against severe COVID-19 prior to winter. This will provide an increase in protection against severe illness and protect the healthcare system during a time of high demand (ATAGI, 2023a).

It is recommended to defer vaccination for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19 (ATAGI, 2023a).

The increase in protection against severe illness from COVID-19 following a booster dose is most beneficial for people at higher risk of severe illness, i.e., older adults and those with relevant medical risk factors. Studies conducted throughout the pandemic, including during Omicron epidemic waves have identified a higher risk of hospitalisation among older adults and adults with immunosuppression or other chronic medical conditions, compared with younger or healthy adults (ATAGI, 2023a).

ATAGI considers a booster dose beneficial for all adults aged 65 years and older. The risk of severe disease increases with each decade of age. With similar levels of hybrid immunity to the Australian population, UK modelling during the Omicron era found that 800 people aged 70 years and above would need to be given a booster to prevent one hospitalisation from COVID-19, compared with 8000 people aged 50 to 59 years and 92,500 people aged 40-49 years. However, a booster dose may still be beneficial for people aged 5-64 years based on individual circumstances such as underlying conditions that increase their risk of severe disease (ATAGI, 2023a).

For children and adolescents aged 5-17 years with risk factors for severe illness, a booster dose may be beneficial; decision-making around booster vaccination should be based on an individual risk-benefit assessment with their immunisation provider.

Topic 2: Cold chain storage and disposal

Cold chain storage:

Standard cold chain (+2°C to +8°C) procedures should be followed for all transport, storage and handling of the AstraZeneca (VAXZEVRIA) vaccine. For a review of the cold chain procedures please refer to Module 2 and also the *Strive for 5* guidelines (Department of Health and Aged Care [DHAC], 2019a).

The MDVs should be stored in their original outer packaging (carton) to protect them from light until ready for use.

The vaccine can be **stored** in cold chain conditions of **+2°C to +8°C** for a **maximum of 9 months** as per the expiry date printed on the vial. **Do not freeze the vaccine.**

If unopened vials are outside of cold chain requirements for a **single** period of time as specified below, is within the allowable storage conditions and the vials can be used. As long as the unopened vials are returned to standard cold chain conditions (+2°C to +8°C) as soon as possible:

- **A maximum of 12 hours in temperatures between +8°C to +30°C.**
- **A maximum of 72 hours at temperatures between +2°C to -3°C.**

These times are not cumulative. If **either** of these time limits have been reached, then the vial must be discarded into the clinical waste (AstraZeneca, 2021a). If multiple excursions occur within these thresholds, then the cold chain breach (CCB) must be reported to the Vaccine Operation Centre (VOC) on **1800 318 208**.

Once opened, the MDV can be used until one of the following has been reached:

- **6 hours cumulative total time has passed with the opened vaccine at room temperature, up to 30°C** (time that the vial has spent due to unforeseen circumstances while unopened in +8°C t o+30°C is not included in this time).
- **48 hours total time since opening (vial penetrated by a needle) and stored in cold chain conditions of +2°C to +8°C.** (A vial can be re-refrigerated after being opened if the vial has not been stored at room temperature for more than 6 hours, total cumulative time).

(AstraZeneca, 2021a; ATAGI, 2021b)

If you suspect your vaccines may have been involved in a CCB, either within the clinical setting or during transit:

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 Vaccine Operations Centre (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.

If you are unsure whether a cold chain breach has occurred, please contact the VOC on 1800 318 208. If you are concerned about the appearance of the vial, label as **DO NOT USE** and seek advice from the VOC.

A quick reference poster guide can be used for CCB management including reporting. Please note the requirement to contact the VOC in the event of a cold chain breach is specific to COVID-19 vaccines, and not stated in the National Vaccine Storage Guidelines.

Please see Appendix 5 for the steps to be followed if a potential CCB occurs.

Waste and Disposal:

All sharps with syringes still attached (such as after administration) should be discarded in a sharps waste container. The vials and other consumables should be disposed of in accordance with local requirements in the clinical waste bin.

Prior to disposal, the outer packaging (carton) should be defaced by striking through at least one panel of the carton with a sharpie or similar marker.

The AstraZeneca (VAXZEVRIA) vaccine contains GMOs. Any unused vaccine or waste material should be disposed of in accordance with local requirements in a clinical waste bin and reported through the COVID-19 Vaccine Administrative System (CVAS).

Incidents of fewer than 10 vials at a time must be reported as minor wastage in the weekly Stock Management Report in CVAS.

Major Wastage (10 or more vials)

A major wastage incident (e.g. damaged vials, expired vaccines or breach of cold chain requirements) is classified as one that includes 10 or more vials at a time.

If more than 10 vials at a time are wasted, providers must submit a Wastage Report through the COVID-19 Vaccine Administrative System (CVAS) within 2 hours of the incident. You are no longer required to call the VOC to additionally report the wastage incident.

Any wastage of fewer than 10 vials in one incident should be reported through the minor wastage section of your weekly Stock Management report in CVAS (due no later than 9pm local time Friday every week).

Surfaces with any spillages of vial contents should be cleaned up immediately using a spill kit similarly to spills of other viral vaccines as per the National Health and Medical Research Council (NHMRC*) Australian Guidelines for the Prevention and Control of Infection in Healthcare* (2019). Spills of the AstraZeneca (VAXZEVRIA) vaccine are relatively low-risk as the viral vector is replication deficient (Office of the Gene Technology Regulator [OGTR], 2021).

A spill kit should contain the safety equipment and all items required to clean up a spill including gloves, masks, paper towels and a disposal bag etc (NHMRC, 2019).

If a spill kit is not available, then the spilled contents can be decontaminated with an appropriate virucidal disinfectant. Choose a virucidal disinfectant that is listed on the Australian Register of Therapeutic Goods (ARTG) and where the manufacturer has confirmed its suitability for adenovirus decontamination (AstraZeneca, 2021a).

Dose preparation:

Prior to each vaccination, ensure all relevant expiries are checked.

The MDV must be inspected prior to preparation to ensure integrity of the sample as discussed in Topic 1.

If you are concerned about the appearance of the vial, label as **DO NOT USE** and seek advice from the National Vaccine Operation Centre (VOC) on **1800 318 208**.

Ensure that the vial has not expired and that it has not reached the maximum time since opening (needle first penetrated the bung). If the vial has been opened and there is no clear indication of the date and time of opening, the vial must be disposed of and accounted for in the weekly Stock Management Report in CVAS.

There is available space on the MDV to record the date and time first opened.

A sterile 19 to 21 gauge, bevelled drawing up needle is preferred for drawing-up. To extract the full 10 doses from the MDV, care should be taken to draw up the 0.5 mL individual dose volume exactly. A 2 mL or 3 mL syringe is recommended for doses of 0.5 mL or greater such as with the AstraZeneca (VAXZEVRIA) vaccine, if stock is available, otherwise a 1 mL syringe can be used.

Multiple doses can be drawn-up at once. Each filled syringe must be stored with a capped administration needle and appropriately labelled as well as stored at the appropriate temperature. If doses are not planned on being administered one after another then each dose should only be withdrawn as required.

ATAGI advice must be followed.

Although there are data supporting stability of vaccine doses after withdrawal into a syringe for up to 6 hours at room temperature (as reflected in the AstraZeneca vaccine product information), 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 (DHAC, 2021g; ATAGI, 2021b).

Pre-drawn vaccine doses in syringes are treated differently than diluted or open vials. Please refer to the ATAGI Transport, storage and handling webpage for ATAGI recommendations on open vials.

Some liquid remaining within the vial after removing all doses is normal. If low dead-space syringes and/or needles are used an extra 0.5 mL dose may be drawn up.

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

If a full dose cannot be drawn up from the remaining liquid in the MDV, it must be discarded as doses cannot be drawn from multiple MDVs and combined (AstraZeneca, 2021a).

When handling the vaccine vial, ensure you do not shake the vial (AstraZeneca, 2021a).

Home visits – 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 total maximum storage period of **6 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 can be administered as soon as practical and not exceeding the total maximum storage period of **1 hour if at room temperature**

More information can be found at the end of the ATAGI recommendations for Transporting, storing and handling COVID-19 vaccines (ATAGI, 2021b).

Topic 3: Preparation and administration

Dosing and schedule

The AstraZeneca (VAXZEVRIA) vaccine is administered as an intramuscular (IM) injection containing 0.5mL of vaccine. Double-check the details of the vaccine and dose before administration, ideally with another health professional as described in Module 4 (AstraZeneca, 2021a).

A total of two (2) doses are required to be administered to each recipient to complete a primary vaccination course. The Australian Technical Advisory Group on Immunisation (ATAGI) recommend a dose interval of 12 weeks. However, if this interval is not possible due to a significant medical intervention for example, then the vaccine is approved by the TGA to be administered with a minimum dose interval of 4 weeks (TGA, 2021a).

ATAGI prefers use of the same COVID-19 vaccine for the 2 doses of the primary course. An alternative vaccine brand for dose 2 should be used if there are specific medical contraindications or precautions, or the same vaccine brand is not available in Australia. It is preferable to use the same brand for both doses of the primary course, but an alternative brand can be used for the second dose for other reasons. Examples include if a person is unable to access the same brand or does not accept a second dose of the same brand. Emerging data support the safety and efficacy of mixed schedules (ATAGI, 2021b).

For more information on the recommended COVID-19 vaccine brand if an alternative vaccine brand is required for dose 2 please review the ATAGI clinical guidance for COVID-19 vaccine providers.

The recommended interval for administration of a second COVID-19 vaccine dose using any alternative brand is 4 to 12 weeks after the first dose, regardless of first dose brand. An interval longer than 12 weeks is acceptable if the second dose cannot be administered during this time window (ATAGI, 2021b).

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

See Appendix 3 for the Vaccine preparation and Vaccine administration checklist.

Severely immunocompromised individuals

A third primary dose of COVID-19 vaccine is recommended for all people aged 6 months or older with severe immunocompromise who are receiving a 2-dose primary course. The third dose should be given from 2 months after the second vaccine dose. A minimum interval of 4 weeks may be considered in exceptional circumstances (e.g., anticipated intensification of immunosuppression; outbreaks). People who have received a second dose more than 6 months ago should receive a third dose as soon as feasible (ATAGI, 2021w).

The third dose is intended to address the risk of lowered response or non-response to the standard 2-dose schedule. For more details on vaccine effectiveness in people who are immunocompromised, see the TGA VAXZEVRIA vaccine Product Information.

Individuals who currently are not severely immunocompromised but who will commence significant immunosuppressive therapy 2 or more weeks after their second dose do not require a third dose, as it can be expected that an adequate response to 2 primary doses will be achieved (ATAGI, 2021w).

For a comprehensive list of immunocompromising conditions and therapies for which a 3rd primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

An age-appropriate formulation of an mRNA COVID-19 vaccine or the Novavax (NUVAXOVID) (for people aged ≥ 12 years) is recommended for the third dose. Most studies of third doses of COVID-19 vaccine in immunocompromised people have used mRNA vaccines.

There is very limited evidence of the efficacy of Novavax (NUVAXOVID) in immunocompromised people.

The AstraZeneca (VAXZEVRIA) vaccine was not preferred but could have been used for the third dose in adults if there were contraindications to mRNA and Novavax (NUVAXOVID) vaccines.

Booster dose recommendations

ATAGI **recommends** 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:

- 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.

ATAGI advises the following groups should **consider** a 2023 booster dose 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.

Development of seasonal immunisation policy to manage COVID-19 is limited as the evolution as well as duration and strength of protection against serious SARS-CoV-2 illness is uncertain at this time (ATAGI, 2023a).

Booster doses are not currently recommended for children aged under 5 years, or for children and adolescents aged 5 to 17 years who are not at increased risk of severe disease as defined above. Severe COVID-19 in children is uncommon and the primary course of COVID-19 vaccines generates a strong immune response. The benefit from additional doses of vaccine is likely to be small. Current evidence does not suggest that booster doses are needed at this time.

Booster dose: vaccine preference recommendations

Any age-appropriate COVID-19 vaccine, including original (ancestral virus-based) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer lasting protection against severe disease.

However, bivalent mRNA booster vaccines are preferred over other vaccines. These include any of the bivalent Original/Omicron BA.1 vaccines or bivalent Original/Omicron BA.4-5 vaccines.

For more information on which vaccines are available for each age group refer to the COVID-19 vaccine doses and administration webpage. Bivalent Original/Omicron BA.1 vaccines are only registered for use in people aged 18 years and over. Bivalent Original/Omicron BA.4-5 vaccines are registered for use from 12 years of age.

Although not preferred, the previously supplied AstraZeneca (VAXZEVRIA) or Novavax (NUVAXOVID) vaccines could be used as a booster dose in people aged 18 years and older in the following circumstances:

- people who have a contraindication to mRNA vaccines (including those who have had a serious adverse event following mRNA vaccines, such as a history of anaphylaxis or myocarditis attributed to an mRNA vaccine)
- people who do not prefer an mRNA vaccine.

Although not TGA-registered as a booster in this age group, Novavax (NUVAXOVID) can be used as a booster in people aged 12 years or older if no other COVID-19 vaccine brand is suitable for that person.

There is a growing body of evidence supporting the safety and effectiveness of Pfizer (COMIRNATY) and Moderna (SPIKEVAX) vaccines as booster doses. Data on the use of AstraZeneca (VAXZEVRIA) as a booster dose are more limited (see COVID-19 Vaccine information). There are very limited data on the use of Novavax (NUVAXOVID) as a booster.

Booster dose: recommended intervals

Administration of a 2023 COVID-19 booster dose should aim to occur prior to June 2023 and at a time of 6 months or greater following the most recent COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (whichever is the most recent) (ATAGI, 2023a).

The evidence underpinning booster dose recommendations will continue to be reviewed and this clinical guidance may be refined. For more details see: COVID-19 vaccine information.

Vaccine administration errors (VAEs)

A vaccine administration error occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training undertaken to minimise the risk of errors occurring (ATAGI, 2022a).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible vaccine administration errors (VAEs), including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022a). The VOC on **1800 318 208** is available to provide advice to clinicians regarding VAEs.

Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Please see Appendix 4 for the steps to be followed if a Vaccine administration error occurs.

Administration:

Do not mix or contaminate the vaccine with any other medication or liquid (AstraZeneca, 2021a).

A new sterile syringe and needle must be used for administration to each individual.

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 individual. An aseptic procedure must be used throughout the procedure as there is a potential for a greater frequency of injection site reactions using this technique. Steps to complete this process are exactly the same as described in Module 4, except the needles are not changed. In this case only an administration needle is used to both draw up and administer the vaccine (ATAGI, 2021a). Seek advice from your Public Health Unit (PHU) when this may be appropriate.

A dose that has just been withdrawn from a vial which has a capped administration needle on it may be transported from the vaccine preparation area to the administration area. The room temperature should be below 30°C.

If required refer to guidance on Vaccinating your patients against COVID-19.

A sterile 22 to 25 gauge, 25mm length needle is recommended for administration, except for individuals with obesity when a 38mm length needle is recommended. Safety needles are also strongly recommended if available. Refer to Module 4 for more information.

Administer intramuscularly (IM), preferably into the deltoid using aseptic technique. **DO NOT** inject intravenously, subcutaneously or intradermally (AstraZeneca, 2021a).

ATAGI is aware of scientific reports proposing that inadvertent injection of a COVID-19 vaccine into a blood vessel may be a contributing cause of serious adverse events following immunisation, such as thrombosis with thrombocytopenia syndrome (TTS). ATAGI has reviewed the available evidence and

considers injection technique highly unlikely to be a contributor to these adverse events, for several reasons:

- The majority of cases of TTS occur after the first dose of the AstraZeneca (VAXZEVRIA) vaccine. If intravascular injection was an important contributor, there would not be this differential distribution of cases by vaccine dose.
- Direct injection into a blood vessel is unlikely in recommended injection sites.
- TTS typically occurs some days or even weeks after vaccination, which does not fit with the proposed theory of direct vascular injury which occurs early in animal models.

(DHAC, 2021j)

Based on a review of the available evidence, ATAGI does not recommend routinely aspirating (drawing back) needles before injection. This practice was rejected some decades ago, due to several disadvantages including prolonging the procedure, potentially associated pain, and increasing the risk of needle-syringe disconnection. Not aspirating is supported by the current advice in the Australian Immunisation Handbook (ATAGI, 2022q).

ATAGI will continue to review emerging evidence on the underlying mechanisms, prevention and treatment of TTS, myocarditis and other serious adverse events of special interest.

A minimum 15-minute observation period must be completed post administration to monitor for adverse events.

After administration, the vaccine dose administered including batch number must be entered into the Australian Immunisation Register (AIR) as described in Module 5 Topic 4 to facilitate traceability (AstraZeneca, 2021a).

COVID-19 vaccines can be co-administered (i.e. on the same day) with an influenza vaccine. COVID-19 vaccines can also be co-administered with other vaccines if required, however, given the current limited evidence on the concomitant use of COVID-19 vaccines with other vaccines, providers need to balance the opportunistic need for co-administration with giving the vaccines on separate visits. There is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time. Co-administration or near administration (e.g. within days) with another vaccine may also make the attribution of potential adverse events more challenging (ATAGI, 2021b).

Data on the potential for co-administration with other vaccines is currently being reviewed and detailed information on this will be included in the *ATAGI Clinical Guidance for COVID-19 vaccine providers* (ATAGI, 2021b).

It is recommended that all individuals who have received an AstraZeneca (VAXZEVRIA) dose receive the batch number for adverse event reporting. It is expected that ALL adverse events experienced following immunisation (AEFI) are reported by the individual after receiving a COVID-19 vaccination. More information is covered in Module 6.

Administration of vaccines under sedation:

Procedural guidelines for administration of vaccines under sedation in practice have been developed or are currently being developed in some health services. ATAGI advises that detailed clinical guidance should be developed collaboratively with input from anaesthetic groups, jurisdictional health services and relevant specialists (ATAGI, 2022g).

More information can be found in the ATAGI advice on use of sedation for COVID-19 vaccination.

Topic 4: Precautions and contraindications

A pre-screening checklist must be completed to check for any contraindications or circumstances for which precaution is required before administration (covered in Module 5 Topic 3). The precautions relating to AstraZeneca (VAXZEVRIA) are the same as those reviewed in Module 5 Topic 2. Please review these again as required.

Further clinical studies are planned to evaluate long-term effectiveness and safety, as well as effectiveness in the wider population, including use in pregnant women, individuals under 18 years of age and individuals who are immunocompromised.

Individuals who have previously had COVID-19 were able to safely receive the AstraZeneca (VAXZEVRIA) vaccine, however, if pregnant when the second dose is due a bivalent mRNA vaccine is preferred as the second dose as there are substantial data on their safe use in pregnancy.

There are three (3) true contraindications to receiving the previously supplied AstraZeneca (VAXZEVRIA) vaccine:

- An anaphylactic or hypersensitivity reaction to a **previous** AstraZeneca (VAXZEVRIA) vaccine dose or to any of its contained ingredients as listed in Topic 1 (AstraZeneca, 2021a).
- Experiencing major venous and/or arterial thrombosis in combination with thrombocytopenia following vaccination with any COVID-19 vaccine.
- Previous episode of capillary leak syndrome (AstraZeneca, 2021a; ATAGI, 2021d).

If an individual has a contraindication following a first dose of a COVID-19 vaccine, an alternative brand should be considered for the second dose, the recommended interval for administration of a second dose is 4 to 12 weeks after the first dose. A longer interval is acceptable if the second dose cannot be administered during this time window. People should be made aware of the risks and benefits of receiving an alternative vaccine brand for the second dose.

Precautions:

As with other vaccinations, administration of the previously supplied AstraZeneca (VAXZEVRIA) vaccine should not have been delayed for a minor infection, illness or low-grade fever (<38.5°C). Vaccination should be delayed in individuals experiencing an acute severe febrile illness with a temperature ≥ 38.5°C (AstraZeneca, 2021a).

No precautions are required for individuals with anaphylaxis to food, venom, latex or other medications, or allergic conditions (ASCIA, 2021).

Past infection is not a contraindication to vaccination. ATAGI recommends that vaccination should be deferred for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19 (ATAGI, 2023a). People who have received an anti-SARS-CoV-2 monoclonal antibody or convalescent plasma should defer future doses of COVID-19 vaccine for at least 90 days (ATAGI, 2021b).

Waiting for a 6-month period after infection before COVID-19 vaccination is intended to optimise protection for that person. A longer gap between infection and vaccination is likely to lead to a better immune response and result in longer protection from reinfection (ATAGI, 2022f).

Infection with certain SARS-CoV-2 variants has previously been shown to reduce the risk of reinfection with a variant other than Omicron for at least 6 months. However, recent evidence shows that people with prior infection with a variant other than Omicron are likely to be reinfected with the SARS-CoV-2 Omicron variant more often than with other variants, such as Delta.

The risk of reinfection with Omicron after an Omicron infection is not yet known, but it is likely the reinfection rates will be lower in this context for a period of time, as compared with prior infection with a variant other than Omicron.

Testing using polymerase chain reaction (PCR) or rapid antigen testing (RAT) to detect current or past infection with SARS-CoV-2 before vaccination is neither necessary nor recommended.

Individuals who have prolonged symptoms from COVID-19 beyond four months can be vaccinated on a case-by-case basis.

People under the age of 60 - ATAGI recommends that the mRNA **COVID-19 vaccines or Novavax (NUVAXOVID) are the preferred vaccines for those aged under 60 years**. The recommendation was revised due to a higher risk and observed severity of thrombosis and thrombocytopenia syndrome (TTS) related to the use of the AstraZeneca (VAXZEVRIA) vaccine observed in Australia in the 50-59 year old age group than reported internationally and initially estimated in Australia (ATAGI, 2021n).

The previously supplied AstraZeneca (VAXZEVRIA) vaccine could have been used in adults aged between 18 to 59 years if the benefits were likely to outweigh the risks for that individual and the person made an informed decision based on an understanding of the risks and benefits.

For those aged 60 years and above, the benefit of vaccination in preventing COVID-19 with the previously supplied AstraZeneca (VAXZEVRIA) outweighed the risk of TTS.

People of any age without contradictions who have had the first dose of the AstraZeneca (VAXZEVRIA) without any serious adverse events could have received the second dose (ATAGI, 2021n).

Thrombosis with thrombocytopenia syndrome (TTS) - TTS is a very rare, new and unexpected adverse event that appears to be causally linked with the AstraZeneca (VAXZEVRIA) vaccine. TTS involves blood clots (thrombosis) and low levels of blood platelets (thrombocytopenia) and mostly occurs within the first 21 days after vaccination. The blood clots can occur in different parts of the body, such as a venous thrombosis in the brain (cerebral venous sinus thrombosis or CVST) or in the abdomen (such as splanchnic vein thrombosis) or arterial thrombosis and concomitant thrombocytopenia (AstraZeneca, 2021a).

In Australia, the rate of TTS is estimated to be about 1 to 2 cases per 100,000 people vaccinated with the AstraZeneca (VAXZEVRIA) vaccine (ATAGI, 2021b). But for those under 50 years of age, the rate is currently estimated to be higher at 3.1 cases per 100,000 (ATAGI, 2021m). These estimates are based on the small numbers of people who have been vaccinated in Australia but are similar to rates seen in some countries overseas.

We believe that a higher proportion of less severe cases may be being reported in Australia. This may be due to high levels of awareness in the community and among the medical profession around TTS along with less strain on the healthcare system around COVID infections with much lower infection rates than internationally (ATAGI, 2021h).

The TGA have reviewed the classification of confirmed and probable TTS cases using the recently proposed Centre for Disease Control (CDC) two tier criteria:

- Tier 1 – Criteria are defined as clots in an unusual location such as the brain or abdomen AND a low platelet count with or without a positive test for antibodies that activate platelets (anti-PF4 antibodies).
- Tier 2 – Criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

(ATAGI, 2021m)

It is not yet clear if women are at higher risk. More women than men have been vaccinated in some countries as they are a large proportion of frontline healthcare workers and have been prioritised for vaccination (ATAGI, 2021d). While some case series report more cases in women, others have found no difference by sex (ATAGI, 2021b).

Based on current information, we do not know if there are any pre-existing medical conditions or other risk factors that may contribute to developing TTS or make it worse if it occurs including a past history of clots or of any clotting tendencies (ATAGI, 2021d; ATAGI, 2021b). It appears to be an idiosyncratic reaction.

Previous thrombotic event – mRNA vaccines and Novavax (NUVAXOVID) were preferred over the previously available AstraZeneca (VAXZEVRIA) in people with the following conditions as these have been identified as having a potential similar mechanism to TTS:

- A past history of cerebral venous sinus thrombosis (CVST).
- Heparin-induced thrombocytopenia (HIT).
- A past history of idiopathic splanchnic (mesenteric, portal and splenic) venous thrombosis.
- Anti-phospholipid syndrome with thrombosis and/or miscarriage*.

* People with antiphospholipid antibodies with no clinical manifestations (e.g. thrombosis, miscarriage) are not considered to have the syndrome and therefore may have had the AstraZeneca (VAXZEVRIA) vaccine.

Based upon current research, the following groups of people could have received the previously supplied AstraZeneca (VAXZEVRIA) vaccine:

- People who have had a past history of other types of clots such as deep vein thrombosis (DVT) and pulmonary embolism (PE) or have risk factors for these clots.
- People with a predisposition to form blood clots, such as those with Factor V Leiden, or other non-immune thrombophilic disorders
- People with a family history of clots or clotting conditions.
- People currently receiving anticoagulant medications.
- People with a history of ischaemic heart disease or cerebrovascular accident.
- People with a current or past history of thrombocytopenia.

For adults over 60 years of age who have a history of blood clots, the benefits of vaccination are considered to outweigh the risk of TTS (ATAGI, 2021d). There is no evidence that people who have had a past history of other types of blood clots have an increased risk of TTS or becoming more ill from it if it occurs.

The overall rate of blood clots such as DVTs and PEs (1 per 1000) have not risen in countries that have extensively used the AstraZeneca (VAXZEVRIA) vaccine. Some of the blood clots that occur post administration of the AstraZeneca (VAXZEVRIA) vaccine will be coincidental and not causally related

to the vaccine (ATAGI, 2021d). There are currently no data on safety of 3rd doses of vaccine in relation to the risk of thrombosis and thrombocytopenia syndrome (TTS) after AstraZeneca (VAXZEVRIA) (ATAGI, 2021w).

For more information please review the Information for immunisation providers on Thrombosis with Thrombocytopenia Syndrome (TTS) following COVID-19 vaccination document and the joint statement from ATAGI and THANZ on Thrombosis with Thrombocytopenia Syndrome (TTS) and the use of COVID-19 Vaccine AstraZeneca.

Children and adolescents – The safety and efficacy of the AstraZeneca (VAXZEVRIA) vaccine has not been tested in those under 18 years of age and therefore has not been established (AstraZeneca, 2021a).

If AstraZeneca (VAXZEVRIA) was inadvertently given as a first dose to a person aged between 12 and 17 years, an mRNA vaccine should be used for the second dose.

Significant co-morbidities and older adults – There are currently limited data available for the efficacy and safety in individuals over 65 years of age. However, the vaccine has been shown to create an immune response in this group and can be used based on the efficacy and safety demonstrated in the general clinical trial population.

The decision to immunise an elderly patient should be decided on a case-by-case basis with consideration of age, co-morbidities and their environment taking into account the benefits of vaccination and potential risks. Further information from ongoing clinical trials and post-market monitoring is expected in the coming months. Additional details can be found in the Product Information and *Australian Public Assessment Report (AusPAR)*

The previously supplied AstraZeneca (VAXZEVRIA) vaccine was recommended for use in all individuals over 60 years, however, if someone is very frail or close to the end of life you may choose not to give them the vaccine. As the over 65 group are at most risk of severe disease and death due to COVID-19, they are also the most likely to benefit from vaccination. There is currently no evidence to suggest that the AstraZeneca (VAXZEVRIA) vaccine is less effective at preventing severe illness or death compared with other vaccines currently approved for use in Australia.

Adults with pre-existing co-morbidities showed similar, suitable immune responses and vaccine efficacy, compared to the general study population without co-morbidities. Participants aged 65 years and over who received two doses showed SARS-CoV-2 specific neutralising antibody levels comparable with those in serum samples from people who had recovered from COVID-19 (convalescent sera). Additional information on the efficacy of AstraZeneca (VAXZEVRIA) in adults aged 65 years and over is anticipated from a phase III clinical trial underway in the USA and South America with over 30,000 participants, including at least 25% of participants aged 65 years and over (ATAGI, 2021b).

An interim sub-analysis of data on people with specified medical conditions in the Phase II/III trials showed vaccine efficacy in this group was similar to that in people without such conditions. A total of 2,068 (39.3%) participants had at least one pre-existing comorbidity (defined as a BMI ≥30 kg/m^2, cardiovascular disorder, respiratory disease or diabetes). A pooled data analysis (as of 7 December 2020) showed that participants who had one or more comorbidities had a VE of 58.3% (95% CI: 33.6 - 73.9) (ATAGI, 2021b).

The potential benefits should be assessed against the risks at an individual level, especially if the person is frail. The COVID-19 vaccination decision guide for frail older people, including those in

residential aged care facilities can be used by the older adult to make an informed decision. Additionally, a new decision guide is now available for people receiving palliative care and/or end-of-life care.

Immunocompromised individuals – Immunocompromised individuals are at higher risk of severe COVID-19 disease and are highly recommended to have the vaccine. This includes people who are on immunosuppression medication, on high-dose steroids or are immunodeficient. Being immunocompromised does not increase potential adverse risks. However, it is not known if individuals with an impaired immune system exhibit the same response as immunocompetent individuals (AstraZeneca, 2021a).

For more information review ATAGIs COVID-19 vaccination decision guide for people with immunocompromise.

Ideally, vaccination should occur on a different day to regular infusion treatments, such as immunoglobulin replacement therapy or immunosuppressant infusions (ASCIA, 2021).

ATAGI recommends a 3rd primary dose of COVID-19 vaccine in severely immunocompromised populations to address the risk of suboptimal or non-response to the standard 2 dose schedule. The 3rd dose is intended to maximise the level of immune response to as close as possible to the general population (ATAGI, 2021w).

ATAGI recognises that a substantial proportion of vaccinated individuals among some groups with severe immunocompromise conditions show suboptimal response to COVID-19 vaccine, and that this is likely to place them at ongoing increased risk of SARS-CoV-2 infection despite vaccination. ATAGI considers it important to offer a third primary dose to provide a higher level of protection for these individuals, aiming to attain a level as close as possible to that seen in healthy individuals. Provision of a 3rd dose to severely immunocompromised individuals does not guarantee equivalent protection to immunocompetent individuals, therefore ongoing risk mitigation measures are warranted (ATAGI, 2021w).

Antibody testing is not recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination, including in immunocompromised individuals after a 2nd or 3rd dose. There are no serological assays that provide a definitive correlate of immunity to SARS-CoV-2 (ATAGI, 2021w).

For a comprehensive list of immunocompromising conditions and therapies for which a 3rd primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

ATAGI advises 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 should **consider** a 2023 booster dose 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 (ATAGI, 2023a).

A booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19 (ATAGI, 2023a).

Bleeding risk – Caution is advised with individuals who may have thrombocytopenia, a coagulation disorder, or are receiving anticoagulation therapy because of the IM injection breaking the skin and therefore, increasing the risk of bleeding and bruising (AstraZeneca, 2021a).

Allergies

The precautions relating to the previously supplied AstraZeneca (VAXZEVRIA) vaccine are the same as the ones reviewed in Module 5, Topic 2. Please review these again as required.

Consultation with a clinical immunology, allergy or vaccinology specialist is recommended prior to administering a COVID-19 vaccine to an individual who has had a generalised reaction (without anaphylaxis) to a previous dose of COVID-19 vaccine or one of the ingredients of the AstraZeneca (VAXZEVRIA) vaccine. The Australasian Society of Clinical Immunology and Allergy (ASCIA, 2021) position statement can be read for more specific details here and also ATAGI have some advice on allergy precautions here.

For specialist advice and assistance, please contact your local public health unit (PHU).

Pregnancy, fertility and breastfeeding:

Pregnancy (Category B1) – Bivalent mRNA vaccines are the recommended COVID-19 vaccines for pregnant women. This is based on the growing body of evidence supporting the safety of mRNA vaccines in pregnancy, whereas there are still very limited data on the safety of other COVID-19 vaccines (AstraZeneca (VAXZEVRIA) and Novavax (NUVAXOVID)) in pregnancy. However, people who cannot access an mRNA vaccine could have considered vaccination with AstraZeneca (VAXZEVRIA) or Novavax (NUVAXOVID) if the benefits to the individual outweigh the potential risks.

Pregnant women with COVID-19 have a higher rate of hospitalisation, intensive care unit admission and mechanical ventilation, but not death, than age-matched non-pregnant women. The risk of preterm delivery is also increased. There is no evidence to suggest that SARS-CoV-2 infection in pregnancy increases the risk for congenital anomalies (ATAGI, 2021b).

There is still very limited data on the safety of AstraZeneca (VAXZEVRIA) in pregnancy. However, people who cannot access an mRNA vaccine could have considered vaccination with AstraZeneca (VAXZEVRIA) if the benefits to the individual outweighed the potential risks. Women who have received their first dose of AstraZeneca (VAXZEVRIA) vaccine and are pregnant could have received a second dose of AstraZeneca (VAXZEVRIA). Pregnant women should speak with their health care provider about the best choice for them.

If AstraZeneca (VAXZEVRIA) was inadvertently administered during pregnancy, routine monitoring for adverse events following immunisation is advised (ATAGI, 2021b).

Breastfeeding – There is no data on the safe use of the vaccine with breast-fed newborns and infants and therefore a risk cannot be excluded (AstraZeneca, 2021a).

It is recommended that women who are breastfeeding or who are planning pregnancy an mRNA or Novavax (NUVAXOVID) vaccine.

Fertility – It is recommended that women who are planning pregnancy receive an mRNA or Novavax (NUVAXOVID) vaccine (ATAGI, 2021j).

It is not known whether the AstraZeneca (VAXZEVRIA) vaccine affects fertility or not as there is no data available (AstraZeneca, 2021a).

For further information, refer to the COVID-19 vaccination – Shared decision making guide for women who are pregnant, breastfeeding, or planning pregnancy.

Topic 5: Adverse events

General adverse events have been discussed in Module 6, Topic 2. All adverse events following immunisation (AEFI) should be reported. Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website. Individuals and healthcare workers can report side-effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website.

Safety data has been collated from four clinical trials conducted in the United Kingdom, Brazil and South Africa in over 23,500 participants ≥18 years old. The participants were randomised to either receive a COVID-19 vaccine or a control, at least 12,000 received a minimum of one (1) AstraZeneca (VAXZEVRIA) vaccine dose (AstraZeneca, 2021a).

A majority of the adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. After vaccination, symptoms similar to having a cold may be experienced, due to the body's immune response, which is normal and expected.

The following list identifies the frequency of very common adverse events following immunisation (AEFI) in completed clinical trials:

- Injection site tenderness (>60%), pain (>50%), warmth (>15%) and itch (>10%).
- Headache (>50%).
- Fatigue (>50%).
- Myalgia (>40%).
- Malaise (>40%).
- Pyrexia/fever and chills (>30%).
- Arthralgia/joint pain (>20%).
- Nausea (>20%).

(AstraZeneca, 2021a)

Common symptoms to be aware of include:

- Injection site swelling and redness (common).
- Pyrexia/fever (common).

A slightly lower frequency and milder adverse reactions were reported after the second dose when compared with the first. Adverse events were generally milder and reported less frequently in adults over 65 years of age (AstraZeneca, 2021a).

The profile of adverse events after the 3rd dose is similar to that of preceding doses, and studies have not reported vaccine-related serious adverse events. However, these studies were conducted in small numbers of patients, and rare side effects may not have been detected. There are currently no data on safety of 3rd doses of vaccine in relation to the risk of thrombosis and thrombocytopenia syndrome (TTS) after AstraZeneca (VAXZEVRIA). ATAGI will continue to monitor the evidence around safety of additional doses of COVID-19 vaccine (ATAGI, 2021w).

Studies suggest that the common mild and transient side effects after booster doses are comparable to those following primary vaccine doses. However, there are limited data on the incidence of rare but potentially serious adverse events following booster doses (ATAGI, 2021x).

Very rare events – Thrombosis with thrombocytopenia syndrome (TTS) is a very rare unexpected adverse event that appears to be causally-linked with the AstraZeneca (VAXZEVRIA) vaccine. In Australia, the rate of TTS is estimated to be about 1 to 2 cases per 100,000 people vaccinated with AstraZeneca (VAXZEVRIA). But for those under 50 years of age, the rate is currently estimated to be about 3.1 cases per 100,000, 2.7 per 100,000 in those aged 50-59 and 1.6 in those 60 years and over.

This is a distinct syndrome that involves thrombosis *with* thrombocytopenia, with onset of symptoms mostly around 4 to 30 days following vaccination. The site of thrombosis in reported cases are unusual, varied and usually venous. Most cases have included cerebral venous sinus thrombosis (CVST) or thrombosis of the splanchnic (abdominal) circulation. Although very rare, TTS can cause disability and even death, with a fatal outcome in about 19% of the cases reported in the UK (ATAGI, 2021h).

Based on current information, we do not know if there are any pre-existing medical conditions that may contribute to developing TTS or make it worse if it occurs. The rate of TTS reported in Australia and overseas is higher in younger adults and it may be more common in women. However, cases have also been reported in men and in older people.

It is not yet clear if women are at higher risk. More women than men have been vaccinated in some countries as they are a large proportion of frontline healthcare workers and have been prioritised for vaccination (ATAGI, 2021d).

Based on current information, mRNA vaccines **and the recombinant vaccine Novavax (NUVAXOVID)** are not associated with TTS (ATAGI, 2021h).

Venous thromboembolic events without thrombocytopenia - Venous thromboembolic events without accompanying thrombocytopenia, including CVST, have been reported following vaccination with AstraZeneca (VAXZEVRIA). Although a causal relationship has not been established, these may need different treatment approaches than TTS and can be fatal. Healthcare professionals should consult applicable guidance (AstraZeneca, 2021a).

Immune thrombocytopenia – There have been reported cases of immune thrombocytopenia (ITP) following vaccination with AstraZeneca (VAXZEVRIA), including a fatal outcome (AstraZeneca, 2021a).

Identification and referral of suspected cases

Any patient with concerning signs or symptoms potentially related to TTS as well as other coagulopathies following receipt of AstraZeneca (VAXZEVRIA) should be referred to an emergency department for assessment and investigation, including consultation with a haematologist (ATAGI, 2021h).

Primary care providers should consider the potential for a patient having TTS if they present with symptoms of possible thrombosis or thrombocytopenia 4 to 42 days after receiving a dose of AstraZeneca (VAXZEVRIA). Suspected cases should be immediately referred to an emergency department if they are acutely unwell.

Concerning signs or symptoms include:

- An unusual and severe headache that starts or persists at least 48 hours after vaccination which does not improve with simple analgesia.
- Signs and symptoms of raised intracranial pressure or focal neurological deficits or seizures.
- Signs or symptoms suggestive of thrombosis in other anatomical locations (e.g. abdominal pain suggestive of thrombosis in the splanchnic circulation, or chest pain suggestive of pulmonary embolism).
- Signs suggestive of clinically significant thrombocytopenia, such as petechial rash or bleeding, or bruising not at the vaccine injection site that cannot be explained.

Cases of isolated thrombocytopenia or isolated thrombosis after vaccination are unlikely to represent TTS. Clinical judgement should be used to guide investigations and management (ATAGI, 2021h).

TTS can now be treated very effectively and emerging evidence suggests that early detection and management of cases, including referral to hospital, can prevent the development of more serious complications. THANZ have developed guidance on identification and treatment of TTS for doctors.

Patients suspected to have this condition should **NOT** receive any heparin or platelet transfusions Further information is available on the Department of Health and Aged Care website (ATAGI, 2021h).

There is no evidence that people who have had a past history of other types of blood clots have an increased risk of TTS or becoming more ill from it if it occurs. The overall rate of blood clots (1 per 1000) has not risen in countries which have extensively used the AstraZeneca (VAXZEVRIA) vaccine (DHAC, 2021h). Some of the blood clots that occur after the AstraZeneca (VAXZEVRIA) vaccine will be coincidental and not causally related to the vaccine (ATAGi, 2021h).

For more information please review the Information for immunisation providers on Thrombosis with Thrombocytopenia Syndrome (TTS) following COVID-19 vaccination document.

People who develop ITP within 42 days after receiving AstraZeneca (VAXZEVRIA) should consult a haematologist regarding whether to proceed with the second dose using the same or an alternate vaccine, and the timing of the second dose (ATAGI, 2021b).

Other rare events

The first dose of AstraZeneca (VAXZEVRIA) has been found to be associated with a small risk of immune thrombocytopenia (ITP). Two other serious but rare adverse events have been reported after AstraZeneca (VAXZEVRIA) vaccination overseas, for which a causal association has not yet been confirmed. These are Guillain Barre syndrome and capillary leak syndrome (ATAGI, 2021b).

Capillary leak syndrome (CLS) has been reported rarely in the first days following AstraZeneca vaccine in the UK and Europe, including in people with a history of capillary leak syndrome. One case has been reported in Australia but a causal link with the vaccine could not be established. Capillary leak syndrome is a rare but severe relapsing-remitting condition where capillary fluid leaks into surrounding tissues and can be fatal. CLS is characterised by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia. People with an acute episode of CLS following vaccination require prompt recognition and treatment. Intensive support therapy is usually warranted. COVID-19 Vaccine AstraZeneca (VAXZEVRIA) is contraindicated in people with a past history of capillary leak syndrome (ATAGI, 2021b; AstraZeneca, 2021a).

Neurological events:

Guillain-Barré Syndrome (GBS) – GBS has been reported very rarely following vaccination with AstraZeneca. A causal relationship has not been established. Healthcare professionals should be alert of signs and symptoms of demyelinating disorders to ensure correct diagnosis, in order to initiate adequate supportive care and treatment, and to rule out other causes.

Demyelinating disorders - Very rare events of demyelinating disorders have been reported following AstraZeneca (VAXZEVRIA) vaccination. A causal relationship has not been established.

All immunisers are strongly encouraged to report **ALL** adverse events following administration of AstraZeneca (VAXZEVRIA) that are serious, unexpected or require medical attendance. The batch number should also be included in this reporting to monitor any potential issues with manufacturing, transport or storage. Refer to Module 5 for national and jurisdictional reporting requirements and pathways.

Anaphylaxis can occur after administration of any medicine. Anaphylaxis and angioedema have occurred following the administration of AstraZeneca (VAXZEVRIA) (AstraZeneca, 2021a). As with all vaccines, immunisation providers must be prepared to respond to an individual developing anaphylaxis. The anaphylaxis rate in Australia appears similar to any other vaccine (DHAC, 2021h). Follow all management steps outlined in *Module 6, Topic 3*.

The AstraZeneca (VAXZEVRIA) vaccine has no or limited effects on the ability to use machines and drive. However, if experienced, some of the AEFI may temporarily affect an individual's ability to drive or use machines (AstraZeneca, 2021a).

Consumer medicine information and the COVID-19 vaccination – Patient resources can be given to individuals receiving the vaccine which detail what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for your state or territory, please review this website.

Module Summary

- The AstraZeneca (VAXZEVRIA) vaccine is a single recombinant, non-replicating viral vector vaccine.
- The MDVs contain either 5mL of vaccine which equates to 10 doses of 0.5mL vaccinations.
- The unopened (no needle puncture) MDVs can be stored at +2°C to +8°C for up to 9 months. Check the expiry date on the MDV before use.
- Once opened the MDV can be used for a maximum of 48 hours in cold chain storage (+2°C to +8°C) but only a maximum 6 hours at room temperature (up to 30 °C).
- The pre-drawn vaccine should be administered immediately after being drawn up and within 1 hour if stored at room temperature (up to 30°C).
- The previously supplied AstraZeneca (VAXZEVRIA) vaccine was given as a 2-dose primary schedule intramuscularly into the deltoid, or 3-dose primary schedule for people who are severely immunocompromised.
- ATAGI prefers use of the same COVID-19 vaccine for the 2 doses of the primary course. An alternative vaccine brand for dose 2 should be used if there are specific medical contraindications or precautions, if the same vaccine brand is not available, or for other reasons.

- The recommended dose interval was 4 to 12 weeks between dose 1 and 2. The recommended dose interval for dose 3, if required, was 2 months after the second dose.
- Booster doses can be administered 6 months after the last COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (whichever is the most recent). Although not preferred, AstraZeneca (VAXZEVRIA) could have been used as a booster dose if there were no alternative.
- All adverse events must be reported as this is a novel vaccine.
- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

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Multi-choice Questions:

1. Which of these statements about storage and preparation for the AstraZeneca (VAXZEVRIA) vaccine is CORRECT?
    a. The unopened MDVs can be stored in cold chain storage (+2°C to +8°C) for a maximum of 9 months.
    b. An opened MDV can be left at room temperature (up to 30°C) for a maximum of 12 hours.
    c. The vaccine must be administered within 24 hours of being drawn-up into the syringe.

2. What were the minimum and maximum recommended intervals between the first and second primary course doses of the AstraZeneca (VAXZEVRIA) vaccine in a standard setting?

    a. Minimum = 3 weeks. Maximum = 1 year.
    b. Minimum = 4 weeks. Maximum = 6 months.
    c. Minimum = 4 weeks. Maximum = 12 weeks.

3. What was ATAGI's recommendation regarding the use of AstraZeneca (VAXZEVRIA) vaccine as a booster dose?

    a. For individuals 18 years and older, AstraZeneca (VAXZEVRIA) can be used if either an mRNA vaccine is contraindicated, or a person declines vaccination with an mRNA vaccine.
    b. For individuals 16 years and older who are severely immunocompromised, AstraZeneca (VAXZEVRIA) can be used if either an mRNA vaccine is contraindicated, or a person declines vaccination with an mRNA vaccine.
    c. For individuals 18 years and older, AstraZeneca (VAXZEVRIA) should be used if a person's primary course was AstraZeneca (VAVZEVRIA).
    d. For individuals 16 years and older, AstraZeneca (VAXZEVRIA) should be used if a person's primary course was AstraZeneca (VAVZEVRIA).

4. Which of these sentences regarding the dose and administration of the AstraZeneca (VAXZEVRIA) is CORRECT?

    a. A single dose is 0.5 mL and is recommended to be drawn up in a 1 mL, 2 mL or 3 mL syringe. Each MDV contains 10 doses.
    b. A single dose is 0.3 mL and is recommended to be drawn up in a 2 mL or 3 mL syringe. Each MDV contains 10 doses.
    c. A single dose is 0.5 mL and is recommended to be drawn up in a 1 mL or 2 mL syringe. Each MDV contains 10 doses.
    d. A single dose is 0.5 mL and is recommended to be drawn up in a 4 mL syringe. Each MDV contains 10 doses.

Additional Module 3: Moderna COVID-19 vaccine (DECOMMISSIONED)

(21/09/2023)

MODULE DECOMMISSIONED - Effective January 2023, Moderna (SPIKEVAX) (red cap) vaccine is no longer being supplied in Australia. Therefore, *no further content updates will be made to this module from May 2023.*

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 30 minutes. Each topic must be worked through in order and there are multiple-choice questions to pass before this module is complete.

Learning objectives

At the end of Additional Module 3: Moderna (SPIKEVAX) (red cap) vaccine, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of the Moderna (SPIKEVAX) (red cap) vaccine.
- Understand the contraindications, warnings, adverse reactions, and recommendations for co-administration with other vaccines for the Moderna (SPIKEVAX) (red cap) vaccine.
- Demonstrate appropriate storage and handling of the Moderna (SPIKEVAX) (red cap) vaccine, including handling of vaccines before the time of use, thawing, and storage following vial opening.
- Demonstrate appropriate dose preparation including verification before administration of the Moderna (SPIKEVAX) (red cap) vaccine.
- Understand the appropriate administration of the Moderna (SPIKEVAX) (red cap) vaccine.

Topics

1. Introduction and summary
2. Cold chain and thawing
3. Preparation and administration
4. Precautions and contraindications
5. Adverse events

Topic 1: Introduction and summary

MODULE DECOMMISSIONED - Effective January 2023, Moderna (SPIKEVAX) (red cap) vaccine is no longer being supplied in Australia. Therefore, *no further content updates will be made to this module from May 2023.*

THE FOLLOWING INFORMATION REMAINS FOR REFERENCE PURPOSES ONLY.

This module was the primary module for Moderna (SPIKEVAX) (red cap). Some information, such as dosing and administration, is only relevant for individuals aged **12 years and older**.

On 17 February 2022, the Therapeutic Goods Administration (TGA) approved the Moderna (SPIKEVAX) (red cap) vaccine for use in children aged 6 to 11 years old.

On 19 July 2022, the TGA provisionally approved the Moderna (SPIKEVAX) (blue cap, purple label) vaccine for use in children aged 6 months to 5 years old.

On 29 August 2022, the TGA provisionally approved the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine for use in individuals aged 18 years and older.

On 17 February 2023, the TGA provisionally approved the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine for use in individuals aged 12 years and older.

Additional Module 3c must be successfully completed by providers before administering Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) to individuals aged 18 years and older.

Additional Module 3d must be successfully completed by providers before administering Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) to any individuals aged 12 years and older.

Moderna (SPIKEVAX) (red cap)

The Moderna vaccine is also known as the SPIKEVAX (Elasomeran) COVID-19 vaccine (Moderna Australia, 2021).

The previously supplied Moderna (SPIKEVAX) (red cap) vaccine was the second mRNA COVID-19 vaccine to be provisionally approved by the Therapeutic Goods Administration (TGA) for use in Australia. It is registered for people aged **6 years and over** (Moderna Australia, 2021; TGA, 2021b).

On 8 December 2021, the TGA also provisionally approved Moderna (SPIKEVAX) (red cap) as a booster dose for individuals 18 years and over.

On 17 February 2022, the TGA provisionally approved the Moderna (SPIKEVAX) (red cap) vaccine for use in children aged 6 to 11 years old. Please see decommissioned **Additional Module 3a** for more information.

This vaccine uses new technology to induce immunity, similar to the Pfizer (COMIRNATY) vaccines. Messenger ribonucleic acid or mRNA vaccines use a genetic code called RNA to prompt the production of the coronavirus' specific spike protein. Once the mRNA enters the body's cells, the cells use the instructions contained in the RNA to make the spike protein. The cells display the spike protein on their surface and break down the mRNA that was delivered by the vaccine. Immune cells then recognise the spike protein as foreign and begin building an immune response against it. This elicits both T-cell and B-cell responses to generate neutralising antibodies, which may contribute to protection against COVID-19 (TGA, 2021c).

The RNA from the vaccine does not change or interact with a person's DNA in any way.

Further information can be found on the TGA's Product information and the Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance for COVID-19 vaccine providers. The consumer medicine information (CMI) summary can also be given to individuals receiving the vaccine.

Each pack contains 10 multidose vials (MDV) containing either:

- 10 **primary course** doses of **0.5mL** per dose for people **12 years and over**,
- 20 **booster** (half doses) of **0.25mL** per dose for people **18 years and over**, or
- 20 **primary course** doses of **0.25mL** per dose for people **6 to 11 years** (Please see **Additional Module 3b** for more information.)

Inside the vial, the vaccine is a sterile white to off-white suspension for injection with a total volume of 5mL. This product is a ready-to-use formulation and does not require dilution (Moderna Australia, 2021).

The vial is made of glass with a chlorobutyl rubber stopper and a flip-off plastic cap with an aluminium seal (Moderna Australia, 2021).

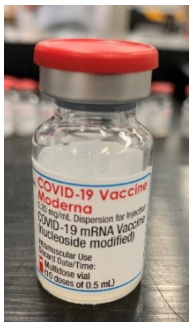

Figure 1. *Moderna (SPIKEVAX) (red cap) vaccine vial.*

The active ingredient is the mRNA embedded in the SM-102 lipid nanoparticles (LNP). Other ingredients include:

- Heptadecan-9-yl 8-[2-hydroxyethyl-(6-oxo-6-undecoxyhexyl)amino]octanoate
- Cholesterol (enhances membrane fluidity)
- Distearoylphosphatidylcholine
- 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000
- Trometamol
- Trometamol hydrochloride
- Acetic acid
- Sodium acetate trihydrate
- Sucrose (sugar)
- Water for injections

(Moderna Australia, 2021)

The Moderna (SPIKEVAX) (red cap) vaccine is produced using a cell-free vitro transcription process and does not include preservatives or any components of animal or human origin. Moderna (SPIKEVAX) (red cap) vaccine contains less than 1mmol (23mg) of sodium per 0.5mL dose and is therefore essentially 'sodium-free' (Moderna Australia, 2021).

Protection:

Moderna (SPIKEVAX) (red cap) vaccine has demonstrated efficacy against symptomatic COVID-19 of approximately 94% from two weeks after the second dose (ATAGI, 2021b).

Phase 3 clinical trials (the COVE study) included about 30,000 participants 18 years and older from the United States of America. Phase 3 clinical trial results reported in the New England Journal of Medicine on 4 February 2021 demonstrated Moderna's (SPIKEVAX) (red cap) vaccine to be 94.1% efficacious in preventing symptomatic COVID-19, including severe disease, from two weeks after the second dose (ATAGI, 2021b). Individuals who were immunocompromised, pregnant or with a history of SARS-CoV-2 infection were excluded from the trial.

Among all cases included in the COVE study, no cases of severe COVID-19 were reported in the vaccine group compared with 30 of the 185 (16%) cases reported in the placebo group (Moderna Australia, 2021)

The final blinded analysis of Phase 3 of the COVE study shows a 93% efficacy which is maintained at least 6 months after the second dose (Moderna US, 2021).

The vaccine efficacy of Moderna (SPIKEVAX) (red cap) to prevent COVID-19, regardless of prior SARS-CoV-2 infection (determined by baseline serology and nasopharyngeal swab sample testing) from 14 days after dose 2 was 93.6% (95% Confidence Interval [CI]: 88.5-96.4%) (Moderna Australia, 2021).

In the US Mayo Clinic Health System study, Moderna (SPIKEVAX) (red cap) vaccine was found to be 92% (95% CI: 82-97%) effective against PCR-positive SARS-CoV-2 infection from day 14 after dose 2. From seven days after the second dose, this vaccine was 86% (95% CI: 72-94%) effective against hospitalisation, and 100% (95% CI: 43-100%) against ICU admission (ATAGI, 2021b).

In a large Canadian study, Moderna (SPIKEVAX) (red cap) was found to be 94% (95% CI: 86-97%) effective against laboratory-confirmed symptomatic SARS-CoV-2 infection from 7 days after dose 2, and 96% (95% CI: 74-100%) effective against severe outcomes, including hospitalisation and death, from the day of dose 2 (ATAGI, 2021b).

Individuals may not develop optimal protection until 14 days after the second dose. As with all vaccines, 100% immunity is not guaranteed for all individuals. The duration of protection achieved from Moderna (SPIKEVAX) (red cap) vaccine beyond 6 months is unknown as this is still being determined through ongoing clinical trials (Moderna, Australia).

Further research is ongoing in children and adolescents, pregnant women and people who are immunocompromised.

More information can be found in the:

- Product Information for COVID-19 vaccine Moderna (SPIKEVAX) (red cap),
- COVID-19 vaccine information,
- ATAGI Clinical guidance for COVID-19 vaccine providers,
- COVID-19 Vaccination: How COVID-19 vaccines work, and
- COVID-19 vaccination – Patient resources.

Protection against different variants

A test-negative case–control study in Canada was conducted with more than 400,000 symptomatic cases and showed that effectiveness against PCR-positive symptomatic disease ≥21 days after dose 1

was 70% (95% CI: 52 - 81) for Delta variant cases compared to 84% (95% CI: 80 - 86) for Alpha variant cases. Effectiveness against hospitalisation or death ≥21 days after dose 1 was 95% (95% CI: 67 - 99) for Delta variant cases compared to 80% (95% CI:74 - 85) for Alpha variant cases (ATAGI, 2021b).

Studies in the USA and Qatar reinforce these results. Effectiveness against PCR-confirmed infection ranges from 76-86%, severe disease ranges from 81-100% after dose 2 (ATAGI, 2021b).

The effectiveness of currently available COVID-19 vaccines against the Omicron variant is not yet known. Laboratory studies suggest that a booster dose of an mRNA COVID-19 may be required to induce adequate neutralising antibody titres against this variant.

Benefits of doses including boosters

Evolving evidence based on early vaccine effectiveness data and analysis of antibody levels after the first booster dose suggest there is gradual waning of immunity against the Omicron variant. This is most prominent for vaccine effectiveness against symptomatic infection (ATAGI, 2022d). The reduction in protection is similar for Delta and other virus variants. However, protection against severe disease has been shown to remain high and wane to a lesser degree than against infection or non-severe disease in many studies, including for the Delta variant. Protection against transmission from vaccinated individuals who are infected also appears to wane over time.

The safety and efficacy of a primary course of the Moderna (SPIKEVAX) (red cap) vaccine to prevent-COVID-19 was demonstrated in a large randomised controlled clinical trial in adults aged 18 years and older. A cohort of 1,080 participants from this trial were randomly selected as the comparison group for a booster study. 2 50µg (0.25mL) of the Moderna (SPIKEVAX) (red cap) vaccine was administered to 344 participants 12 years and older who had received a two-dose primary course of either 100µg or 50µg of the Moderna (SPIKEVAX) (red cap) at least 6 months prior.

The protective effectiveness of a booster dose was inferred from a comparison of neutralising antibody titres and seroresponse rates against both the Delta variant and an older strain of SARS-CoV-2 measured 28 days after a single 50µg booster dose, compared to 28 days after the second 100µg primary series dose (day 57). The geometric mean ratio (GMR) in the booster cohort compared with the unboosted cohort was 1.8 (95% CI 1.5 – 2.1), suggesting that antibody concentrations are higher after the booster dose than after the primary course (ATAGI, 2021aa).

Administration of a COVID-19 vaccine booster dose 6 months or more after completion of the primary vaccine course has been demonstrated to augment immune responses and is anticipated to increase protection, particularly in older people where waning is more pronounced.

The increase in protection against severe illness from COVID-19 following a booster dose is most beneficial for people at higher risk of severe illness, i.e., older adults and those with relevant medical risk factors. Studies conducted throughout the pandemic, including during Omicron epidemic waves have identified a higher risk of hospitalisation among older adults and adults with immunosuppression or other chronic medical conditions, compared with younger or healthy adults (ATAGI, 2023a).

Topic 2: Cold chain and thawing

Ultra-Cold Chain storage for frozen vials

Always store the vials in their original carton and packaging until ready to use to protect the vials from ultraviolet (UV) light and sunlight.

Moderna (SPIKEVAX) (red cap) vaccines must be **stored frozen at -25°C to -15°C** for a maximum of **9 months**. The freezer should be set to -20°C. **DO NOT** store on dry ice or go below -50°C.

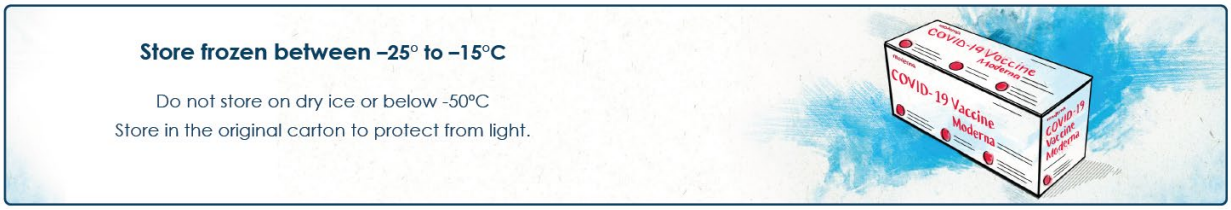

Figure 2. *Frozen Storage* (Moderna Australia, 2021, p. 3).

Cold Chain storage for thawed vials

Thawed Moderna (SPIKEVAX) (red cap) vaccines require storage and transport using standard cold chain requirements at **+2°C to +8°C** as per the national *Strive for 5* guidelines, jurisdictional requirements and facility policies.

Vaccine cannot be refrozen once thawed.

Unopened, thawed vials can be stored at **+2°C to +8°C** for a maximum of **30 days from the thawed date (within the 9-month shelf life)**, which may be before the facility received the vials. **Of these 30 days, 12 hours can be used for transportation at +2°C to +8°C, and 24 hours in storage at 8°C to 25°C.** The thawed date will be clearly displayed on the carton (secondary packaging).

Delivery acceptance

THIS PAGE IS INTENTIONALLY BLANK as no further Moderna (SPIKEVAX) (red cap) deliveries will occur in Australia.

Unpacking Moderna (SPIKEVAX) (red cap) vaccine deliveries

Thawed Moderna deliveries

Thawed Moderna (SPIKEVAX) (red cap) vaccines require storage and transport using standard cold chain requirements at **+2°C to +8°C** as per the national *Strive for 5* guidelines, jurisdictional requirements, and facility policies. Vaccine cannot be refrozen once thawed.

Once received and the vaccine delivery accepted, transfer the vial trays into cold chain storage. **Unopened, thawed vials** can be stored at **+2°C to +8°C** for a **maximum of 30 days** from the thawed date, which will be before the facility received the vials. The thawed date was clearly displayed on the carton (secondary packaging). **Of these 30 days, 12 hours can be used for transportation at +2°C to +8°C, and 24 hours in storage at 8°C to 25°C.**

The **USE BY** date is the earliest of:

- Thaw date + 30 days or
- Manufacturer expiry date including any extensions in shelf life

As with all COVID-19 vaccines, Moderna (SPIKEVAX) (red cap) should be stored in the original carton until use to protect it from light. Care needs to be taken to avoid all unnecessary exposure to light

until the vials are ready to be administered. Thawed vials that are ready to be used and prepared syringes can be handled in room light conditions (Moderna Australia, 2021).

The fridge temperature must be recorded when vaccines are finally stored and continually monitored. Rotate stock so that the newest stocks are placed at the back and stock with the earliest expiry dates are in front.

Thawing the vial (if required)

Moderna (SPIKEVAX) (red cap) vaccine vials need to be thawed before use. Thawing can occur by one of two methods:

- Place the individual vials or whole vial pack into a cold chain **(+2°C to +8°C) fridge for 2 hours and 30 minutes** for the vial to thaw fully.
- Place the individual vials on a workbench in a temperature of **+15°C to +25°C for 1 hour** for the vial to thaw fully. **Vials thawed** using this method should then be **stored at +2°C to +8°C in cold chain conditions and used within 24 hours.**

(Moderna Australia, 2021)

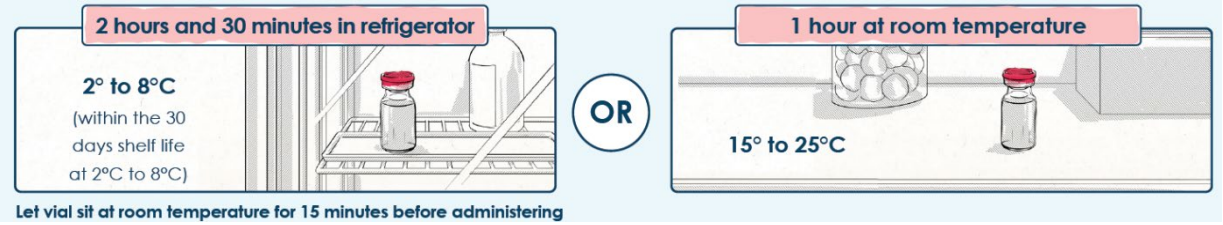

Figure 3. *Thaw each vial before use* (Moderna Australia, 2021, p.3).

An **unopened thawed vial** can be maintained through normal cold chain practices **(+2°C to +8°C)** for a **maximum of 30 days** within the 9-month shelf life. The 30-day timeframe includes any time spent thawed or thawing in transportation and at room temperature.

Thawed Moderna (SPIKEVAX) (red cap) vaccine can also be stored, **unopened at room temperature between +8°C and +25°C for up to 24 hours within the 30-day shelf-life** (Moderna Australia, 2021; ATAGI, 2021b).

DO NOT shake the vial to confirm the vial has thawed or at any other time.

DO swirl gently after thawing.

Once thawed, Moderna (SPIKEVAX) (red cap) vaccine **CANNOT** be re-frozen (Moderna Australia, 2021).

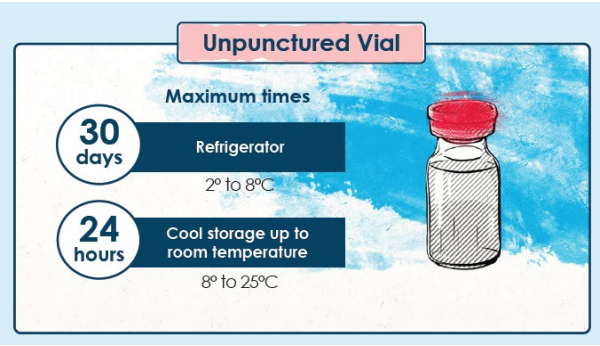

Figure 4. *Instructions once thawed – Unpunctured vial* (Moderna Australia, 2021, p. 3).

Storing opened vials

After initial puncture, vials can be stored up to 19 hours at +2°C to +25°C (TGA, 2022d). 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.

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.

Home visits – 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 total maximum storage period of **6 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 can be administered as soon as practical and not exceeding the total maximum storage period of **1 hour if at room temperature**.

Pre-drawn vaccine doses in syringes are treated differently than diluted or open vials. Please refer to the ATAGI Transport, storage and handling webpage for ATAGI recommendations on diluted or open vials.

More information can be found at the end of the ATAGI recommendations for Transporting, storing and handling COVID-19 vaccines (ATAGI, 2021b).

Prior to each vaccination, ensure all relevant expiry dates and times are checked.

Topic 3: Preparation and administration

Dose preparation

The vaccine should be prepared and administered using aseptic technique to maintain sterility of the suspension (Moderna Australia, 2021).

After thawing is complete, the vial is ready to be administered. **DO NOT** dilute the contents (Moderna Australia, 2021).

If **thawing** was completed by placing the vial in a **room temperature environment**, the vial cannot be used **after 24 hours**. If **thawed** in **cold chain conditions**, then the vial must be used within **30 days** or be discarded.

Expiry dates must be followed precisely to prevent expired stock being administered. There are two expiry dates that must be observed on Moderna (SPIKEVAX) (red cap) vaccines, the manufacture expiry date and the thawed expiry date. Both must be checked prior to every vaccine administration.

The manufacture expiry date indicates the expiry for the vaccine when stored frozen. The thaw 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 individual vials or the secondary packaging (carton) of the vials when delivered thawed.

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

To prevent administration errors all sites should clearly label the thawed use by 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 (VAEs). If vaccines are administered outside of either expiry date, it is considered a VAE. The Vaccine Operations Centre (VOC) on **1800 318 208** is available to provide advice and guidance to clinicians regarding the management of VAEs. Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information (ATAGI, 2022a).

The expiry date is exactly **30 days** from the time the vials have been taken out of ultra-cold chain storage to thaw. Keep the vials in the carton (secondary packaging) until they are ready to be used to keep track of the thawed date and therefore expiry.

IMPORTANT – Moderna recommends leaving the vial to sit at room temperature for **15 minutes** before administration if it has been taken from the fridge **(+2°C to +8°C)**. ATAGI (2021b) state that this is not required. However, they recommend providers confirm that the syringe containing the dose is not cold to touch prior to administration to minimise discomfort from receiving an injection of a chilled product (ATAGI, 2021b).

Chemical and physical stability has been shown with storage of Moderna (SPIKEVAX) (red cap) for 19 hours at +2°C to +25°C after initial puncture. However, because this vaccine contains no antimicrobial preservatives, **ATAGI recommends that opened vials should be stored at +2°C to +8°C, and the cumulative storage time of opened vials at +2°C to +25°C should not exceed 6 hours** (Moderna Australia, 2021; ATAGI, 2021b).

ATAGI recommendations must be followed over Product Information.

If you suspect your vaccines may have been involved in a cold chain breach (CCB), either within the clinical setting or during transit:

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 Vaccine Operations Centre (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.

A quick reference poster guide can be used for CCB management including reporting. There is no poster as yet for UCC breaches. Please note the requirement to contact the VOC in the event of a cold chain breach is specific to COVID-19 vaccines, and not stated in the National Vaccine Storage Guidelines.

Please see Appendix 5 for the steps to be followed if a potential CCB occurs.

Ensure that the vial has not expired, that is has been less than **30 days since being thawed** and that it has been **less than 6 hours since the vial was opened**, by checking the date and time recorded on the vial.

Write on the vial, the date and time of opening immediately when opened for the first time in the white space provided as shown in figure 5 to the left.

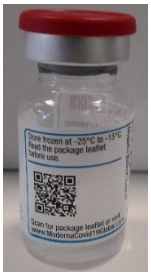

Figure 5. *Moderna (SPIKEVAX)* (red cap) *vaccine vial showing space to write date and time the vial was opened.*

The thawed vaccine will be a white to off-white suspension and may contain white or translucent product-related particulates. Visually inspect the vial prior to withdrawal for other particulate matter and/or discolouration. If either of these conditions exist or you are concerned, call the Vaccine Operations Centre (VOC) on **1800 318 208**.

DO NOT shake the vial and contents. **DO** swirl the vial and contents gently between each withdrawal (Moderna Australia, 2021).

A single **primary course** dose of Moderna (SPIKEVAX) (red cap) vaccine was **0.5mL** and contained 100 micrograms of mRNA. Care should be taken to draw up the 0.5 mL dose volume exactly and that the correct dose type is being given. Double-check this before administration.

A single **booster** dose of Moderna (SPIKEVAX) (red cap) vaccine (for individuals over 18 years old) was **0.25mL** and contained 50 micrograms of mRNA. Care should be taken to draw up the 0.25 mL dose volume exactly and that the correct dose type is being given. Double-check this before administration.

A sterile 19 or 21-gauge, bevelled drawing-up needle is preferred for drawing-up. To extract the full 10 doses from the vial, care should be taken to draw up the individual dose exactly. A 1mL, 2mL or 3mL syringe can be used for doses of 0.5mL or greater such as with the Moderna (SPIKEVAX) (red cap) **primary course** dose if stock is available. A 1mL syringe must be used for the Moderna (SPIKEVAX) (red cap) **booster** dose which was only 0.25mL. If available, low dead volume needles and syringes should be used.

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

After initial puncture, vials can be stored up to 19 hours at +2°C to +25°C (TGA, 2022d). 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.

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.

(ATAGI, 2021b; DHAC, 2021g)

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

If a full dose cannot be drawn up from the remaining liquid in the MDV, it must be discarded as doses cannot be drawn from multiple MDV and combined.

Administration

Administer intramuscularly, preferably into the deltoid muscle of the upper arm. **DO NOT** inject intravenously, subcutaneously or intradermally (Moderna Australia, 2021).

Do not mix or contaminate the vaccine with any other medication or liquid (Moderna Australia, 2021).

ATAGI is aware of scientific reports proposing that inadvertent injection of a COVID-19 vaccine into a blood vessel may be a contributing cause of serious adverse events following immunisation, such as myocarditis. ATAGI has reviewed the available evidence and considers injection technique highly unlikely to be a contributor to these adverse events, for several reasons:

- The majority of myocarditis cases occur after the second dose of the mRNA vaccines. If intravascular injection was an important contributor, there would not be this differential distribution of cases by vaccine dose.
- Direct injection into a blood vessel is unlikely in recommended injection sites.

(DHAC, 2021l)

Based on a review of the available evidence, ATAGI does not recommend routinely aspirating (drawing back) needles before injection. This practice was rejected some decades ago, due to several disadvantages including prolonging the procedure, potentially associated pain, and increasing the risk of needle-syringe disconnection. Not aspirating is supported by the current advice in the Australian Immunisation Handbook (ATAGI, 2022q).

ATAGI will continue to review emerging evidence on the underlying mechanisms, prevention and treatment of TTS, myocarditis and other serious adverse events of special interest.

In certain mass vaccination situations, it is acceptable to use the same needle to draw-up and administer the vaccine to an individual. An aseptic technique must be used throughout the procedure as there is potential for a greater frequency of injection site reactions using this technique (ATAGI, 2021g). Steps to complete this process are the same as described in Module 4, except the needles are not changed. The needle can be recapped using aseptic technique if not being administered immediately (ATAGI, 2021g). Seek advice from your Public Health Unit (PHU) regarding situations when this may be appropriate, and for guidance completing these steps. Review the ATAGI MDV advice for more information on mass vaccination.

All sharps with syringes still attached (such as after administration) should be discarded in a sharps waste container. The vials and other consumables should be disposed of in accordance with local requirements in the clinical waste bin.

If required refer to the *COVID-19 – ATAGI information for providers: COVID-19 Vaccination Consent & FAQs* and Information on COVID-19 Moderna (SPIKEVAX) vaccine

After administration, the vaccine dose administered including batch and vial serial number must be entered into the Australian Immunisation Register (AIR) as described in Module 5, Topic 4.

Administration of vaccines under sedation

Procedural guidelines for administration of vaccines under sedation in practice have been developed or are currently being developed in some health services. ATAGI advises that detailed clinical guidance should be developed collaboratively with input from anaesthetic groups, jurisdictional health services and relevant specialists (ATAGI, 2022g).

More information can be found in the ATAGI advice on use of sedation for COVID-19 vaccination.

See Appendix 3 for the Vaccine preparation and Vaccine administration checklist.

Dosing and schedule of the primary course

Moderna (SPIKEVAX) (red cap) vaccine (primary course) was administered as an intramuscular (IM) only injection containing 0.5mL (Moderna Australia, 2021).

A total of two primary course doses of Moderna (SPIKEVAX) (red cap) vaccine for people 6 years and above was required for most people with a recommended interval of 8 weeks (ATAGI, 2022f).

This interval was recommended as it has been shown to improve immune response to vaccination and therefore may improve effectiveness. This longer interval may also reduce the risk of myocarditis and pericarditis, particularly for groups at higher risk of this side effect (those less than 40 years of age) (ATAGI, 2022f).

The dose interval could have been reduced to a minimum of 3 weeks for people at higher risk of severe COVID-19 (including older adults and people with underlying medical conditions), in an outbreak setting, or prior to international travel (ATAGI, 2022f).

ATAGI preferred the use of the same COVID-19 vaccine for the 2 doses of the primary course. An alternative vaccine brand for dose 2 should be used if there are specific medical contraindications or precautions, or the same vaccine brand is not available in Australia. It is preferable to use the same brand for both doses of the primary course, but an alternative brand can be used for the second dose for other reasons. Examples include if a person is unable to access the same brand or does not accept a second dose of the same brand. Emerging data support the safety and efficacy of mixed schedules (ATAGI, 2021b).

For more information on the recommended COVID-19 vaccine brand for dose 2 see the section on Mixed (heterologous) primary schedules on the Clinical recommendations for COVID-19 vaccines website.

Severely immunocompromised individuals

ATAGI recommends a third primary dose of COVID-19 vaccine in severely immunocompromised populations to address the risk of suboptimal or non-response to the standard 2 dose schedule. The third dose is intended to maximise the level of immune response to as close as possible to the general population (ATAGI, 2021w). For a comprehensive list of immunocompromising conditions and therapies for which a third primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

The Moderna (SPIKEVAX) (red cap) vaccine's third primary dose was 0.5mL (100 micrograms).

The recommended interval for the third dose is 2 months after the second dose of the vaccine. A minimum interval of 4 weeks may be considered in exceptional circumstances (e.g., anticipated

intensification of immunosuppression; outbreaks). People who received a second dose more than 6 months ago should receive a third dose as soon as feasible (ATAGI, 2021w).

Individuals who currently are not severely immunocompromised but who will commence significant immunosuppressive therapy 2 or more weeks after their second dose do not require a third dose, as it can be expected that an adequate response to 2 primary doses will be achieved (ATAGI, 2021w). For more information view the ATAGI statement on the use of a third primary dose of a COVID-19 vaccine in individuals who are severely immunocompromised.

Dosing and schedule of booster doses

The Moderna (SPIKEVAX) (red cap) vaccine booster was administered as an intramuscular (IM) only injection containing 0.25mL.

The dosage of the booster dose was 50 micrograms or **0.25mL**. This is **half** of the recommended dose of the Moderna (SPIKEVAX) (red cap) vaccine used for the primary course.

ATAGI **recommends** 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 (ATAGI, 2023a; ATAGI, 2023d):

- 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.

ATAGI advises the following groups should **consider** a 2023 booster dose 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 (ATAGI, 2023a; ATAGI, 2023d).

- 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 (NOTE: 5 to 11 year olds cannot receive a bivalent vaccine and should receive the Pfizer (COMIRNATY) (orange cap) vaccine).

ATAGI advises that a booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19 (ATAGI, 2023a).

Development of seasonal immunisation policy to manage COVID-19 is limited as the evolution as well as duration and strength of protection against serious SARS-CoV-2 illness is uncertain at this time (ATAGI, 2023a).

Booster doses are not currently recommended for children aged under 5 years, or for children and adolescents aged 5 to 17 years who are not at increased risk of severe disease as defined above. Severe COVID-19 in children is uncommon and the primary course of COVID-19 vaccines generates a strong immune response. The benefit from additional doses of vaccine is likely to be small. Current evidence does not suggest that booster doses are needed at this time.

Booster dose: vaccine preference recommendations

Any age-appropriate COVID-19 vaccine, including original (ancestral virus-based) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer-lasting protection against severe disease.

However, bivalent mRNA vaccines are preferred over other vaccines for people aged 12 years and older. These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap)
- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS)
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap)
- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label)

Although not preferred, Novavax (NUVAXOVID) vaccines can be used as a booster dose in people aged 18 years and older in the following circumstances:

- People who have a contraindication to mRNA vaccines (including those who have had a serious adverse event following mRNA vaccines, such as a history of anaphylaxis or myocarditis attributed to an mRNA vaccine)
- People who do not prefer an mRNA vaccine.

Although not TGA-registered as a booster in this age group, Novavax (NUVAXOVID) can be used as a booster in people aged 12 years or older if no other COVID-19 vaccine brand is suitable for that person.

Pfizer (COMIRNATY) (orange cap) can be used in children aged 5 to 11 years.

The evidence underpinning booster dose recommendations will continue to be reviewed and this clinical guidance may be refined. For more details see: COVID-19 vaccine information.

Vaccine administration errors (VAEs)

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training undertaken to minimise the risk of errors occurring (ATAGI, 2022a).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible VAEs, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022a). The VOC on **1800 318 208** is also available to provide advice to clinicians regarding the management of VAEs.

Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Please see Appendix 4 for the steps to be followed if a Vaccine administration error occurs.

Disposal and wastage

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Major Wastage (10 or more vials)

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Topic 4: Precautions and contraindications

Pre-screening

A pre-screening checklist is required to check for any contraindications or circumstances for which precaution is required before administration. Pre-screening is covered in detail in Module 5 Topic 3. This topic reviews a few special population groups with manufacturer's recommendations on administering the Moderna (SPIKEVAX) (red cap) vaccine to members of these groups.

Contraindications

Contraindications include anaphylaxis or a severe hypersensitivity reaction to a previous dose of an mRNA COVID-19 vaccine including Moderna (SPIKEVAX) (red cap) vaccine. Anaphylaxis to any of its contained components as listed in Topic 1 (Moderna Australia, 2021).

For information on allergies and precautions with people who may have allergies please refer to the Australasian Society of Clinical Immunology and Allergy (ASCIA), *Allergy, Immunodeficiency, Autoimmunity and COVID-19 Vaccination Position Statement* and the *ATAGI clinical guidance for COVID-19 vaccine providers*.

Precautions

The precautions relating to Moderna (SPIKEVAX) (red cap) vaccine are the same as the ones reviewed in Module 5, Topic 2. Please review these again as required.

Vaccination should not be delayed for a minor infection, illness or low-grade fever. However, it should be postponed in individuals experiencing an acute, severe febrile illness (axillary temperature ≥38.5°C) such as COVID-19 or an acute infection (Moderna Australia, 2021; ATAGI, 2021b).

Care should be taken in individuals who may have a coagulation disorder, thrombocytopenia or an increased risk of bleeding and bruising such as being on anticoagulation therapy as bleeding and bruising may occur following an IM injection (Moderna Australia, 2021).

Immunocompromised individuals – Includes individuals receiving immunosuppressant therapy. The efficacy, safety and immunogenicity have not been fully assessed in these individuals and therefore the efficacy may be lower (Moderna Australia, 2021).

ATAGI highly recommends that these individuals receive the vaccine as normal and there are no specific safety concerns with receiving the vaccine (ATAGI, 2021b). For more information, review ATAGI's COVID-19 vaccination decision guide for people with immunocompromise.

Ideally, vaccination should occur on a different day to regular infusion treatments, such as immunoglobulin replacement therapy or immunosuppressant infusions (Australasian Society of Clinical Immunology and Allergy [ASCIA], 2021).

ATAGI recommends a third primary dose of COVID-19 vaccine in severely immunocompromised populations to address the risk of suboptimal or non-response to the standard 2 dose schedule. The third dose is intended to maximise the level of immune response to as close as possible to the general population (ATAGI, 2021w).

ATAGI recognises that a substantial proportion of vaccinated individuals among some groups with severe immunocompromise conditions show suboptimal response to COVID-19 vaccine, and that this is likely to place them at ongoing increased risk of SARS-CoV-2 infection despite vaccination. ATAGI considers it important to offer a third primary dose to provide a higher level of protection for these individuals, aiming to attain a level as close as possible to that seen in healthy individuals. Provision of a third dose to severely immunocompromised individuals does not guarantee equivalent protection to immunocompetent individuals, therefore ongoing risk mitigation measures are warranted (ATAGI, 2021w).

Antibody testing is not recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination, including in immunocompromised individuals after a second or third dose. There are no serological assays that provide a definitive correlate of immunity to SARS-CoV-2 (ATAGI, 2021w).

For a comprehensive list of immunocompromising conditions and therapies for which a third primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

ATAGI advises 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 should **consider** a 2023 booster dose 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 (ATAGI, 2023a).

A booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19 (ATAGI, 2023a).

Adults with medical conditions – The ongoing phase III trial enrolled individuals with stable medical conditions that put them at increased risk of severe COVID-19. An analysis of this subgroup demonstrated vaccine efficacy similar to the efficacy estimated in those without risk factors for severe disease (90.9% [95% CI: 74.7 – 96.7%) vs. 95.1% [95% CI: 89.6 – 97.7%]) (ATAGI, 2021b).

Older adults >85 years of age who are frail – The clinical trials for Moderna (SPIKEVAX) (red cap) vaccine included older adults aged 65 years and older. Both vaccine doses were safe, the efficacy was maintained and was well tolerated in this age group and no dose adjustment is needed for those 65 years and older. Also, older adults had fewer side effects than younger adults (Moderna Australia, 2021).

In the ongoing phase III trial, 24.8% of participants were aged 65 years or over. In this subgroup, vaccine efficacy against symptomatic disease was estimated to be 86.4% (95% CI: 61.4 – 95.2%), as compared with 95.6% (95% CI: 90.6 – 97.9%) among patients aged 18-64 years (ATAGI, 2021b).

The potential benefits should be assessed against the risks at an individual level, especially if the person is frail. The COVID-19 vaccination decision guide for frail older people, including those in residential aged care facilities can be used by the older adult to make an informed decision. Additionally, a new decision guide is now available for people receiving palliative care and/or end-of-life care.

Myocarditis and Pericarditis – The mRNA vaccines Moderna (SPIKEVAX) and Pfizer (COMIRNATY) have been safely given to hundreds of millions of people around the world. These mRNA COVID-19 vaccines have a very rare risk of heart inflammation (myocarditis, pericarditis or combined, myopericarditis). This is more commonly seen in males aged under 30 years after the second dose.

In some countries, myocarditis and pericarditis have been reported more commonly after Moderna (SPIKEVAX) (red cap) than after Pfizer (COMIRNATY) (purple cap). Most people who have had these conditions after their vaccine have recovered fully.

ATAGI states that the benefits of vaccination outweigh this very rare risk and vaccination is still recommended for all eligible age groups. For current information on the frequency and severity of myocarditis and pericarditis following Moderna (SPIKEVAX) (red cap) and Pfizer (COMIRNATY) (purple cap), please refer to the COVID-19 vaccine weekly safety report, published by the Therapeutic Goods Administration (TGA).

Symptoms typically appear within 1-5 days of vaccination and include chest pain, palpitations (irregular heartbeat), syncope (fainting) or shortness of breath. People who experience any of these symptoms after having an mRNA COVID-19 vaccine should seek prompt medical attention (ATAGI & CSANZ, 2021).

The previously available Moderna (SPIKEVAX) (red cap) vaccine was recommended for all eligible people aged 12 years and over who do not have any contraindications to the vaccine. For further information refer to the *Clinical guidance for COVID-19 vaccine providers*.

The highest reporting rates of myopericarditis were following the second dose of Pfizer (COMIRNATY) (purple cap) in males 16-17 years old with 71.5 cases per million doses administered, followed by males aged 12-15 with 42.6 cases per million. In males aged 18-24 the reporting rate was 37.7 per million following the second dose of Moderna (SPIKEVAX) (red cap) (ATAGI, 2021b).

Most pre-existing cardiac conditions are **NOT** regarded as contraindications to vaccination. People with a history of any of the following conditions **CAN** receive an mRNA vaccine but should consult a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- Recent (i.e. in the past 3 months) or current inflammatory cardiac illness e.g. myocarditis, pericarditis or endocarditis
- Complex or severe congenital heart disease including single ventricle (Fontan) circulation.
- Acute decompensated heart failure.

(ATAGI & CSANZ, 2021; ATAGI, 2021b)

The previously available Moderna (SPIKEVAX) (red cap) was recommended for people with a history of most chronic cardiovascular conditions and **COULD** have been given to people in the following groups **without any specific precautions**:

- Prior myocarditis, pericarditis or endocarditis (i.e. 3 months or more prior to vaccination).
- Coronary artery disease.
- Myocardial infarction.
- Stable heart failure.
- Arrhythmias.
- Prior history of rheumatic heart disease (RHD).
- Kawasaki disease.
- Congenital heart disease.
- Cardiomyopathy.
- Cardiac transplant.
- People with implantable cardiac devices.

(ATAGI & CSANZ, 2021; ATAGI, 2021b).

People with a history of myocarditis, pericarditis or endocarditis more than 3 months ago could be vaccinated with Moderna (SPIKEVAX) (red cap) without any additional precautions (ATAGI & CSANZ, 2021).

People who developed myocarditis or pericarditis attributed to their first dose of Moderna (SPIKEVAX) (red cap) vaccine were advised to defer further doses of an mRNA COVID-19 vaccine and to discuss this with their treating doctor (ATAGI & CSANZ, 2021). There are currently no data on safety of third doses of vaccine in relation to the risk of myocarditis after mRNA vaccines (ATAGI, 2021w).

For more information please review COVID-19 vaccines and cardiac inflammation information on the Department of Health and Aged Care's website.

Previous thrombotic event – ATAGI considers that there is no evidence of a risk of thrombotic disease after Moderna (SPIKEVAX) (red cap) vaccination in people with a history of clotting conditions and recommended Moderna (SPIKEVAX) (red cap) vaccination in such people (ATAGI, 2021b; ATAGI, 2021d).

ATAGI recommended Moderna (SPIKEVAX) (red cap) vaccination in people with:

- Previous or current deep venous thrombosis and/or pulmonary embolism.
- Risk factors for thrombosis (such as use of oral contraceptives or smoking).
- Thrombocytopenia (low platelets that can occur with clotting conditions).
- Known thrombophilic disorders.
- Anticoagulant medication (e.g. warfarin).
- A history of cardiovascular disease (such as myocardial infarction or stroke).
- People with a confirmed medical history of cerebral venous sinus thrombosis (CVST).
- People with a confirmed medical history of heparin induced thrombocytopenia (HIT).
- A history of idiopathic splanchnic (mesenteric, portal, or splenic) thrombosis.
- A history if antiphospholipid syndrome with thrombosis.

(ATAGI, 2021b)

Past infection with SARS-CoV-2 – Past infection with SARS-CoV-2 is not a contraindication to vaccination. ATAGI recommends that booster doses should be deferred for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19 (ATAGI, 2023a). People who have received an anti-SARS-CoV-2 monoclonal antibody or convalescent plasma should defer future doses of COVID-19 vaccine for **at least 90 days** (ATAGI, 2021b).

Waiting for a 6 month period after infection before COVID-19 vaccination is intended to optimise protection for that person. A longer gap between infection and vaccination is likely to lead to a better immune response and result in longer protection from reinfection (ATAGI, 2022f).

Infection with certain SARS-CoV-2 variants has previously been shown to reduce the risk of reinfection with a variant other than Omicron for at least 6 months. However, recent evidence shows that people with prior infection with a variant other than Omicron are likely to be reinfected with the SARS-CoV-2 Omicron variant more often than with other variants, such as Delta.

The risk of reinfection with Omicron after an Omicron infection is not yet known, but it is likely the reinfection rates will be lower in this context for a period of time, as compared with prior infection with a variant other than Omicron.

Testing using polymerase chain reaction (PCR) or rapid antigen testing (RAT) to detect current or past infection with SARS-CoV-2 before vaccination is neither necessary nor recommended.

Individuals who have prolonged symptoms from COVID-19 beyond four months can be vaccinated on a case-by-case basis. People with a past COVID-19 infection should receive a standard primary schedule and booster if 16 years and older (ATAGI, 2021b).

Pregnancy, breastfeeding and fertility recommendations

Pregnancy – mRNA vaccines (Pfizer (COMIRNATY) or Moderna (SPIKEVAX)) are the recommended COVID-19 vaccines for pregnant women. This is based on the growing body of evidence supporting the safety of mRNA vaccines in pregnancy, whereas there are still very limited data on the safety of Novavax (NUVAXOVID) in pregnancy. However, people who cannot access an mRNA vaccine can consider vaccination with Novavax (NUVAXOVID) if the benefits to the individual outweigh the potential risks.

There were no vaccine-related adverse events during pregnancy or postnatal development in animal testing completed for the Moderna (SPIKEVAX) vaccines.

Pregnant women with COVID-19 have a higher rate of hospitalisation, intensive care unit admission and mechanical ventilation, but not death, than age-matched non-pregnant women. The risk of preterm delivery is also increased. There is no evidence to suggest that SARS-CoV-2 infection in pregnancy increases the risk for congenital anomalies (ATAGI, 2021b).

Over time, 'real-world' evidence from other countries has accumulated and reports show that mRNA COVID-19 vaccines, such as Moderna (SPIKEVAX), are safe to use in pregnant women. Emerging research also demonstrates that pregnant women have a similar immune response to mRNA vaccines to non-pregnant women and are therefore likely to have similar protection against COVID-19. Furthermore, research shows that the antibodies produced by vaccination cross the placenta and may provide some protection to newborn babies (ATAGI, 2021b).

Within animal testing, COVID-19 antibodies produced in response to the Moderna (SPIKEVAX) COVID-19 vaccine were present in the foetus and newborn (Moderna Australia, 2021).

Breastfeeding – It is not known if Moderna (SPIKEVAX) is excreted in human breast milk (Moderna Australia, 2021). Women do not need to stop breastfeeding before or after vaccination.

Fertility – Getting vaccinated before conceiving can provide protection for women against COVID-19 throughout their pregnancy. Vaccination does not affect fertility. Women are not required to have a pregnancy test before getting vaccinated (ATAGI, 2021b).

Animal studies do not indicate any direct or indirect harmful effects regarding fertility in females. The effect on male fertility has not been determined (Moderna Australia, 2021).

Further information is available in the *Shared decision making guide for women who are pregnant, breastfeeding, or planning pregnancy* (ATAGI, 2021b).

Co-administration

COVID-19 vaccines can be co-administered (i.e. on the same day) with an influenza vaccine. COVID-19 vaccines can also be co-administered with other vaccines if required, however, given the current limited evidence on the concomitant use of COVID-19 vaccines with other vaccines, providers need to balance the opportunistic need for co-administration with giving the vaccines on separate visits. There is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time. Co-administration or near administration (e.g. within days) with another vaccine may also make the attribution of potential adverse events more challenging (ATAGI, 2021b).

Data on the potential for co-administration with other vaccines is currently being reviewed and detailed information on this will be included in the ATAGI Clinical Guidance for COVID-19 vaccine providers (ATAGI, 2021b).

No interaction studies have been performed with Moderna (SPIKEVAX) vaccines and other medications (Moderna Australia, 2021).

Topic 5: Adverse events

General adverse events have been discussed in Module 6 Topic 2. All adverse events following immunisation (AEFI) from the administration of Moderna (SPIKEVAX) (red cap) must be reported. The batch number should also be included to monitor any potential issues with manufacturing, transport or storage (Moderna Australia, 2021).

Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side-effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website. For more information, please refer to Core Module 6.

The Consumer Medicines Information (CMI) can be given to people following their vaccination.

The following list identifies the frequency of very common AEFI in completed phase 3, randomised, placebo-controlled clinical trials:

- Site pain - >92% of individuals.
- Fatigue - >70% of individuals.
- Headache - >64% of individuals.
- Myalgia - >61% of individuals.
- Arthralgia - >46% of individuals.
- Chills - >45% of individuals.
- Nausea and vomiting - >23% of individuals.
- Axillary swelling/tenderness - >19% of individuals.
- Fever - >15% of individuals.
- Injection site swelling - >14% of individuals.
- Redness at the injection site - >10% of individuals.

(Moderna Australia, 2021)

Other AEFI to be aware of include:

- Delayed injection site reactions (>7 days after vaccination) including pain, erythema and swelling common).
- Injection site urticaria (hives) (common).
- Injection site pruritus (itchiness) (uncommon).
- Lymphadenopathy/lymphadenitis/lymph node pain/axillary mass (uncommon).
- Facial swelling in people who had a history of dermatological fillers (rare).

(Moderna Australia, 2021)

The profile of adverse events after the third dose is similar to that of preceding doses, and studies have not reported vaccine-related serious adverse events. However, these studies were conducted in small numbers of patients, and rare side effects may not have been detected. There are currently no data on safety of third doses of vaccine in relation to the risk of myocarditis after mRNA vaccines. ATAGI will continue to monitor the evidence around safety of additional doses of COVID-19 vaccine (ATAGI, 2021w).

Adverse events following Moderna (SPIKEVAX) (red cap) vaccine administration lasted for one to three days on average. A slightly lower frequency of adverse events was reported in older individuals compared to younger individuals. Side effects were reported higher when receiving the second dose compared to the first dose (Moderna Australia, 2021; ATAGI, 2021b).

Rare side-effects

Myocarditis and pericarditis – A risk of myocarditis and pericarditis has been observed in people who have received mRNA COVID-19 vaccines in overseas studies, particularly in males under 30 years of age after the second vaccine dose. Most myocarditis and pericarditis cases linked to mRNA vaccination have been mild and patients have recovered quickly. Longer-term follow-up of these cases is ongoing (ATAGI & CSANZ, 2021).

Symptoms typically appear within 1-5 days of vaccination and include: chest pain, palpitations (irregular heartbeat), syncope (fainting) or shortness of breath. People who experience any of these symptoms after having an mRNA COVID-19 vaccine should seek prompt medical attention.

Initial investigations for people presenting with symptoms or signs of myocarditis or pericarditis should include ECG, troponin, chest X-ray, and other investigations for other differential diagnoses as clinically indicated (ATAGI & CSANZ, 2021).

Thrombosis with thrombocytopenia syndrome (TTS) – There were no notable patterns or numerical imbalances between treatment groups and placebo groups regarding thrombotic events and administration of any of the Moderna (SPIKEVAX) vaccines. Moderna (SPIKEVAX) vaccines are not associated with a risk of thrombosis with thrombocytopenia (TTS) (ATAGI, 2021b).

Anaphylaxis and hypersensitivities – Anaphylaxis and hypersensitivities can occur after administering any medicine. As with all vaccines, immunisation providers must be prepared to respond to an individual developing anaphylaxis. Follow all management steps outlined in Module 6 – Safety, surveillance and reporting for adverse events following COVID-19 vaccination, Topic 3 – Managing AEFIs.

Bell's Palsy – Bell's Palsy (acute peripheral facial paralysis) has been reported in a few people post-vaccination with a Moderna (SPIKEVAX) vaccine. However, there is currently no available

information to determine whether or not there is a causal relationship between these events and vaccination (Moderna Australia, 2021).

Ability to use machinery – Moderna (SPIKEVAX) vaccines have no or limited effects on the ability to use machines and drive. However, if experienced, some of the AEFI may temporarily affect an individual's ability to drive or use machines (Moderna Australia, 2021).

Consumer medicine information and the COVID-19 vaccination – Patient resources can be given to individuals receiving the vaccine which detail what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for your state or territory, please review this website.

Module Summary

- The previously available Moderna (SPIKEVAX) (red cap) vaccine uses mRNA technology.
- The vial needs to be thawed before administration. If available, low dead volume needles and syringes should be used.
- Do NOT dilute the Moderna (SPIKEVAX) (red cap) vaccine.
- Specialised UCC storage and transport is required if keeping the vial frozen, at -25°C to -15°C. Dry Ice CANNOT be used.
- Unopened and thawed MDVs can be stored at +2°C to +8°C for up to 30 days.
- Once opened the vials can be used for a maximum of 6 hours at either room temperature or at +2°C to +8°C in cold chain conditions.
- The vial or drawn-up dose should not be cold to touch prior to administration to minimise discomfort from receiving an injection of a chilled product.
- For people aged 12 and over the Moderna (SPIKEVAX) (red cap) vaccine was given as a **100 microgram/0.5mL** 2-dose primary schedule intramuscularly, preferably into the deltoid. Or a 3-dose primary schedule for people who are severely immunocompromised.
- The recommended dose interval was 8 weeks between dose 1 and 2. The recommended dose interval for dose 3, if required, was 2 months after the second dose.
- The Moderna (SPIKEVAX) (red cap) booster was given as a single **50 microgram/0.25mL** dose for people 12 years and above.
- Booster doses can be administered 6 months after the last COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (whichever is the most recent).
- All adverse events must be reported as this is a novel vaccine.
- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

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Multi-choice Questions:

1. Which of these statements about storage and transport for the Moderna (SPIKEVAX) (red cap) vaccine is CORRECT?

    a. The thawed vials can be stored in cold chain storage (+2°C to +8°C) for a maximum of 3 months.
    b. Once opened, the vial must be discarded after 24 hours.
    c. Individual vials can be thawed by leaving them on the bench in temperatures up to +25°C for 1 hour.
    d. If vials are thawed, unopened and maintained at +2°C to +8°C they can be re-frozen if needed but only once.

2. For which of the following conditions should a person seek advice from their GP, 190eutralizing specialist or cardiologist before receiving the Moderna (SPIKEVAX) (red cap) vaccine?

    a. Acute decompensated heart failure
    b. Myocarditis, pericarditis or endocarditis 12 months ago.
    c. A previous myocardial infarction or coronary artery disease.
    d. Kawasaki disease.

3. Doses for Moderna (SPIKEVAX) (red cap) vaccine, for people 12 years and over for the primary course or 18 years and over for the booster dose, are:

    a. 0.5mL per primary dose given intramuscularly with a recommended interval of 8 weeks. 0.25mL per booster dose given intramuscularly with a minimum interval of 6 months from the 2nd primary dose.
    b. 0.3mL per primary dose given intramuscularly with a recommended interval of 4 to 8 weeks. 0.15mL per booster dose given intramuscularly with a minimum interval of 5 months from the 2nd primary dose.
    c. 0.5mL per primary dose given subcutaneously with a recommended interval of 8 weeks. 0.25mL per booster dose given intramuscularly with a minimum interval of 6 months from the 2nd primary dose.
    d. 0.5mL per primary and booster dose given intramuscularly with a recommended interval of 8 to 12 weeks between primary doses and 4 months for the booster dose.

4. At which point after vaccination is it thought that optimal protection is developed?

    a. 7 days after dose 2
    b. 14 days after dose 1
    c. 7 days after dose 1
    d. 14 days after dose 2

Additional Module 3a: Moderna (SPIKEVAX) COVID-19 Vaccine for children 6 to 11 years old

(DECOMMISSIONED)

(21/09/2023)

MODULE DECOMMISSIONED – Effective January 2023, Moderna (SPIKEVAX) (red cap) vaccine is no longer being supplied in Australia. Therefore, *no further content updates will be made to this module from May 2023.*

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 15 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete.

Learning objectives

At the end of Additional Module 3a: Moderna (SPIKEVAX) (red cap) vaccine for children 6 to 11 years old, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of the Moderna (SPIKEVAX) (red cap) vaccine for children 6 to 11 years old.
- Understand the contraindications, warnings, adverse reactions, and co-administration of Moderna (SPIKEVAX) (red cap) vaccine for children 6 to 11 years old with other vaccines.
- Understand appropriate administration of the Moderna (SPIKEVAX) (red cap) vaccine for children 6 to 11 years old.

Topics

1. Introduction and summary
2. Administration
3. Precautions
4. Adverse events

Topic 1: Introduction and summary

MODULE DECOMMISSIONED – Effective January 2023, Moderna (SPIKEVAX) (red cap) vaccine is no longer being supplied in Australia. Therefore, *no further content updates will be made to this module from May 2023.*

THE FOLLOWING INFORMATION REMAINS FOR REFERENCE PURPOSES ONLY.

This module builds on the decommissioned Additional Module 3 and this module will not repeat information covered in that module. As required, please review Additional Module 3.

On 17 February 2022, the Therapeutic Goods Administration (TGA) provisionally approved the Moderna (SPIKEVAX) (red cap) vaccine for use in children **6 to 11 year olds** (TGA, 2021d).

Children who turn 12 after their first dose are recommended to receive a BA.4-5-containing bivalent vaccine i.e. Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) or Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine to complete their primary vaccine course (ATAGI, 2023d).

Each Moderna (SPIKEVAX) (red cap) dose for children 6 to 11 years of age was half that of the dose used for the primary course for people 12 years and older; but the same as the booster dose, **0.25mL or 50 micrograms** of mRNA (embedded in SM-102 lipid nanoparticles) (Moderna, 2022a).

2 primary doses of 0.25mL were recommended 8 weeks apart for most children 6 to 11 years of age.

Dose type	Volume/dose	Syringe size
Moderna (SPIKEVAX) (red cap) **primary** dose (**12 years and above**)	0.5mL / 100 micrograms	1mL, 2mL or 3mL syringe
Moderna (SPIKEVAX) (red cap) **booster** dose (**18 years and above**)	0.25mL / 50 micrograms	1mL, 2mL or 3mL syringe
Moderna (SPIKEVAX) (red cap) **primary** dose (**6 to 11 years**)	0.25mL / 50 micrograms	1mL syringe
Moderna (SPIKEVAX) (blue cap, purple label) **primary** dose (**6 months to 5 years**)	0.25mL / 25 micrograms	1mL syringe

Table 1. *Dose types and the dose volume for previously available Moderna (SPIKEVAX) vaccines in different situations*.

ATAGI recommended that the previously available **Moderna (SPIKEVAX)** (red cap) vaccine could have been used for primary vaccination in children aged **6 to 11 years** as an alternative to Pfizer (COMIRNATY) (orange cap).

Parents and carers could have discussed the benefits of receiving the Moderna (SPIKEVAX) (red cap) with their healthcare provider with the understanding that this vaccine was likely to be effective for preventing COVID-19, but mild to moderate short-term adverse reactions are common in this age group (ATAGI, 2022b).

Children aged 6 to 11 years with medical risk factors for severe illness, Aboriginal and Torres Strait Islander children, and children living in crowded conditions or outbreak areas are most likely to benefit from COVID-19 vaccination given their increased risk of severe outcomes and/or exposure to COVID-19 (ATAGI, 2021y).

Protection

As with all vaccines, vaccination with Moderna (SPIKEVAX) (red cap) may not fully protect all recipients from developing COVID-19. The best immune response for individuals is expected 14 days after their second dose. The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials (Moderna, 2022).

There are currently limited data on the effectiveness of SARS-CoV-2 vaccines in preventing transmission or asymptomatic infection in children. At present, there are limited real-world use data available pertaining to the efficacy and safety of Moderna (SPIKEVAX) (red cap) in large populations

of children, noting that this vaccine has not been used extensively overseas for this age group. Data on immune responses to Moderna (SPIKEVAX) (red cap) for children aged 6-11 years, and real-world data on adults immunised with Moderna (SPIKEVAX) (red cap), together indicate that Moderna (SPIKEVAX) (red cap) is likely to be very effective at reducing the likelihood of severe COVID-19 in children, including against the Omicron variant (ATAGI, 2022b).

Moderna (SPIKEVAX) (red cap) demonstrated comparable immunogenicity (for both neutralising antibody and binding antibody) in the pivotal clinical trial in children 6 to 11 years of age (0.25mL/50 micrograms per dose) when compared to immunogenicity data in young adults (18 to 25 years, 100 micrograms/0.5mL per dose). An evaluation of efficacy as a secondary endpoint in the 6 to 11 years Moderna (SPIKEVAX) (red cap) trial also suggested good protection against COVID-19, noting the overall number of cases available for evaluation was small (ATAGI, 2022b).

More information can be found in the:

- Product Information,
- COVID-19 vaccine information,
- ATAGI Clinical guidance for COVID-19 vaccine providers, and
- COVID-19 Vaccination: How COVID-19 vaccines work.

Why should children be vaccinated with a COVID-19 vaccine?

In children aged 6-11 years of age, COVID-19 is generally asymptomatic or causes a short illness with mild symptoms. Children at increased risk of severe outcomes from COVID-19 include those with pre-existing obesity, chronic pulmonary disease, congenital heart disease and neurological disease, as well as those with neurodevelopmental disorders or epilepsy (ATAGI, 2022b).

COVID-19 may be complicated by paediatric inflammatory multisystem syndrome temporarily associated with having COVID-19 (PIMS-TS, also known as MIS-C), a rare and potentially life-threatening syndrome that occurs in ~1 in 3,000 children after COVID-19 infection. There is emerging evidence to suggest vaccination in children may prevent PIMS-TS (ATAGI, 2022b).

At a population level, several modelling studies conducted for earlier SARS-CoV-2 variants have suggested that a vaccination program in young children may indirectly reduce COVID-19-related hospitalisations, admissions to intensive care units and deaths in the overall population. In addition to an anticipated reduction in illness (which is mostly mild), vaccination is also indirectly expected to reduce the need for isolation in children, disruption to education and social activities, and potentially a reduction in parental absenteeism (ATAGI, 2022b).

More details on the indirect and direct benefits of COVID-19 vaccination in children are provided within the COVID-19 vaccines for children, Department of Health and Aged Care webpage.

Topic 2: Administration

Administration

Should an overdose have occurred (for example, incorrect administration of the adult dose to a child aged 6 –11 years), an adverse event following immunisation (AEFI) report should be submitted to the TGA using established mechanisms as discussed in Additional Module 3. All AEFI reports are reviewed by the TGA.

DO NOT inject intravascularly, subcutaneously or intradermally (ATAGI, 2021b). An IM injection into the deltoid of a child 6 to 11 years old remains recommended, noting that the deltoid area is likely to be smaller than in a person 12 years of age and older.

A new sterile syringe and needle must be used for administration to each individual. Do not mix or contaminate the vaccine with any other medication or liquid. If a full dose cannot be extracted from one vial, then that part dose and vial must be discarded (Moderna, 2022).

ATAGI recommendations must be followed over guidance in the product information.

The manufacturer's recommended schedule and TGA approval for the 6 to 11 years Moderna (SPIKEVAX) (red cap) vaccine is 2 doses of the 0.25mL 50 microgram primary course doses, 4 weeks apart. However, ATAGI recommends **2 of the 0.25mL 50 microgram primary course doses, 8 weeks apart**.

To extract the full 20 doses from the MDV, low dead-volume 1mL Luer-Lock syringes and needles are strongly recommended when available. Standard needles and 1mL syringes can be used if this is the supplied and available stock. The syringe and needle should have a combined dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract all doses from a single vial.

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

After administration, the vaccine dose administered, including batch and vial serial number, must be entered into the Australian Immunisation Register (AIR) as described in Module 5, Topic 4.

The interval between doses can be shortened in special circumstances to a minimum of 4 weeks for children at risk of moderate-severe COVID-19 disease, including in those needing a third dose as part of their primary course due to significant immunosuppression, those at high risk of severe COVID, including NDIS participants, and pre-international travel (ATAGI, 2022b).

Parents/guardians and providers are encouraged to weigh up the benefits of earlier protection with the benefit of having a longer dose interval.

The extended interval may improve immunogenicity and vaccine effectiveness following the second dose, based on data obtained in adults. In addition, this longer dosing interval may reduce the risk of myocarditis and pericarditis, as suggested by a Canadian study among older age groups.

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Administration of vaccines under sedation

Procedural guidelines for administration of vaccines under sedation in practice have been developed or are currently being developed in some health services. ATAGI advises that detailed clinical guidance should be developed collaboratively with input from anaesthetic groups, jurisdictional health services and relevant specialists (ATAGI, 2022g).

More information can be found in the ATAGI advice on use of sedation for COVID-19 vaccination.

Additional administration considerations for children 6 to 11 years old

Several additional considerations should be made when injecting a child.

Working with Children Check (WWCC) – Vaccinators may require a WWCC or state/territory equivalent. Requirements for working with children differ by jurisdiction and based on the circumstances (e.g. vaccination via primary care providers or in mass vaccination clinics) and should be clarified by the National COVID Vaccine Taskforce with their jurisdictional counterparts (ATAGI, 2021y).

Informed consent – Informed consent should be obtained as per usual consent procedures for other vaccinations. As children aged under 12 years are too young to be assessed as mature minors, consent from a parent or guardian is required for vaccination. Verbal consent is acceptable and written consent is not required (ATAGI, 2021y).

A combined information and consent document was developed for parents/guardians of children aged 6 to 11 years who received the Moderna (SPIKEVAX) (red cap) vaccine. The consent form required the parent/guardian to confirm that they have the authority to provide consent on behalf of that child and can be found here.

Consideration should be given to detecting, understanding and addressing parental concerns about COVID-19 vaccination for their children. Information should be provided that addresses parental concerns about the direct and indirect benefits of vaccination and adverse events following vaccination (particularly any data on myocarditis and pericarditis). Resources should be tailored to the 6 to 11 years old population to show that vaccinating this age group has been carefully considered, with the direct benefits and risks clearly stated (ATAGI, 2021y).

Additional time per child may be required for administering the vaccine, as younger children often require more parental support and a longer time for vaccine administration than older children. It is crucial that parents are given an opportunity to discuss their concerns and ask questions if they are hesitant.

Health practitioners can use The Translating and Interpreting Service (TIS) National's Free Interpreting Service (FIS) to assist with consultations and obtaining informed consent. Providers can use their existing TIS client code to request interpreters for Medicare and non-Medicare patients for COVID-19 vaccination. For phone or on-site interpreting, call the TIS on 13 14 50. TIS provides interpreting support 24 hours a day, 7 days a week, nationwide.

Distraction techniques – Distraction, relaxation and other measures reduce distress and pain after vaccination in young children. Reducing children's distress may encourage parents to present for future vaccinations on time (ATAGI, 2022q). Consider a small reward system for this age group such as the use of stickers, colourful band-aids or lollies.

Distraction could come in the form of a conversation including reassurance with the parent or guardian, or a health professional on one side while another health professional administers the vaccine on the other side. Verbal reassurance and comfort with hand holding may be useful prior and during the administration.

Local anaesthetics and vapocoolant sprays – Topical anaesthetics, such as EMLA, are not recommended for routine use. They could be considered in a child with excessive fear or dislike of needles. These products need to be applied 30–60 minutes before an injection (ATAGI, 2022q).

Injecting position – A younger child could be held by the parent or guardian in a straddle position. The carer hugs the child against their chest with the child straddling both of the carer's legs. The carer is holding the child tightly with their left arm and the child's right arm is tucked under the carer's left armpit. The carer is holding the child's left arm at the elbow against the child's body, using their right hand. The deltoid muscle injection side on the child's left arm is exposed for the injection to occur (pictures can be found in the handbook).

Consider having a place where children may be able to lie down for their injection rather than sitting down, particularly if there is an excessive fear of needles or anxiety-related effects. Do not apply excessive force when holding a child in any position.

A vaccine checklist poster is available showing the different COVID-19 vaccines available for children in Australia and compares their preparation and administration requirements. See COVID-19 vaccines in Australia.

Topic 3: Precautions

ATAGI closely monitors data that becomes available regarding the use of the Moderna (SPIKEVAX) (red cap) vaccine in children from both overseas and within Australia and updates recommendations based on the latest available evidence (ATAGI, 2022b).

Dosing error

As there was no paediatric-specific formulation for the Moderna (SPIKEVAX) vaccine for children aged 6 – 11 years, it was important to note the risk of an over-dosing error with the Moderna (SPIKEVAX) (red cap) vaccine for this age group. Inadvertent administration of a 0.5mL/100 microgram dose to a child 6 to 11 years of age may lead to an increase in the number or severity of adverse reactions or events as was observed in the first (dose-finding) part of the clinical trial conducted by Moderna.

Should an overdose have occurred (for example, incorrect administration of the adult dose to a child aged 6 –11 years), an adverse event following immunisation (AEFI) report should be submitted to the TGA using established mechanisms as discussed in Additional Module 3. All AEFI reports are reviewed by the TGA.

Any 0.5mL Moderna (SPIKEVAX) (red cap) vaccine dose given to a child aged 6 to 11 years of age is recommended to be reported as a Vaccine Administration Error (VAE). The Vaccine Operations Centre (VOC) on **1800 318 208** is available to provide advice and guidance to clinicians regarding the management of VAEs. Refer to Additional Module 3 and *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

On the second visit, the correct 0.25mL / 50 microgram dose should have been administered to complete the primary course.

Anaphylaxis – As per Additional Module 3.

Previous SARS-CoV-2 infection – As per Additional Module 3.

Immunocompromised individuals – A third COVID-19 vaccine dose of Moderna (SPIKEVAX) (red cap), for those 6 to 11 years was recommended for children who are severely immunocompromised. This 0.25mL/50 micrograms dose was recommended to be administered from 2 months after the second primary course dose. More information about third primary doses for severely immunocompromised individuals is available here.

Myocarditis and pericarditis – Myocarditis and pericarditis are very rare adverse events linked to the use of an mRNA COVID-19 vaccine. Preliminary data from older age groups suggest that myocarditis may occur at an increased frequency following vaccination with mRNA vaccines including Moderna (SPIKEVAX) (red cap), although the absolute risk remains low.

The risk of myocarditis and pericarditis is much lower in children aged 5 to 11 years compared to adolescents. The risk also looks lower after a booster than the primary course. In children aged 6 months to less than 5 years, there is no clear attributable risk of myocarditis and pericarditis after COVID-19 vaccines.

Further detail regarding myocarditis and pericarditis following mRNA vaccines is available here

Concurrent illness – As per Additional Module 3.

Vaccine co-administration – ATAGI supports co-administration of routine childhood vaccines with COVID-19 vaccines, given the importance of ensuring protection against other vaccine-preventable diseases and maintaining high vaccine uptake (ATAGI, 2021y).

While there are limited data on the immunogenicity and safety of COVID-19 vaccines co-administered with other vaccines, based on first principles it is unlikely there will be an impact on the immunogenicity or effectiveness of vaccines given on the same day. Expected adverse events such as local reactions and fever may be increased in the setting of co-administration. It is recommended that parents and guardians be made aware of this prior to vaccine administration (ATAGI, 2021y; ATAGI, 2022b).

Data on the potential for co-administration with other vaccines is currently being reviewed and detailed information on this will be included in the ATAGI Clinical Guidance for COVID-19 vaccine providers (ATAGI, 2021b).

Topic 4: Adverse events

Preliminary data suggest that most side effects are mild to moderate and transient in nature, similar to those observed in children who have received the Pfizer (COMIRNATY) (orange cap) vaccine. However, the frequency of some short-term systematic side effects, such as fever and nausea/vomiting, may be more common in children who received the Moderna (SPIKEVAX) (red cap) vaccine than the Pfizer (COMIRNATY) (orange cap) vaccine.

Very common adverse events include:

- Injection site pain - >94% of individuals.
- Fatigue - >64% of individuals.
- Headache - >54% of individuals.
- Chills - >30% of individuals.
- Myalgia - >28% of individuals.
- Nausea/vomiting - >24% of individuals
- Fever - >23% of individuals.
- Injection site redness - >18% of individuals.
- Axillary swelling/tenderness - >18% of individuals.
- Injection site swelling - >17% of individuals
- Arthralgia - >16.1% of individuals

(Moderna, 2022)

While fever rates were observed to be higher among children 6 to 11 years old (23.9%) when compared to 18 to less than 25 year olds (18.1%), the fever generally lasted a shorter duration (<24 hours). No febrile seizure and no grade 4 fevers were reported in clinical trials.

Consumer medicine information and the COVID-19 vaccination – Patient resources can be given to parents or guardians of children receiving the vaccine which detail what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for your state or territory, please review this website.

Module Summary

- The previously available Moderna (SPIKEVAX) (red cap) vaccine for children aged 6 to 11 years of age is the same formula/vaccine used for those 12 years of age and older, **but is half the dose.**
- 2 primary doses of **0.25mL** were recommended 8 weeks apart for most children 6 to 11 years of age. 3 primary doses were recommended for children 6 to 11 years old who are severely immunocompromised with an interval of 2 months after the second primary dose.
- Moderna (SPIKEVAX) (red cap) was previously available for children aged 6 to 11 years old and **could not** be given to children 5 years old and younger. ATAGI recommends that Pfizer (CORMINATY) (orange cap) vaccine can be given to children who are 5 years of age or the Pfizer (COMIRNATY) (maroon cap) to children who are 6 months to 4 years.
- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

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Multi-choice questions

1. What was ATAGI's recommended dose and interval of the previously available Moderna (SPIKEVAX) (red cap) for a child aged between 6 and 11 years?

    a. 0.25mL 4 weeks apart
    b. 0.25mL 8 weeks apart
    c. 0.5mL 8 weeks apart
    d. 0.5mL 4 weeks apart

2. Which of the statements regarding the previously available Moderna (SPIKEVAX) (red cap) dosing is CORRECT?

    a. The 6 to 11 year old dosing of Moderna (SPIKEVAX) (red cap) should have been used for both primary doses, even if the child turned 12 after their first dose.
    b. The 12 years and older Moderna (SPIKEVAX) (red cap) dosing should have been used for both doses for children who are due to turn 12 before their second primary dose is due.
    c. The 6 to 11 year old Moderna (SPIKEVAX) (red cap) dosing should have been used for children who are turning 6 that year, even if they have not turned 6 before their first dose.
    d. The 6 to 11 year old Moderna (SPIKEVAX) (red cap) dosing should have been used for the first dose for children who are 11 years old. If the child turns 12 before the second dose, they should receive the 12 years and older Moderna (SPIKEVAX) (red cap) dosing for their second dose.

3. Which of the below statements were **CORRECT** regarding ATAGI recommendations?

    a. ATAGI recommended that Pfizer (COMIRNATY) (orange cap) is **preferred** over the Moderna (SPIKEVAX) (red cap) vaccine for children aged **6 to 11 years of age**.
    b. ATAGI expressed **no preference** but recommended the mRNA vaccine Pfizer (COMIRNATY) (orange cap) for children aged **5-11 years old**, and the Moderna (SPIKEVAX) (red cap) vaccine as an alternate option for children aged **6 to 11 years of age**.
    c. ATAGI recommended that Moderna (SPIKEVAX) (red cap) was **preferred** over the Pfizer (COMIRNATY) (orange cap) vaccine for children aged **6 to 11 years of age**.
    d. ATAGI recommended that Pfizer (COMIRNATY) (orange cap) was **preferred** over the Moderna (SPIKEVAX) (red cap) vaccine for children aged **5 to 12 years of age**.

What should have been done if an 11-year-old accidentally received a 0.5mL / 100 microgram dose of Moderna (SPIKEVAX) (red cap) as the first primary course dose?

    e. Give the correct dose of 0.25mL / 50 micrograms again now and enter the correct dose into the AIR.
    f. Report this as a Vaccine Administration Error (VAE) to your local PHU or public health authority of your state/territory and to the VOC**.** On the second visit administer the same dose as mixed doses cannot be used in children under 12 years of age.
    g. Report this as a Vaccine Administration Error (VAE) to your local PHU or public health authority of your state/territory and to the VOC**.** On the second visit administer the correct 0.25mL / 50 microgram dose to complete the primary course.
    h. Report this as a Vaccine Administration Error (VAE) to your local PHU or public health authority of your state/territory and to the VOC**.** On the second visit re-administer the first primary course dose with the correct 0.25mL / 50 microgram dose as the first dose is considered invalid.

Additional Module 3b: Moderna (SPIKEVAX) COVID-19 vaccine for children 6 months to <5 years old (Blue/Purple)

(21/09/2023)

MODULE DECOMMISSIONED – Effective May 2023, Moderna (SPIKEVAX) (blue cap, purple label) vaccine is no longer being supplied in Australia. Therefore, *no further content updates will be made to this module from May 2023.*

This module is suitable for healthcare professionals who will be authorised to administer COVID-19 vaccines to children aged 6 months to <5 years.

The recommended time for completing the module is 15 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete.

Learning objectives

At the end of Additional Module 3b: Moderna (SPIKEVAX) (blue cap, purple label) vaccine for children 6 months to <5 years old, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of the Moderna (SPIKEVAX) (blue cap, purple label) vaccine for children 6 months to <5 years old.
- Understand the contraindications, warnings, adverse reactions, and co-administration of Moderna (SPIKEVAX) (blue cap, purple label) vaccine for children 6 months to <5 years old with other vaccines.
- Understand appropriate administration of the Moderna (SPIKEVAX) (blue cap, purple label) vaccine for children 6 months to <5 years old.

Topics

1. Introduction and summary
2. Administration
3. Precautions
4. Adverse events

Topic 1: Introduction and summary

MODULE DECOMMISSIONED – Effective May 2023, Moderna (SPIKEVAX) (blue cap, purple label) vaccine is no longer being supplied in Australia. Therefore, *no further content updates will be made to this module from May 2023.*

THE FOLLOWING INFORMATION REMAINS FOR REFERENCE PURPOSES ONLY.

This module builds on Additional Module 3 and Additional Module 3a. This module will not repeat the information covered in those modules. Please review Additional Modules 3 and 3a.

The previously supplied Moderna (SPIKEVAX) (blue cap, purple label) vaccine for use in children 6 months to 5 years old was provisionally approved by the Therapeutic Goods Administration (TGA) on 19 July 2022 (TGA, 2021d).

The vaccine was recommended for **eligible** children aged 6 months to 4 years and **all** children aged 5 years as an alternative COVID-19 vaccine to Pfizer (COMIRNATY) (orange cap). From May 2023, the Moderna (SPIKEVAX) (blue cap, purple label) vaccine is no longer supplied in Australia.

The Moderna (SPIKEVAX) (blue cap, purple label) vaccine for children aged 6 months to 5 years was a new formulation with a concentration of 100 mcg/mL in multi-dose vials containing **10 doses, each 0.25 mL**.

*Figure 1: Moderna (SPIKEVAX) (*blue cap, purple label*) vaccine vial.*

Figure 2: Secondary packaging – A carton of 10x10 Moderna (SPIKEVAX) (blue cap, purple label) *vaccine vials.*

The vial has a blue cap with a purple label, referred to in this training program as Moderna (SPIKEVAX) (blue cap, purple label) whilst the pack has purple highlights to distinguish it from other Moderna products.

Each multi-dose vial (MDV) contains 10 doses of 0.25mL for intra-muscular injection.

This vaccine MUST NOT be diluted.

Two primary doses of 0.25mL/25 mcg **(0.25mL of Moderna (SPIKEVAX) (blue cap, purple label))** was recommended 8 weeks apart for **eligible** children 6 months to 5 years of age. A minimum interval of 4 weeks can be considered in special circumstances. See ATAGI Clinical recommendations for COVID-19 vaccines for Recommended and variations on primary vaccination schedule.

ATAGI recommended that immunisation providers were vigilant for the potential for dosing errors with the Moderna vaccine for children as the **Moderna (SPIKEVAX) vaccine dose increases from 25 mcg in 5-year-old children (0.25mL of Moderna (SPIKEVAX) (blue cap, purple label)) to 50 mcg for those aged 6 to 11 years (0.25mL of Moderna (SPIKEVAX) (red cap)).** Therefore, there is a risk of dosing errors, including over-dosing, with the Moderna vaccines for children.

ATAGI also recommended that immunisation providers are vigilant for the potential for dosing errors with the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine due to the use of the same blue coloured vaccine vial caps as that of the Moderna (SPIKEVAX) (blue cap, purple label) vaccine for children aged 6 months to 5 years formulation (ATAGI, 2022m). Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) has a **green label**, whereas Moderna (SPIKEVAX) (blue cap, purple label) for children aged 6 months to 5 years has a **purple label**.

To minimise the risk of administration errors, providers should preferably prepare and store doses of the Moderna (SPIKEVAX) (blue cap, purple label) vaccine separately from other vaccines. Doses withdrawn in advance of administration should be clearly labelled (ATAGI, 2022m).

Refer to *Table 1. Dose types and dose volume for Moderna (SPIKEVAX) vaccines for different age groups*.

Category	Moderna (SPIKEVAX) (blue cap, purple label) 100mcg/mL vial	Moderna (SPIKEVAX) (red cap) 200mcg/mL vial	Moderna bivalent BA/1 (SPIKEVAX) (blue cap, green label) 100mcg/mL vial
	 *Image 2: Moderna (SPIKEVAX) (blue cap, purple label) vial*	 *Image 3: Moderna (SPIKEVAX) (red cap) vial*	 *Image 4: Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vial*
Approved age for use by ATAGI	6 months to <6 years	≥6 years	≥18 years
Cap colour	Blue cap with purple label	Red cap	Blue cap with green label
Dose type and volume/dose	Moderna **primary** dose (**6 months to 5 years**) – 0.25mL / 25 micrograms	Moderna **primary** dose (**6 to 11 years**) – 0.25mL / 50 micrograms	Moderna **booster** dose (**18 years and older**) – 0.5mL / 50 micrograms
		Moderna **primary** dose (**12 years and above**) – 0.5mL / 100 micrograms	
		Moderna **booster** dose (**18 years and above**) – 0.25mL / 50 micrograms	

Table 1. Dose types and dose volume for Moderna (SPIKEVAX) vaccines for different age groups.

The previously available Moderna (SPIKEVAX) (red cap) vaccine should NOT have been administered to patients under the age of 6 years.

Parents and carers of children who are severely immunocompromised may discuss the benefits of receiving Moderna (SPIKEVAX) (blue cap, purple label) with their healthcare provider with the understanding that this vaccine may be effective for preventing COVID-19, but that mild to moderate short-term adverse reactions, such as fever, were common in this age group (ATAGI, 2022k).

Protection

As with all vaccines, vaccination with Moderna (SPIKEVAX) (blue cap, purple label) may not fully protect all recipients from developing a COVID-19 infection. The best immune response for individuals is expected 14 days after their second dose. The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials (Moderna, 2022b).

There are currently limited data available on the effectiveness of SARS-CoV-2 vaccines in preventing transmission or asymptomatic infection in children aged 6 months to 5 years. The efficacy demonstrated in the clinical trials conducted for this age group was against the BA.1 Omicron variant. It is expected that there will be a decline in protection against infection with subsequent subvariants, especially with the current BA.4 and BA.5 subvariants which demonstrate a greater degree of immune escape (ATAGI, 2022k).

Moderna (SPIKEVAX) (blue cap, purple label) demonstrated equivalent or better immunogenicity (for neutralising antibody responses) in the pivotal clinical trial in children 6 months to 5 years of age (0.25mL/25 micrograms per dose) when compared to immunogenicity data in young adults (18 to 25 years, 100 micrograms/0.5mL per dose). The neutralising antibody response was found to be higher in children aged 6 to 23 months, and equivalent in those aged 2 to 5 years and 18 to 25 years (ATAGI, 2022k).

More information can be found in the:

- Product Information,
- COVID-19 vaccine information,
- ATAGI Clinical guidance for COVID-19 vaccine providers,
- COVID-19 Vaccination: How COVID-19 vaccines work
- COVID-19 vaccination – Patient resources.

Why should children be vaccinated with a COVID-19 vaccine?

In Australia and internationally there has been a significant number of COVID-19 infections occurring in children aged 6 months to 5 years. Even though the number of infections has been high amongst this age group, studies have shown that severe infections have been low (that is those that require hospitalisation, intensive care admissions or that result in death) (ATAGI, 2022k).

In both healthy and immunocompromised children, severe COVID-19 infection is very rare. Unpublished hospitalisation data from tertiary paediatric hospitals and the Paediatric Active Enhanced Disease Surveillance (PAEDS) network reviewed by ATAGI, have revealed that there has been a low burden of severe disease in children who have been infected with the currently circulating Omicron variants (ATAGI, 2022k).

COVID-19 may be complicated by paediatric inflammatory multisystem syndrome temporarily associated with having COVID-19 (PIMS-TS, also known as MIS-C), a rare and potentially life-threatening syndrome that occurs in ~1 in 3,000 children after COVID-19 infection. With the

currently circulating Omicron variants, the rates of PIMS-TS are up to 95% lower and episodes are observed to be milder. Children aged 6 months to 5 years are at a lower risk of PIMS-TS than older children (ATAGI, 2022k).

ATAGI recommends COVID-19 vaccination for **children aged 6 months to 5 years** with severe immunocompromise, disability, and those who have complex and/or multiple health conditions which increase the risk of severe COVID-19. These include children with the following or similar conditions:

- Severe primary or secondary immunodeficiency, including those undergoing treatment for cancer, or on immunosuppressive treatments as listed in the ATAGI advice on third primary doses of COVID-19 vaccine in individuals who are severely immunocompromised
- Bone marrow or stem cell transplant, or chimeric antigen T-cell (CAR-T) therapy
- Complex congenital cardiac disease
- Structural airway anomalies or chronic lung disease
- Type 1 diabetes mellitus
- Chronic neurological or neuromuscular conditions or
- A disability that requires frequent assistance with activities of daily living, such as severe cerebral palsy or Down Syndrome (Trisomy 21).

(ATAGI, 2022k)

ATAGI does not currently recommend vaccination for children aged 6 months to 5 years who are **not** in the above risk categories for severe COVID-19 as these children have a very low likelihood of severe illness from COVID-19. However, this is under ongoing consideration based on data on the disease burden and epidemiology, vaccine supply, emerging data on vaccine use in this age group, and availability of new COVID-19 vaccines for this age group (ATAGI, 2022k).

More details on the indirect and direct benefits of COVID-19 vaccination in children are provided here

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Topic 2: Cold chain and thawing

Thawed storage and deliveries

Deliveries of **thawed** vaccines were received at **+2°C to +8°C** and had the following label applied.

The **USE BY** date is the earliest of:

- Thaw date + 30 days
- Manufacturer expiry date including any extensions in shelf life

Frozen storage and deliveries

Storage and transport of unopened Moderna (SPIKEVAX) (blue cap, purple label) vaccine required ultra-cold chain (UCC) management. These vials can be stored frozen at **-50°C to -15°C.**

Deliveries of frozen full pack vaccines to hospitals and state clinics were received at **-50°C to -15°C**

Refer to Additional Module 3 Topic 2 for more details

Topic 3: Administration

Administration

Administer the vaccine as an intramuscular injection (IMI). The recommended site for infants **<12 months** is the vastus lateralis muscle in the anterolateral thigh. **DO NOT** use the deltoid muscle for infants <12 months (ATAGI, 2022q). **DO NOT** inject intravascularly, subcutaneously or intradermally (Moderna, 2022b).

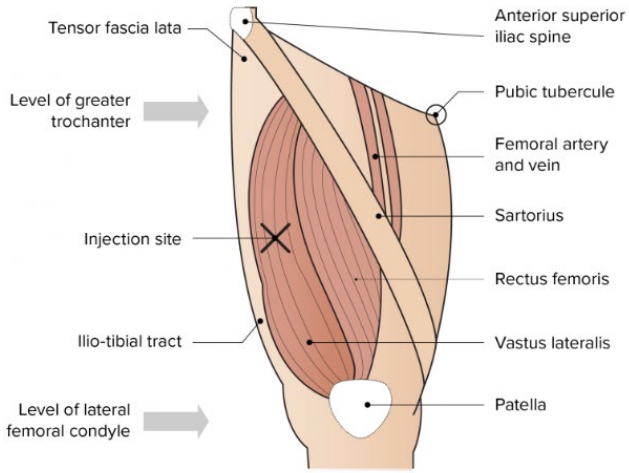

Image 5: Anatomical markers used to identify the vastus lateralis injection site on the anterolateral thigh for infants <12 months

For children **≥12 months** administer the vaccine as an intramuscular injection (IMI) in the deltoid muscle. **DO NOT** inject intravascularly, subcutaneously or intradermally (Moderna, 2022b).

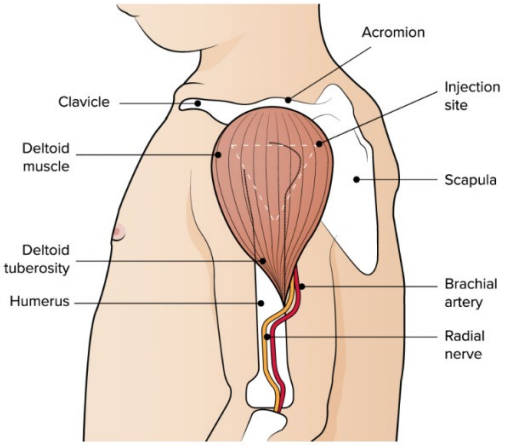

Image 6: Anatomical markers used to identify the deltoid injection site

A single **primary course** dose of Moderna (SPIKEVAX) (blue cap, purple label) vaccine for infants and children 6 months to 5 years is 0.25mL and contains 25 micrograms **(0.25mL of 100 mcg/mL)** of mRNA vaccine. **Care must be taken to draw up the dose to the exact 0.25 mL dose volume. Always double-check the dose volume and the vial label before administration.**

A new sterile syringe and needle must be used for administration to each individual as per Module 4. Do not mix or contaminate the vaccine with any other medication or liquid. **Moderna (SPIKEVAX)** (blue cap, purple label) **6 months to 5 years MUST NOT be diluted.** If a full dose cannot be extracted from one vial, then that part dose and vial must be discarded (Moderna, 2022b).

ATAGI recommendations must be followed over guidance in the Product Information.

The interval between doses can be shortened in special circumstances to a minimum of 4 weeks for children at risk of moderate-severe COVID-19 disease, including in those needing a third dose as part of their primary course due to significant immunosuppression, those at high risk of severe COVID, including NDIS participants, and before international travel (ATAGI, 2022b).

The manufacturer's recommended schedule and TGA approval for the 6 months to 5 years Moderna (SPIKEVAX) (blue cap, purple label) vaccine is 2 doses of the 0.25mL/25 microgram primary course doses, 4 weeks apart. However, ATAGI recommends **2 of the 0.25mL/25 microgram primary course doses, 8 weeks apart**.

ATAGI advises that the recommended longer dosing interval is to allow more time to observe international data on potentially rare adverse events in this age group. It may also improve immunogenicity. In adult populations, extending the interval to 8 weeks or longer has resulted in higher antibody levels, improved vaccine effectiveness and potentially longer duration of protection compared with the standard interval. Extended dosing intervals have not yet been directly studied in children (ATAGI, 2022k). Parents/guardians and providers are encouraged to weigh up the benefits of earlier protection with the benefit of having a longer dose interval.

After administration, the vaccine dose administered, including batch number, must be entered into the Australian Immunisation Register (AIR) as described in Module 5, Topic 4.

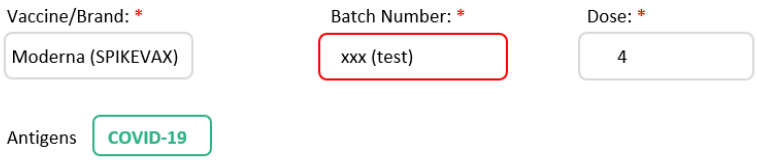

Image 7: Data required for COVID-19 vaccines to be entered into the AIR

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Topic 4: Precautions

ATAGI closely monitors data that becomes available regarding the use of the Moderna (SPIKEVAX) (blue cap, purple label) vaccine in children from both overseas and within Australia and updates recommendations based on the latest available evidence (ATAGI, 2022b).

Dosing errors

Should a vaccine administration error, including an overdose, have occurred (for example, the incorrect administration of the 6 to 11 year dose to a child aged 6 months to 5 years), an adverse event following immunisation (AEFI) report should be submitted to the TGA or your state/territory health department using established mechanisms as discussed in Additional Module 3. All AEFI reports are reviewed by the TGA.

Any error of administration including 0.25mL/50 microgram Moderna (SPIKEVAX) (red cap) vaccine dose given to a child aged 6 months to 5 years of age should be reported as a Vaccine Administration Error (VAE) to your local public health unit (PHU) or public health authority of your state/territory or to the Vaccine Operations Centre (VOC) on **1800 318 208** (check with your employer about your organisation's processes for reporting VAEs). Refer to Additional Module 3 and *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Anaphylaxis – As per Additional Module 3.

Previous SARS-CoV-2 infection – As per Additional Module 3.

Immunocompromised individuals – A third primary COVID-19 vaccine dose of Moderna (SPIKEVAX) (blue cap, purple label), for those 6 months to 5 years was recommended for children who are severely immunocompromised. This 0.25mL/25 micrograms **(0.25mL of 100 mcg/mL)** dose was recommended to be administered 8 weeks after the second primary course dose. A minimum interval of 4 weeks may be considered in exceptional circumstances.

More information about third primary doses for severely immunocompromised individuals is available here.

Myocarditis and pericarditis – Myocarditis and pericarditis are very rare adverse events linked to the use of an mRNA COVID-19 vaccine. Preliminary data from older age groups suggest that myocarditis may occur at an increased frequency following vaccination with mRNA vaccines including Moderna (SPIKEVAX) (blue cap, purple label), although the absolute risk remains low.

These rates are likely to be lower than those in adolescents, as has been observed with the Pfizer (COMIRNATY) vaccine; data reveal that for every million doses of vaccine administered in male children and adolescents in the US, there are approximately 46 cases of myocarditis in boys aged 12-15 years, compared to only 4 cases for boys aged 5-11 years (ATAGI, 2022b).

The clinical trial conducted for children aged 6 months to 5 years revealed no confirmed myocarditis or pericarditis for this age group.

Further detail regarding myocarditis and pericarditis following mRNA vaccines is available here.

Concurrent illness – As per Additional Module 3.

Vaccine co-administration – ATAGI recommends that where possible a minimum interval of 7-14 days is recommended between a Moderna (SPIKEVAX) (blue cap, purple label) vaccine and other vaccines in children aged 6 months to 5 years, to minimise the risk of adverse events such as fever (ATAGI 2022k).

Data on the potential for co-administration with other vaccines are currently being reviewed and detailed information will be included in the ATAGI Clinical Guidance for COVID-19 vaccine providers (ATAGI, 2021b).

Topic 5: Adverse events

General adverse events have been discussed in Module 6 Topic 2.

Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side-effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website. For more information, please refer to Core Module 6.

Preliminary data suggest that most side effects for children aged 6 months to 5 years are mild to moderate and transient in nature, similar to those observed in other age groups who have received the Moderna (SPIKEVAX) (red cap) vaccine. Fever rates, however, were higher amongst infants and children aged 6 months to 5 years after both dose 1 and dose 2 of the vaccine.

Very common adverse events include:

Age Group	Adverse Event	Percentage of individuals affected
6 months to 23 months	Irritability/crying	81.5%
	Pain at the injection site	56.2%
	Sleepiness	51.1%
	Loss of appetite	45.7%
	Fever	21.8%
	Swelling at the injection site	18.4%
	Erythema at the injection site	17.9%
	Axillary swelling/tenderness	12.2%

Age Group	Adverse Event	Percentage of individuals affected
24 months to 36 months	Irritability/crying	71.0%
	Pain at the injection site	76.8%
	Sleepiness	49.7%
	Loss of appetite	42.4%
	Fever	26.1%
	Swelling at the injection site	15.7%
	Erythema at the injection site	17.9%
	Axillary swelling/tenderness	11.5%

Age Group	Adverse Event	Percentage of individuals affected
37 months to 5 years	Fatigue	61.9%
	Pain at the injection site	83.8%
	Headache	22.9%
	Myalgia	22.1%
	Nausea/vomiting	15.2%
	Fever	20.9%

	Chills	16.8%
	Swelling at the injection site	8.2%
	Erythema at the injection site	9.5%
	Axillary swelling/tenderness	14.3%

(Moderna, 2022b)

In vaccine recipients aged 6 to 23 months with evidence of prior SARS-CoV-2 infection, the rate of fever was 20.2%, higher than among vaccine recipients without evidence of prior infection. A 1-year-old female experienced serious adverse events of a grade 3 fever 6 hours after dose 1 of the vaccine and a febrile convulsion 1 day after dose 1 of the vaccine. Both these events were considered related to vaccination. For vaccine recipients 2 to 5 years of age with evidence of prior SARS-CoV-2 infection, the rate of fever (20.3%) was also higher compared to vaccine recipients without evidence of prior infection (Moderna, 2022b).

Prophylactic paracetamol to reduce the risk of fever is not recommended prior to or immediately after vaccination. However, paracetamol or ibuprofen can be given as required after vaccination for any discomfort or fever (ATAGI, 2022k).

Consumer medicine information and the COVID-19 vaccination – Patient resources can be given to parents or guardians of children receiving the vaccine which detail what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for notification in your state or territory, please review this website.

Module Summary

- The previously available Moderna (SPIKEVAX) (blue cap, purple label) vaccine is an mRNA vaccine. The vaccine is distinguishable by its blue cap and purple label.
- The Moderna (SPIKEVAX) (blue cap, purple label) vaccine for children aged 6 months to 5 years of age was a different formula/vaccine to that used for those 6 to 11 years of age and older (Moderna (SPIKEVAX) (red cap))**. Clinicians should be aware of the risk of dosing errors.**
- The Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) has a similar coloured **blue cap** to that of the Moderna (SPIKEVAX) (blue cap, purple label) vaccine. **Clinicians should be aware of the risk of dosing errors.**
- The Moderna (SPIKEVAX) (red cap) vaccine **CANNOT** be administered to patients under the age of 6 years old.
- The Moderna (SPIKEVAX) (blue cap, purple label) **CANNOT** be given to children aged 6 years and older, even if they received one dose of the Moderna (SPIKEVAX) (blue cap, purple label) before they turned 6.
- The Moderna (SPIKEVAX) (blue cap, purple label) **CANNOT** be given to infants <6 months old.
- 2 primary doses of 0.25mL/25 micrograms were recommended 8 weeks apart for **eligible** children 6 months to 5 years of age. 3 primary doses were recommended for children 6 months to 5 years of age who are severely immunocompromised with an interval of 8 weeks after the second primary dose.
- For this age group, a minimum interval of 7-14 days was recommended between a Moderna (SPIKEVAX) (blue cap, purple label) vaccine and other vaccines, to minimise the risk of adverse events such as fever.

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Multi-choice questions

1. What was ATAGI's recommended dose and interval of Moderna (SPIKEVAX) (blue cap, purple label) for a child aged between 6 months and 5 years?

    a. 0.25mL/25 micrograms 3 weeks apart
    b. 0.25mL/25 micrograms 8 weeks apart
    c. 0.25mL/50 micrograms 8 weeks apart
    d. 0.25mL/50 micrograms 4 weeks apart

2. Which of the statements regarding Moderna (SPIKEVAX) (blue cap, purple label) dosing was CORRECT?

    a. The 6 months to 5-year-old dosing of Moderna (SPIKEVAX) (blue cap, purple label) is not recommended to be used for both primary doses, even if the child turns 6 after their first dose.

b. The 6 years and older Moderna (SPIKEVAX) (red cap) dosing should be used for both doses for children who are due to turn 6 before their second primary dose is due.
c. The 6 months to 5-year-old Moderna (SPIKEVAX) (blue cap, purple label) dosing can be used for children who have already turned 6 years old.
d. The 6-month to 5-year-old Moderna (SPIKEVAX) **(blue cap, purple label)** or Pfizer (COMIRNATY) (orange cap) dosing can be used for the first dose for children who are 5 years old. If the child turns 6 before the second dose, it is preferable for them to receive the same brand of vaccine which was used for their first dose.

3. Moderna (SPIKEVAX) (blue cap, purple label) was provided in two presentations. How is the correct multi-dose vial identified for infants and children aged 6 months to 5 years?

a. 0.2mg/mL multi-dose vials WITH A RED cap, RED label
b. 0.1mg/mL multi-dose vial WITH A BLUE cap, PURPLE label
c. 0.5mg/mL multi-dose vials WITH A BLUE cap, GREEN label
d. 0.1mg/mL multi-dose vial WITH A PURPLE cap, RED label

4. Which of the following statements on the site of administration is INCORRECT for infants aged <12 months?

a. The Moderna (SPIKEVAX) (blue cap, purple label) vaccine should be administered as an intramuscular injection.
b. The recommended site for infants <12 months is the vastus lateralis muscle in the anterolateral thigh
c. The deltoid muscle MUST NOT be used for infants <12 months old.
d. The Moderna (SPIKEVAX) (blue cap, purple label) vaccine can be injected intravascularly, subcutaneously or intradermally in children aged 6 months to 5 years

Additional Module 3c: Moderna (SPIKEVAX BIVALENT) BA.1 COVID-19 Booster Vaccine

(21/09/2023)

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 15 minutes. Each topic must be worked through in order and there are multiple-choice questions to pass before this module is complete.

Learning objectives

At the end of Additional Module 3c: Moderna bivalent BA.1 (SPIKEVAX) (blue gap, green label) vaccine for individuals aged 18 years and older, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine for individuals aged 18 years and older.
- Understand the contraindications, warnings, adverse reactions, and recommendations for co-administration with other vaccines for the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine for individuals aged 18 years and older.
- Demonstrate appropriate dose preparation including verification before administration of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine for individuals aged 18 years and older.
- Understand the appropriate administration of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine for individuals aged 18 years and older.

Topics

1. Introduction and summary
2. Administration
3. Precautions
4. Adverse events

Topic 1: Introduction and summary

This module builds on the Additional Module 3 and this module will not repeat the information covered in that module. As required, please review Additional Module 3.

The SPIKEVAX (Elasomeran/Imelasomeran) COVID-19 vaccine is also known as the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine (which term will be used in this module).

On 29 August 2022, the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine was provisionally approved by the Therapeutic Goods Administration (TGA) for use in individuals aged 18 years and older (TGA, 2022c).

This vaccine uses new technology to induce immunity, similar to the other Moderna (SPIKEVAX) vaccines and the Pfizer (COMIRNATY) vaccines.

The Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine contains 50mcg of mRNA, comprising equal quantities encoding the spike protein from the original SARS-CoV-2 virus and Omicron BA.1 variant.

Elasomeran is a single-stranded messenger RNA (mRNA) produced using a cell-free in-vitro transcription from corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2. Imelasomeran contains mRNA encoding full-length, codon-optimised pre-fusion stabilised conformation variant of the SARS-CoV-2 spike (S) glycoprotein (Omicron variant, B.1.1.529) (TGA, 2022c; Moderna Australia, 2022).

Further information can be found on the Product Information, and the Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance for COVID-19 vaccine providers. The Consumer Medicine Information (CMI) summary can also be given to individuals receiving the vaccine.

For people aged 18 years and older, ATAGI recommends receiving either a BA.1-containing bivalent vaccine (e.g. Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label)) or a BA.4-5-containing bivalent vaccine **for both the primary course and booster doses**.

Bivalent vaccines are designed to broaden cross-protection from vaccination against Omicron and its subvariants by including an Omicron strain in the vaccine. Circulating strains since 2022 have all evolved as subvariants from the first Omicron variant. Pre-Omicron variants no longer circulate, and reversion to a pre-Omicron variant by a future strain is considered unlikely.

ATAGI, therefore, considers the bivalent vaccines (which protect against either Omicron subvariants BA.1 or BA.4-5) preferable for use in a primary course. ATAGI notes that use of bivalent vaccines for primary vaccination is consistent with evolving advice from the World Health Organization's Strategic Advisory Group of Experts on Immunization (SAGE) and the European Medicines Agency's Emergency Task Force, and that off-label use has been permitted in the United Kingdom.

The safety of bivalent vaccines is similar to monovalent original vaccines when used as a booster dose. ATAGI has no additional concerns regarding the safety or effectiveness of bivalent vaccines compared with monovalent vaccines when used for a primary course.

The ATAGI COVID-19 2023 Booster Advice provides guidance on which individuals are recommended, or can consider, a COVID-19 vaccine booster dose for additional protection against severe COVID-19. Booster doses of the COVID-19 vaccine should be given at least 6 months after the most recent COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (whichever is the most recent) (ATAGI 2022o; ATAGI, 2023a).

ATAGI **does not** currently recommend use of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine in anyone under 18 years as it is not registered for this age group (ATAGI, 2022m).

Image 1. Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) green box and vaccine vial

The Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine is presented as a **blue-capped** multidose vial (100 mcg/mL). Each pack contains 10 multidose vials (MDV):

- Five (5) doses (of 0.5mL volume each) can be withdrawn from each 2.5mL vial.

Inside the vial, the vaccine is a sterile white to off-white suspension for injection with a total volume of 2.5mL. This product is a ready-to-use formulation and **does not** require dilution (Moderna Australia, 2022).

The vial is made of glass with a chlorobutyl rubber stopper and a **blue** flip-off plastic cap with an aluminium seal (Moderna Australia, 2022).

To minimise the risk of administration errors, providers should preferably prepare and store doses of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine separately from other vaccines. Doses withdrawn in advance of administration should be clearly labelled (ATAGI, 2022m).

Refer to *Table 1. Dose types and dose volume for Moderna (SPIKEVAX) vaccines for different age groups*.

Please note: Moderna (SPIKEVAX) (red cap) and Moderna (SPIKEVAX) (blue cap, purple label) vaccines are no longer available in Australia.

Category	Moderna (SPIKEVAX) (blue cap, purple label) 100mcg/mL vial	Moderna (SPIKEVAX) (red cap) 200mcg/mL vial	Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) 100mcg/mL vial
	 *Image 2: Moderna (SPIKEVAX) (blue cap, purple label) vial*	*Image*  *3: Moderna (SPIKEVAX) (red cap) vial*	 *Image 4: Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vial*
Approved age	6 months to 5 years	≥6 years	≥18 years
Cap colour	Blue cap with purple label	Red cap	Blue cap with green label
Dose type and volume/dose	**Primary** dose (**6 months to 5 years**) – 0.25mL / 25 micrograms	**Primary** dose (**6 to 11 years**) – 0.25mL / 50 micrograms **Primary** dose (**12 years and above**) – 0.5mL / 100 micrograms **Booster** dose (**18 years and above**) – 0.25mL / 50 micrograms	**Primary** and **booster** dose (**18 years and older**) – 0.5mL / 50 micrograms

Table 1. Dose types and dose volume for Moderna (SPIKEVAX) vaccines for different age groups.

Protection

Compared with the Moderna (SPIKEVAX) (red cap), the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine generates approximately a 1.6 to 1.9 times higher level of antibody response against the original virus as well as against multiple SARS-CoV-2 Omicron subvariants (ATAGI, 2022m; Moderna Australia, 2022).

Evidence supporting the use of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine is limited to immunogenicity and safety data from the Moderna P205 study 4 weeks after a second booster (fourth dose). Participants aged ≥18 years received Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine as their second booster dose, at least 3 months following a Moderna (SPIKEVAX) primary course (100mcg doses) and Moderna (SPIKEVAX) first booster dose (50mcg) (ATAGI, 2022m; Moderna Australia, 2022).

Safety, reactogenicity and immunogenicity data are available from an ongoing Phase 2/3 open-label study in participants 18 years of age and older (mRNA-1273-P205). In this study, 437 people received the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine and 377 people received the Moderna (SPIKEVAX) (red cap) vaccine as second boosters. There were modestly higher 216eutralizing antibody titres against the Omicron BA.1 variant with the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine, in people with no previous SARS-CoV-2 infection (1.7 times higher in the bivalent group than the original vaccine group [95% CI 1.5 – 2.0]). In people with prior infection, 216eutralizing titres against BA.1 were 1.9 times higher with the bivalent vaccine (95% CI 1.5 – 2.4) (ATAGI, 2022m; Moderna Australia, 2022).

Neutralising antibody titres against the original virus were similar following the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine compared with the Moderna (SPIKEVAX) (red cap) in both those with and without previous SARS-CoV-2 infection (1.3 times higher [95% CI 1.1 – 1.5] and 1.2 times higher [95%CI 1.1 – 1.4], respectively, in the bivalent group) (ATAGI, 2022m; Moderna Australia, 2022).

While the duration of protection is not known with the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine, there is the potential for increased duration of protection as shown by a previous investigational Moderna bivalent vaccine encoding the original virus and the Beta variant, used as a first booster, 6 or more months after a primary Moderna course. This vaccine continued to show higher neutralisation titres than the Moderna (SPIKEVAX) (red cap) vaccine against multiple variants including Omicron at 180 days after the booster dose. It is anticipated that the registered Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine may show a similar pattern (ATAGI, 2022m; Moderna Australia, 2022).

Early immunogenicity and safety data on bivalent vaccines used as primary vaccination are limited. The safety of bivalent vaccines is similar to monovalent original vaccines when used as a booster dose. ATAGI has no additional concerns regarding the safety or effectiveness of bivalent vaccines compared with monovalent vaccines when used for a primary course (ATAGI, 2023d).

While there are currently no efficacy or effectiveness studies of bivalent vaccines when used for the primary vaccination course, early effectiveness studies of bivalent vaccines used as a booster dose suggest equivalent or better protection than original vaccines. There is no reason to expect that using bivalent vaccines for a primary vaccination course would differ (ATAGI, 2023d).

Protection against different variants

- Evidence suggests the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine can provide cross-protection against variants and subvariants not included in the vaccine. Neutralisation titres against the BA.4 and BA.5 subvariants were 1.7 times (95% CI 1.5 – 1.9) higher with the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine compared with the Moderna (SPIKEVAX) (red cap) vaccine, although absolute neutralisation titres were lower than those seen against the BA.1 variant. Binding antibody levels against previous variants such as Alpha and Delta were also similar or slightly higher with the bivalent vaccine than the original vaccine (ATAGI, 2022m).

Topic 2: Cold chain and thawing

Ultra-cold chain (UCC) storage for frozen vials

Always store the vials in their original carton and packaging until ready to use to protect the vials from ultraviolet (UV) light and sunlight.

Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccines must be **stored frozen at -50°C to -15°C** for a maximum of **9 months**. **DO NOT** store below -50°C (Moderna Australia, 2022).

Cold chain storage for thawed vials – As per Additional Module 3

Thawing the vial (if required) – As per Additional Module 3

Punctured multidose vial – As per Additional Module 3

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.

Transportation of thawed vials

If the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine is unable to be transported at -50°C to -15°C, the thawed vials can be transported in a liquid state for up to 12 hours at +2°C to +8°C, that is within the 30 days shelf life at +2°C to +8°C.

Thawed Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccines require storage and transport within **+2°C to +8°C** as per the national *Strive for 5* guidelines, jurisdictional requirements and facility policies.

Vaccines **cannot** be refrozen once thawed.

Topic 3: Preparation and administration

Dose preparation – As per Additional Module 3.

Administration – As per Additional Module 3.

Dosing and schedule

For people aged 18 years and older, ATAGI recommends receiving either a BA.1-containing bivalent vaccine (e.g. Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label)) or a BA.4-5-containing bivalent vaccine **for both the primary course and booster doses**.

Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine is administered as an intramuscular (IM) injection containing 0.5mL vaccine. The Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine contains 50mcg of mRNA, comprising equal quantities encoding the spike protein from the original SARS-CoV-2 virus and Omicron BA.1 variant.

A total of two primary course doses are required for most people. The recommended interval between two doses of Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine is **8 weeks** (ATAGI, 2022f).

The extended dose interval of 8 weeks has been shown to improve the immune response to vaccination and therefore may improve effectiveness. A longer dose interval may also reduce the risk of myocarditis and pericarditis. The longer dose interval is particularly recommended for groups at higher risk of this side effect (those under the age of 40 years) (ATAGI, 2022f).

The dose interval can be reduced to a minimum of **4 weeks** for people at higher risk of severe COVID-19 (including older adults and people with underlying medical conditions), in an outbreak setting, or prior to international travel (ATAGI, 2022f).

Severely immunocompromised individuals

A third primary dose of COVID-19 vaccine is recommended for all people aged 6 months or older with severe immunocompromise who are receiving a 2-dose primary course. The third dose should be given from 2 months after the second vaccine dose. A minimum interval of 4 weeks may be considered in exceptional circumstances (e.g., anticipated intensification of immunosuppression; outbreaks). People who have received a second dose more than 6 months ago should receive a third dose as soon as feasible (ATAGI, 2021w).

The third dose is intended to address the risk of lowered response or non-response to the standard 2-dose schedule. For more details on vaccine effectiveness in people who are immunocompromised, see COVID-19 vaccine information.

Individuals who currently are not severely immunocompromised but who will commence significant immunosuppressive therapy 2 or more weeks after their second dose do not require a third dose, as it can be expected that an adequate response to 2 primary doses will be achieved (ATAGI, 2021w).

For a comprehensive list of immunocompromising conditions and therapies for which a third primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Booster dose recommendations

ATAGI **recommends** 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 (ATAGI, 2023a; ATAGI, 2023d):

- 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.

ATAGI advises the following groups should **consider** a 2023 booster dose 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 (ATAGI, 2023a; ATAGI, 2023d).

- 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.

ATAGI advises that a booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19.

Development of a seasonal immunisation policy to manage COVID-19 is limited, as the evolution, duration and strength of protection against serious SARS-CoV-2 illness are uncertain at this time (ATAGI, 2023a).

Booster doses are **not currently recommended** for children aged under 5 years, or for children and adolescents aged 5 to 17 years who are not at increased risk of severe disease as defined above. Severe COVID-19 in children is uncommon and the primary course of COVID-19 vaccines generates a strong immune response. The benefit from additional doses of vaccine is likely to be small. Current evidence does not suggest that booster doses are needed at this time (ATAGI, 2023a).

Booster dose: vaccine preference recommendations

Any age-appropriate COVID-19 vaccine, including original (ancestral virus-based) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer-lasting protection against severe disease.

However, bivalent mRNA vaccines are preferred over other vaccines for people aged 12 years and older. These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), for people from 12 years of age
- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS), for people from 12 years of age
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap), for people from 18 years of age
- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label), for people from 18 years of age

ATAGI **does not** currently recommend use of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine in anyone under 18 years as it is not registered for this age group (ATAGI, 2022m).

Refer to and download the COVID-19 Vaccines in Australia posters for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Topic 4: Precautions

ATAGI continues to monitor evidence on vaccine effectiveness, the epidemiology of SARS-CoV-2 including its seasonality and emerging subvariants, and on other candidate bivalent COVID-19 vaccines (including BA.4/BA.5 subvariant vaccines). ATAGI will add to its recommendation as further evidence on the bivalent vaccine(s) and knowledge about other uncertainties accumulates.

Vaccine administration errors (VAEs)

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training undertaken to minimise the risk of VAEs occurring (ATAGI, 2022a).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible VAEs, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022a). The Vaccine Operations Centre (VOC) on 1800 318 208 is available to provide advice to clinicians regarding VAEs.

Refer to ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors for further information.

Pre-screening – Pre-screening is covered in detail in Module 5, Topic 3. This topic reviews a few special population groups with manufacturer's recommendations on administering the Moderna (SPIKEVAX) vaccines to members of these groups.

Contraindications – As per Additional Module 3.

Precautions – The precautions relating to Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine are the same as the ones reviewed in Module 5, Topic 2. Please review these again as required.

Children and adolescents – The safety and efficacy of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine in children and adolescents aged less than 18 years of age have not been established (Moderna Australia, 2022). ATAGI **does not** currently recommend use of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine in anyone under 18 years as it is not registered for this age group (ATAGI, 2022m).

Immunocompromised individuals – As per Additional Module 3.

Myocarditis and Pericarditis – The risk of myocarditis or pericarditis, a very rare adverse effect following the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine has not yet been characterised, as this vaccine has not been used extensively in large populations. ATAGI states there is no reason to believe the safety of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine is any different to other Moderna (SPIKEVAX) mRNA vaccines (ATAGI, 2022m).

For more information, see Additional Module 3.

Past infection with SARS-CoV-2 – Past infection with SARS-CoV-2 is not a contraindication to vaccination. ATAGI recommends that vaccination should be deferred for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19 (ATAGI, 2023a).

For more information, see Additional Module 3.

Pregnancy, breastfeeding and fertility recommendations – As per Additional Module 3.

Coadministration of Moderna bivalent vaccine with other non-COVID vaccines is acceptable, as per current ATAGI Clinical recommendations for COVID-19 vaccines.

For more information, see Additional Module 3.

No interaction studies have been performed with Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine and other medications (Moderna Australia, 2022).

Topic 5: Adverse events

General adverse events have been discussed in Module 6, Topic 2. All adverse events following immunisation (AEFI) from the administration of Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green

label) vaccine must be reported. The batch number should also be included to monitor any potential issues with manufacturing, transport or storage (Moderna Australia, 2022).

Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side-effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website. For more information, please refer to Core Module 6.

The Consumer Medicine Information (CMI) can be given to people following their vaccination.

The P205 trial (bivalent original/Omicron BA.1) and bivalent original/Beta trial demonstrate that the safety profile of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine was similar to the first or second booster of the Moderna (SPIKEVAX) (red cap) vaccine, and to the second dose of the primary series of the original vaccine.

The most commonly reported local adverse reactions following a second booster dose of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine were:

- Injection site pain – 77% of individuals,
- Fatigue – 55% of individuals,
- Headache – 44% of individuals and
- Myalgia – 40% of individuals

(Moderna Australia, 2022)

Rare side-effects – As per Additional Module 3.

Consumer medicine information can be given to individuals receiving the vaccine which detail what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for your state or territory, please review this website.

Module Summary

- The Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine uses mRNA technology.
- The multidose vial (MDV) must be thawed before administration.
- Do **NOT** dilute the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine.
- Specialised UCC storage and transport is required if keeping the vial frozen, at -50°C to -15°C.
- ATAGI recommends that, when possible, pre-drawn doses kept at room temperature should be used within 1 hour to minimise any remote potential risk of infection.
- The Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine can be given to people 18 years and older for primary course and booster doses. A single dose contains **50 microgram/0.5mL.**
- ATAGI **does not** currently recommend use of the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine in anyone under 18 years as it is not registered for this age group.
- All adverse events must be reported as this is a novel vaccine.

- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

References:

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Multi-choice Questions:

1. Which of these statements about storage for the Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine is CORRECT?

    a. The thawed vials can be stored in cold chain storage (+2°C to +8°C) for a maximum of 3 months.
    b. Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vials must be **stored frozen at -50°C to -15°C** for a maximum of **9 months**.
    c. If vials are thawed, unopened and maintained at +2°C to +8°C they can be re-frozen if needed but only once.
    d. The thawed vials can be stored at room temperature for a maximum of 48 hours

2. The Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) is recommended for use as:

    a. Primary course and booster doses in people aged 18 years and older
    b. Primary course and booster doses in people aged 12 to 17 years
    c. Booster course doses for immunocompromised individuals 6 months and older
    d. Booster doses for people aged 12 to 17 years

3. How is the correct Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) multi-dose vial for individuals aged 18 years and older identified?

    a. 0.2mg/mL multi-dose vials WITH A RED cap, RED label
    b. 0.1mg/mL multi-dose vial WITH A BLUE cap, PURPLE label
    c. 0.2mg/mL multi-dose vials WITH A RED cap, GREEN label
    d. 0.1mg/mL multi-dose vial WITH A BLUE cap , GREEN label

4. The dose for Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label) vaccine, for people 18 years and over is:

    a. 0.5mL/50 micrograms given intramuscularly
    b. 0.25mL/50 micrograms given intramuscularly
    c. 0.5mL/50 micrograms given subcutaneously
    d. 0.25mL/50 micrograms given intradermally

Additional Module 3d: Moderna Bivalent (BA.4-5) 12 years+ Pre-Filled Syringe (PFS) Booster Vaccine (21/09/2023)

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 30 minutes. Each topic must be worked through in order and there are multiple-choice questions to pass before this module is complete.

Learning objectives

At the end of Additional Module 3d: Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine for individuals aged 12 years and older, it is expected that you will be able to:

- Understand the appropriate **dosing and schedule** for administration of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine for individuals aged 12 years and older.
- Understand the **contraindications, warnings, adverse reactions, and recommendations for co-administration** with other vaccines for the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine for individuals aged 12 years and older.
- Demonstrate appropriate **dose preparation** including verification before administration of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine for individuals aged 12 years and older.
- Understand the appropriate **administration** of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine for individuals aged 12 years and older.

Topics

1. Introduction and summary
2. Cold chain and thawing
3. Preparation and administration
4. Precautions
5. Adverse events

Topic 1: Introduction and summary

The SPIKEVAX BIVALENT Original/Omicron BA.4-5 (Elasomeran/Davesomeran) COVID-19 Vaccine pre-filled syringe (PFS) is also known as the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine (the term which will be used in this module).

On 17 February 2023, the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine was provisionally approved by the TGA for individuals aged 12 years and older (TGA, 2023b).

This vaccine uses similar technology to induce immunity, similar to the other Moderna (SPIKEVAX) vaccines and the Pfizer (COMIRNATY) vaccines.

The Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine contains 50mcg of mRNA, comprising equal quantities encoding the spike protein from the original SARS-CoV-2 virus and from the Omicron BA.4-5 variant (i.e., one dose of 0.5mL contains 25 micrograms of elasomeran and 25 micrograms of davesomeran).

Further information can be found on the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine Product Information and the Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance for COVID-19 vaccine providers. The Consumer Medicine Information (CMI) can also be given to individuals receiving the vaccine.

For people aged 12 years or older, ATAGI advises a bivalent mRNA vaccine (e.g. Moderna bivalent BA.4-5 (SPIKEVAX) (PFS)) is preferred over original (ancestral) vaccines **for both primary course and booster doses (ATAGI, 2023d).**

Bivalent vaccines are designed to broaden cross-protection from vaccination against Omicron and its subvariants by including an Omicron strain in the vaccine. Circulating strains since 2022 have all evolved as subvariants from the first Omicron variant. Pre-Omicron variants no longer circulate, and reversion to a pre-Omicron variant by a future strain is considered unlikely.

ATAGI, therefore, considers the bivalent vaccines (which protect against either Omicron subvariants BA.1 or BA.4-5) preferable for use in a primary course. ATAGI notes that use of bivalent vaccines for primary vaccination is consistent with evolving advice from the World Health Organization's Strategic Advisory Group of Experts on Immunization (SAGE) and the European Medicines Agency's Emergency Task Force, and that off-label use has been permitted in the United Kingdom.

The safety of bivalent vaccines is similar to monovalent original vaccines when used as a booster dose. ATAGI has no additional concerns regarding the safety or effectiveness of bivalent vaccines compared with monovalent vaccines when used for a primary course.

The ATAGI COVID-19 2023 Booster Advice provides guidance on which individuals are recommended, or can consider, a COVID-19 vaccine booster dose for additional protection against severe COVID-19.

Booster doses of the COVID-19 vaccine should be given at least 6 months after the most recent COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (whichever is the most recent) (ATAGI 2022o; ATAGI, 2023a).

ATAGI **does not** currently recommend use of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) as a vaccine in anyone under 12 years as it is not registered for this age group (ATAGI, 2023c).

Figure 1. Example of Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) *vaccine outer packaging.*

Please be aware, Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine packaging is significantly larger than multi-dose vials and will take up much more space in your vaccine fridge. Please keep this in mind when ordering vaccines.

Figure 2. Example of Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) *vaccine pre-filled syringe*

The Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine is presented as a 0.5mL **pre-filled** syringe. Each carton contains 10 pre-filled syringes packaged in 5 clear blisters (each blister containing 2 pre-filled syringes) (TGA, 2023b).

The 0.5mL white to off-white suspension comes in a pre-filled polymeric syringe with bromobutyl rubber coated plunger stopper and a bromobutyl rubber tip cap, without a needle (TGA, 2023b).

Protection

Safety, reactogenicity and immunogenicity data are available from an ongoing Phase 2/3 open-label study in participants 18 years of age and older (mRNA-1273-P205). In this study, 511 people received the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine and 376 people received the Moderna (SPIKEVAX) (red cap) original 50 microgram vaccine as a booster dose.

The Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine obtained superior 226eutralizing antibody responses against Omicron BA.4-5, compared with the Moderna (SPIKEVAX) (red cap) vaccine. In this study, the primary immunogenicity analysis was based on the primary immunogenicity set which includes participants with no evidence of SARS-CoV-2 infection at baseline (pre-booster) (TGA, 2023b).

Early immunogenicity and safety data on bivalent vaccines used as primary vaccination are limited. The safety of bivalent vaccines is similar to monovalent original vaccines when used as a booster dose. ATAGI has no additional concerns regarding the safety or effectiveness of bivalent vaccines compared with monovalent vaccines when used for a primary course (ATAGI, 2023d).

While there are currently no efficacy or effectiveness studies of bivalent vaccines when used for the primary vaccination course, early effectiveness studies of bivalent vaccines used as a booster dose suggest equivalent or better protection than original vaccines. There is no reason to expect that using bivalent vaccines for a primary vaccination course would differ (ATAGI, 2023d).

Topic 2: Cold chain and thawing

Ultra-cold chain (UCC) storage for frozen pre-filled syringes

Always store the pre-filled syringes in their original carton and packaging until ready to use, to protect the syringes from ultraviolet (UV) light and sunlight.

Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine may be **stored frozen at -50°C to -15°C** for a maximum of **9 months**. **DO NOT** store below -50°C (TGA, 2023b).

Cold chain storage for thawed pre-filled syringes

Thawed Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) requires storage and transport using standard cold chain requirements at **+2°C to +8°C** as per the national *Strive for 5* guidelines, jurisdictional requirements and facility policies.

Once thawed and transported in **liquid state at +2°C to +8°C**, **pre-filled syringes should not be refrozen** and should be **stored at +2°C to +8°C** until use (TGA, 2023b).

Unopened, thawed pre-filled syringes can be stored **refrigerated at +2°C to +8°C** for a maximum of **30 days from the thawed date (within the 9-month shelf life)**. The thawed date and thaw use-by date will be clearly displayed on the carton (secondary packaging).

Unopened, thawed pre-filled syringes may be stored at +8°C to +25°C up to 24 hours after removal from refrigerated conditions.

Always store the pre-filled syringes in their original carton and packaging until ready to use to protect the syringes from ultraviolet (UV) light and sunlight.

Delivery acceptance

Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine may arrive thawed by logistic providers.

The person responsible for accepting vaccine deliveries must have cold chain training and awareness. All deliveries received at a facility will be accompanied by a cold chain monitor which monitors temperature during transit and detects temperature excursions.

Deliveries must be checked and stored promptly without delay. Instructions for unpacking the vaccines are provided by the logistics provider depending on the delivery mode being used.

All deliveries must be signed for by the authorised person.

Delivery acceptance reporting must be completed at every site and completed by the authorised person in charge of accepting deliveries of the vaccine. 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.

Stock management reports can be completed by relevant personnel within the administration site who has access to the COVID-19 Vaccine Administrative System (CVAS) for that account.

All providers should submit ordering and stock management through the CVAS at health.gov.au/cvas.

- Delivery Acceptance reports must be completed on the day of delivery (as soon as possible).

- Stock Management reports must be submitted no later than 9pm (local time) Friday every week (if your site is unable to submit the report on or before Friday, please submit the report as soon as possible and contact the Vaccine Operations Centre (VOC) on 1800 318 208 to have your report backdated).
- Orders must be placed by 11:59pm (AEST) Friday for delivery the following fortnight (note that new orders can only be placed if the previous week's stock management report and any outstanding delivery acceptances have been completed).

Providers must record and check the manufacturer expiry date and the thaw use-by date at the time of completing the Delivery Acceptance forms in the CVAS at health.gov.au/cvas.

Thawed Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) deliveries

Thawed Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccines requires storage and transport using standard cold chain requirements at **+2°C to +8°C** as per the national *Strive for 5* guidelines, jurisdictional requirements, and facility policies. **Pre-filled syringes cannot be refrozen once thawed**.

Once received and the vaccine delivery accepted, transfer the pre-filled syringes in their original packaging into cold chain storage. **Unopened, thawed pre-filled syringes** can be stored at **+2°C to +8°C** for a **maximum of 30 days** from the thawed date. The thawed date will be clearly displayed on the carton (secondary packaging).

As with all COVID-19 vaccines, Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine should be stored in the original carton until use to protect it from ultraviolet light and sunlight. Care needs to be taken to avoid all unnecessary exposure to light until the vaccines are ready to be administered. Thawed pre-filled syringes can be handled in room light conditions (TGA, 2023b).

The fridge temperature where the pre-filled syringes are stored must be recorded and continually monitored. Rotate stock so that the newest stock is placed at the back and stock with the earliest expiry dates are in front.

Thawing the pre-filled syringe (if required)

Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) needs to be thawed before use. Pre-filled 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.

Table 1: Thawing instructions for Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) *and cartons before use*

Configuration	Thaw instructions and duration			
	Thaw Temperature (in a refrigerator)	Thaw Duration (minutes)	Thaw Temperature (at room temperature)	Thaw Duration (minutes)
Pre-filled syringe in blister pack	+2°C – +8°C	55	+15°C – +25°C	45
Carton	+2°C – +8°C	155	+15°C – +25°C	140

An **unopened thawed pre-filled syringe** can be maintained through normal cold chain practices **(+2°C to +8°C)** for a **maximum of 30 days** within the **9-month shelf life**. The 30-day timeframe includes any time spent thawed or thawing in transportation and at room temperature.

Unopened, thawed pre-filled syringes may be stored at +8°C to +25°C up to 24 hours after removal from refrigerated conditions.

Once thawed, Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) **CANNOT** be re-frozen (TGA, 2023b).

Topic 3: Preparation and administration

Dose preparation

Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) is for **single use only**. One dose (0.5mL) contains 25 micrograms of elasomeran and 25 micrograms of davesomeran.

DO NOT use the pre-filled syringe to deliver a partial 0.25mL volume. The full 0.5mL volume must be administered.

DO NOT shake or dilute.

Expiry dates must be followed precisely to prevent expired stock from being administered. There are two expiry dates that must be observed on Moderna bivalent BA.4-5 (SPIKEVAX) (PFS): the **manufacturer expiry date** and the **thaw use-by date**. Both must be checked prior to every vaccine administration.

The manufacturer expiry date indicates the expiry for the vaccine when stored frozen. The thaw use-by date commences at the time the pre-filled syringes are removed from the freezer to commence thawing. The thawed date and thawed use-by date will be clearly displayed on the carton (secondary packaging).

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

To prevent administration errors, all sites should clearly label the thawed use by 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 (VAEs). If vaccines are administered outside of either expiry date, it is considered a VAE. The Vaccine Operations Centre (VOC) on **1800 318 208** is available to provide advice and guidance to clinicians regarding the management of VAEs. Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information (ATAGI, 2022a).

If you suspect your vaccines may have been involved in a cold chain breach (CCB), either within the clinical setting or during transit:

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 Vaccine Operations Centre (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.

A quick reference poster guide can be used for CCB management including reporting. There is no poster as yet for UCC breaches. Please note the requirement to contact the VOC in the event of a cold chain breach is specific to COVID-19 vaccines, and not stated in the National Vaccine Storage Guidelines.

Please see Appendix 5 for the steps to be followed if a potential CCB occurs.

Ensure that the pre-filled syringes have not expired by checking the use-by date on the secondary packaging (carton) of the pre-filled syringes.

The thawed vaccine will be a white to off-white suspension and may contain white or translucent product-related particulates. Visually inspect the pre-filled syringe for particulate matter and/or discolouration. If either of these conditions exists or you are concerned, call the Vaccine Operations Centre (VOC) on **1800 318 208**.

Administration

The vaccine should be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm. **DO NOT** inject intravenously, subcutaneously or intradermally (TGA, 2023b).

DO NOT mix or contaminate the vaccine with any other medication or liquid (TGA, 2023b).

ATAGI is aware of scientific reports proposing that inadvertent injection of a COVID-19 vaccine into a blood vessel may be a contributing cause of serious adverse events following immunisation, such as myocarditis. ATAGI has reviewed the available evidence and considers injection technique highly unlikely to be a contributor to these adverse events, for several reasons:

- The majority of myocarditis cases occur after the second dose of the mRNA vaccines. If intravascular injection was an important contributor, there would not be this differential distribution of cases by vaccine dose.
- Direct injection into a blood vessel is unlikely in recommended injection sites.

(DHAC, 2021l)

Based on a review of the available evidence, ATAGI does not recommend routinely aspirating (drawing back) needles before injection. This practice was rejected some decades ago, due to several disadvantages including prolonging the procedure, potentially associated pain and increasing the risk of needle-syringe disconnection. Not aspirating is supported by the current advice in the Australian Immunisation Handbook (ATAGI, 2022q).

ATAGI will continue to review emerging evidence on the underlying mechanisms, prevention and treatment of TTS, myocarditis and other serious adverse events of special interest.

All sharps with syringes still attached (after administration) should be discarded in a sharps waste container.

If required refer to the *COVID-19 – ATAGI information for providers: COVID-19 Vaccination Consent & FAQs* and Information on COVID-19 Moderna (SPIKEVAX) vaccine

After administration, the vaccine dose administered including batch number must be entered into the Australian Immunisation Register (AIR) as described in Module 5, Topic 4. **Administrators are advised to take particular care to record the vaccine dose against the correct vaccine type in the AIR**.

Administration of vaccines under sedation

Procedural guidelines for administration of vaccines under sedation in practice have been developed or are currently being developed in some health services. ATAGI advises that detailed clinical guidance should be developed collaboratively with input from anaesthetic groups, jurisdictional health services and relevant specialists (ATAGI, 2022g).

More information can be found in the ATAGI advice on use of sedation for COVID-19 vaccination.

See Appendix 3 for the Vaccine preparation and Vaccine administration checklist.

Dosing and schedule of doses

For people aged 12 years or older, a bivalent mRNA vaccine i.e. Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine is preferred for primary vaccination.

Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine is administered as an intramuscular (IM) injection containing 0.5mL vaccine. The Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) contains 50 micrograms of mRNA (25 micrograms of elasomeran and 25 micrograms of davesomeran).

A total of two primary course doses are required for most people. The recommended interval between two doses of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine is **8 weeks** (ATAGI, 2022f).

The extended dose interval of 8 weeks has been shown to improve the immune response to vaccination and therefore may improve effectiveness. A longer dose interval may also reduce the risk of myocarditis and pericarditis. The longer dose interval is particularly recommended for groups at higher risk of this side effect (those under the age of 40 years) (ATAGI, 2022f).

The dose interval can be reduced to a minimum of **4 weeks** for people at higher risk of severe COVID-19 (including older adults and people with underlying medical conditions), in an outbreak setting, or prior to international travel (ATAGI, 2022f).

Severely immunocompromised individuals

A third primary dose of COVID-19 vaccine is recommended for all people aged 6 months or older with severe immunocompromise who are receiving a 2-dose primary course. The third dose should be given from 2 months after the second vaccine dose. A minimum interval of 4 weeks may be considered in exceptional circumstances (e.g., anticipated intensification of immunosuppression; outbreaks). People who have received a second dose more than 6 months ago should receive a third dose as soon as feasible (ATAGI, 2021w).

The third dose is intended to address the risk of lowered response or non-response to the standard 2-dose schedule. For more details on vaccine effectiveness in people who are immunocompromised, see COVID-19 vaccine information.

Individuals who currently are not severely immunocompromised but who will commence significant immunosuppressive therapy 2 or more weeks after their second dose do not require a third dose, as it can be expected that an adequate response to 2 primary doses will be achieved (ATAGI, 2021w).

For a comprehensive list of immunocompromising conditions and therapies for which a third primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Booster dose recommendations

ATAGI **recommends** 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 (ATAGI, 2023a; ATAGI, 2023d):

- 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.

ATAGI advises the following groups should **consider** a 2023 booster dose 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 (ATAGI, 2023a; ATAGI, 2023d).

- 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.

Development of seasonal immunisation policy to manage COVID-19 is limited, as the evolution as well as duration and strength of protection against serious SARS-CoV-2 illness are uncertain at this time (ATAGI, 2023a).

Booster doses are **not currently recommended** for children aged under 5 years, or for children and adolescents aged 5 to 17 years who are not at increased risk of severe disease as defined above. Severe COVID-19 in children is uncommon and the primary course of COVID-19 vaccines generates a strong immune response. The benefit from additional doses of vaccine is likely to be small. Current evidence does not suggest that booster doses are needed at this time.

Booster dose: vaccine preference recommendations

Any age-appropriate COVID-19 vaccine, including original (ancestral virus-based) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer lasting protection against severe disease.

However, bivalent mRNA vaccines are preferred over other vaccines for people aged 12 years and older. These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), for people aged 12 years and over.
- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS), for people aged 12 years and over.
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap), for people aged 18 years and over.
- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label), for people aged 18 years and over.

ATAGI **does not** currently recommend use of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine in anyone under 12 years as it is not registered for this age group.

Refer to and download the COVID-19 Vaccines in Australia posters for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Disposal and wastage

In cases of wastage, any unused vaccine or waste material should be disposed of in accordance with local requirements in a clinical waste bin and should be recorded through the COVID-19 Vaccine Administrative System (CVAS) in line with wastage thresholds.

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.

Surfaces with any spillages of the pre-filled syringe contents should be cleaned up immediately using an agent to inactivate the spill (e.g. Ethanol [EtOH]). Health professionals should follow normal

procedures for infection control. Spills of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccines are low-risk.

If 100 or more pre-filled syringes are wasted, providers must submit a Wastage Report through the COVID-19 Vaccine Administrative System (CVAS) immediately after the event, but within at least 2 hours of the incident. You are no longer required to call the VOC to additionally report the wastage incident.

Incidents of fewer than 100 pre-filled syringes at a time must be reported as minor wastage in the weekly Stock Management Report in CVAS (due no later than 9pm local time Friday every week).

Topic 4: Precautions

Vaccine administration errors (VAEs)

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training undertaken to minimise the risk of VAEs occurring (ATAGI, 2022a).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible VAEs, including when a replacement dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022a). The Vaccine Operations Centre (VOC) on **1800 318 208** is available to provide advice to clinicians regarding VAEs.

Please see Appendix 4 for the steps to be followed if a vaccine administration error occurs.

Pre-screening – A pre-screening checklist is required to check for any contraindications or circumstances for which precaution is required before administration. Pre-screening is covered in detail in Module 5 Topic 3. This topic reviews a few special population groups with manufacturer's recommendations on administering the Moderna (SPIKEVAX) vaccines to members of these groups.

Contraindications – Contraindications include anaphylaxis or a severe hypersensitivity reaction to a previous dose of an mRNA COVID-19 vaccine or anaphylaxis to any of its contained components as listed in the Product Information (Moderna Australia, 2021).

For information on allergies and precautions with people who may have allergies please refer to the Australasian Society of Clinical Immunology and Allergy (ASCIA), *Allergy, Immunodeficiency, Autoimmunity and COVID-19 Vaccination Position Statement* and the *ATAGI clinical guidance for COVID-19 vaccine providers*.

Precautions – The precautions relating to Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine are the same as the ones reviewed in Module 5, Topic 2. Please review these again as required.

Children and adolescents – The safety and efficacy of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine in children and adolescents aged less than 12 years of age have not been established (TGA, 2023b). ATAGI **does not** currently recommend use of Bivalent BA.4-5 vaccine as a booster in anyone under 12 years as it is not registered for this age group (ATAGI, 2023a).

Immunocompromised individuals – ATAGI highly recommend that these individuals receive the vaccine as normal as there are no specific safety concerns with receiving the vaccine (ATAGI, 2021b). For more information, review ATAGI's COVID-19 vaccination - Shared decision making guide for people with immunocompromise.

Ideally, vaccination should occur on a different day to regular infusion treatments, such as immunoglobulin replacement therapy or immunosuppressant infusions (Australasian Society of Clinical Immunology and Allergy [ASCIA], 2021).

ATAGI advises 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 should **consider** a 2023 booster dose 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 (ATAGI, 2023a).

A booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19 (ATAGI, 2023a).

Myocarditis and Pericarditis – The risk of myocarditis or pericarditis, a very rare adverse effect following the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine has not yet been characterised, as this vaccine has not been used extensively in large populations. ATAGI states there is no reason to believe the safety of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine is any different to other Moderna (SPIKEVAX) mRNA vaccines.

The mRNA vaccines have been safely given to hundreds of millions of people around the world. These mRNA COVID-19 vaccines have a very rare risk of heart inflammation (myocarditis, pericarditis or combined, myopericarditis). This is more commonly seen in males aged under 30 years after the second dose.

In some countries, myocarditis and pericarditis have been reported more commonly after Moderna (SPIKEVAX) (red cap) than after Pfizer (COMIRNATY) (purple cap) vaccines. Most people who have had these conditions after their vaccine have recovered fully.

ATAGI states that the benefits of vaccination outweigh this very rare risk and vaccination is still recommended for all eligible age groups. For current information on the frequency and severity of myocarditis and pericarditis following Moderna (SPIKEVAX) and Pfizer (COMIRNATY) vaccines, please refer to the COVID-19 vaccine weekly safety report, published by the Therapeutic Goods Administration (TGA).

Symptoms typically appear within 1-5 days of vaccination and include chest pain, palpitations (irregular heartbeat), syncope (fainting) or shortness of breath. People who experience any of these symptoms after having an mRNA COVID-19 vaccine should seek prompt medical attention (ATAGI & CSANZ, 2021).

The highest reporting rates of myopericarditis were following the second dose of Pfizer (COMIRNATY) (purple cap) in males 16-17 years old with 71.5 cases per million doses administered, followed by males aged 12-15 with 42.6 cases per million. In males aged 18-24 the reporting rate was 37.7 per million following the second dose of the previously supplied Moderna (SPIKEVAX) (red cap) (ATAGI, 2021b).

Most pre-existing cardiac conditions are **NOT** regarded as contraindications to vaccination. People with a history of any of the following conditions **CAN** receive an mRNA vaccine but should consult a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- Recent (i.e. in the past 3 months) or current inflammatory cardiac illness e.g. myocarditis, pericarditis or endocarditis
- Complex or severe congenital heart disease including single ventricle (Fontan) circulation.
- Acute decompensated heart failure.

(ATAGI & CSANZ, 2021; ATAGI, 2021b)

Moderna (SPIKEVAX) vaccines are recommended for people with a history of most chronic cardiovascular conditions and **CAN** be given to people in the following groups **without any specific precautions**:

- Prior myocarditis, pericarditis or endocarditis (i.e. 3 months or more prior to vaccination).
- Coronary artery disease.
- Myocardial infarction.
- Stable heart failure.
- Arrhythmias.
- Prior history of rheumatic heart disease (RHD).
- Kawasaki disease.
- Congenital heart disease.
- Cardiomyopathy.
- Cardiac transplant.
- People with implantable cardiac devices.

(ATAGI & CSANZ, 2021; ATAGI, 2021b).

People with a history of myocarditis, pericarditis or endocarditis more than 3 months ago can be vaccinated with Moderna (SPIKEVAX) vaccines without any additional precautions (ATAGI & CSANZ, 2021). People who develop myocarditis or pericarditis attributed to their first dose of Moderna (SPIKEVAX) vaccine are advised to defer further doses of an mRNA COVID-19 vaccine and to discuss this with their treating doctor (ATAGI & CSANZ, 2021).

For more information, please review COVID-19 vaccines and cardiac inflammation information on the Department of Health and Aged Care's website.

Past infection with SARS-CoV-2 – Past infection with SARS-CoV-2 is not a contraindication to vaccination. ATAGI recommends that vaccination should be deferred for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19 (ATAGI, 2023a). People who have received an anti-SARS-CoV-2 monoclonal antibody or convalescent plasma should defer future doses of COVID-19 vaccine for **at least 90 days** (ATAGI, 2021b).

Waiting for a 6-month period after infection before COVID-19 vaccination is intended to optimise protection for that person. A longer gap between infection and vaccination is likely to lead to a better immune response and result in longer protection from reinfection (ATAGI, 2022f).

Infection with certain SARS-CoV-2 variants has previously been shown to reduce the risk of reinfection with a variant other than Omicron for at least 6 months. However, recent evidence shows that people with prior infection with a variant other than Omicron are likely to be reinfected with the SARS-CoV-2 Omicron variant more often than with other variants, such as Delta.

The risk of reinfection with Omicron after an Omicron infection is not yet known, but it is likely the reinfection rates will be lower in this context for a period of time, as compared with prior infection with a variant other than Omicron.

Testing using polymerase chain reaction (PCR) or rapid antigen testing (RAT) to detect current or past infection with SARS-CoV-2 before vaccination is neither necessary nor recommended.

Individuals who have prolonged symptoms from COVID-19 beyond four months can be vaccinated on a case-by-case basis (ATAGI, 2021b).

Pregnancy, breastfeeding and fertility recommendations

Pregnancy – mRNA vaccines are the recommended COVID-19 vaccines for pregnant women. This is based on the growing body of evidence supporting the safety of mRNA vaccines in pregnancy, whereas there are still very limited data on the safety of the other available COVID-19 vaccine Novavax (NUVAXOVID) in pregnancy. However, people who cannot access an mRNA vaccine can consider vaccination with Novavax (NUVAXOVID) if the benefits to the individual outweigh the potential risks.

Pregnant women are recommended to receive a primary course of COVID-19 vaccine. mRNA vaccines are the recommended vaccines for a primary course in pregnant women.

Pregnant women who have already received a primary course should discuss with their immunisation provider whether a booster dose is required during their pregnancy. Pregnancy is not currently considered a risk factor for severe illness in a woman who has already completed a primary course and booster and who does not have any medical risk conditions. There were no vaccine-related adverse events during pregnancy or postnatal development in animal testing completed for the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine (TGA, 2023b).

Pregnant women with COVID-19 have a higher rate of hospitalisation, intensive care unit admission and mechanical ventilation, but not death, than age-matched non-pregnant women. The risk of preterm delivery is also increased. There is no evidence to suggest that SARS-CoV-2 infection in pregnancy increases the risk for congenital anomalies (ATAGI, 2021b).

Over time, 'real-world' evidence from other countries has accumulated and reports show that mRNA COVID-19 vaccines, are safe to use in pregnant women. Emerging research also demonstrates that pregnant women have a similar immune response to mRNA vaccines to non-pregnant women and are therefore likely to have similar protection against COVID-19. Furthermore, research shows that the antibodies produced by vaccination cross the placenta and may provide some protection to newborn babies (ATAGI, 2021b).

Within animal testing, COVID-19 antibodies produced in response to the Moderna (SPIKEVAX) (red cap) vaccine were present in the foetus and newborn (Moderna Australia, 2021).

Breastfeeding - It is not known if Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) is excreted in human breast milk. Women do not need to stop breastfeeding before or after vaccination (TGA, 2023b).

Fertility - Getting vaccinated before conceiving can provide protection for women against COVID-19 throughout their pregnancy. Vaccination does not affect fertility. Women are not required to have a pregnancy test before getting vaccinated (ATAGI, 2021b).

Animal studies do not indicate any direct or indirect harmful effects regarding fertility in females. The effect on male fertility has not been determined (TGA, 2023b).

Further information is available in the *Shared decision making guide for women who are pregnant, breastfeeding, or planning pregnancy* (ATAGI, 2021b).

Co-administration

COVID-19 vaccines can be co-administered (i.e., on the same day) with an influenza vaccine. COVID-19 vaccines can also be co-administered with other vaccines if required. However, given the current limited evidence on the concomitant use of COVID-19 vaccines with other vaccines, providers need to balance the opportunistic need for co-administration with giving the vaccines on separate visits. There is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time. Co-administration or near administration (e.g. within days) with another vaccine may also make the attribution of potential adverse events more challenging (ATAGI, 2021b).

Data on the potential for co-administration with other vaccines is currently being reviewed and detailed information on this will be included in the ATAGI Clinical Guidance for COVID-19 vaccine providers (ATAGI, 2021b).

No interaction studies have been performed with Moderna (SPIKEVAX) vaccines and other medications (TGA, 2023b).

Topic 5: Adverse events

General adverse events have been discussed in Module 6, Topic 2. All adverse events following immunisation (AEFI) from the administration of Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine must be reported. The batch number should also be included to monitor any potential issues with manufacturing, transport or storage (TGA, 2023b).

Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side-effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website. For more information, please refer to Core Module 6.

The consumer resource, Consumer medicine information can be given to people following their vaccination.

The P205 trial (bivalent original/Omicron BA.4-5) and bivalent original/Beta trial demonstrate that the safety profile of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine was similar to the first or second booster of the Moderna (SPIKEVAX) (red cap) vaccine, and to the second dose of the primary series of the Pfizer (COMIRNATY) (purple cap) vaccine.

Rare side-effects

Myocarditis and pericarditis – A risk of myocarditis and pericarditis has been observed in people who have received mRNA COVID-19 vaccines in overseas studies, particularly in males under 30 years of age after the second vaccine dose. Most myocarditis and pericarditis cases linked to mRNA vaccination have been mild and patients have recovered quickly. Longer-term follow-up of these cases is ongoing (ATAGI & CSANZ, 2021).

Symptoms typically appear within 1-5 days of vaccination and include: chest pain, palpitations (irregular heartbeat), syncope (fainting) or shortness of breath. People who experience any of these symptoms after having an mRNA COVID-19 vaccine should seek prompt medical attention.

Initial investigations for people presenting with symptoms or signs of myocarditis or pericarditis should include ECG, troponin testing, chest X-ray, and other investigations for other differential diagnoses as clinically indicated (ATAGI & CSANZ, 2021).

Thrombosis with thrombocytopenia syndrome (TTS) - There were no notable patterns or numerical imbalances between treatment groups and placebo groups regarding thrombotic events and administration of the Moderna (SPIKEVAX) vaccines. Moderna (SPIKEVAX) vaccines are not associated with a risk of thrombosis with thrombocytopenia (TTS) (ATAGI, 2021b).

Anaphylaxis and hypersensitivities – Anaphylaxis and hypersensitivities can occur after administering any medicine. As with all vaccines, immunisation providers must be prepared to respond to an individual developing anaphylaxis. Follow all management steps outlined in Module 6 – Safety, surveillance and reporting for adverse events following COVID-19 vaccination, Topic 3 – Managing AEFIs.

Bell's Palsy – Bell's Palsy (acute peripheral facial paralysis) has been reported in a few people post vaccination with Moderna (SPIKEVAX) vaccine administration. However, there is currently no available information to determine whether or not there is a causal relationship between these events and vaccination (Moderna Australia, 2021).

Ability to use machinery - Moderna (SPIKEVAX) vaccine have no or limited effects on the ability to use machines and drive. However, if experienced, some of the AEFI may temporarily affect an individual's ability to drive or use machines (Moderna Australia, 2021).

The documents Consumer medicine information and the COVID-19 vaccination – Patient resources can be given to individuals receiving the vaccine which detail what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for your state or territory, please review this website.

Module Summary

- The Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine uses mRNA technology.
- The pre-filled syringes must be thawed before administration.
- **DO NOT** shake or dilute.
- The Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) can be given to people 12 years and older for primary course and booster doses. A single dose is **0.5mL** and contains 50 micrograms of mRNA.
- **DO NOT** use the pre-filled syringe to deliver a partial 0.25mL volume.
- Frozen storage and transport are required if keeping the pre-filled syringes frozen, at -50°C to -15°C.
- **Unopened, thawed pre-filled syringes** can be stored **refrigerated at +2°C to +8°C** for a maximum of **30 days from the thawed date (within the 9-month shelf life)**.
- ATAGI **does not** currently recommend use of Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine in anyone under 12 years as it is not registered for this age group.
- All adverse events must be reported as this is a novel vaccine.

- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

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Multi-choice Questions:

1. Which of these statements about storage for Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine is **CORRECT**?

    a. The thawed pre-filled syringes can be stored in cold chain storage (+2°C to +8°C) for a maximum of 3 months.
    b. Once thawed, pre-filled syringes may be stored refrigerated at +2°C to +8°C for a maximum of 30 days.
    c. If pre-filled syringes are thawed, unopened and maintained at +2°C to +8°C they can be re-frozen if needed but only once.
    d. The thawed pre-filled syringes can be stored at room temperature for a maximum of 48 hours.

2. The Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) is recommended for use as:

    a. Primary course and booster doses in people aged 12 years and older
    b. Primary course and booster doses in people aged 5 to 11 years old
    c. Booster doses for immunocompromised individuals 6 months and older
    d. Booster doses for people aged 5 to 11 years old

3. The dose for Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine, for people 12 years and over is:

    a. 0.5mL/50 micrograms given intramuscularly
    b. 0.25mL/50 micrograms given intramuscularly
    c. 0.5mL/50 micrograms given subcutaneously
    d. 0.25mL/50 micrograms given intradermally

4. Which of these statements about dose and preparation of the Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine is **INCORRECT**?

    a. Moderna bivalent BA.4-5 (SPIKEVAX) pre-filled syringes (PFS) are for **single use only**.
    b. Pre-filled syringes can be used to deliver a partial 0.25mL volume if measured correctly.
    c. **DO NOT** shake or dilute the pre-filled syringe.
    d. Any residue remaining in the pre-filled syringe after administration needs to be discarded.

Additional Module 4: Pfizer (COMIRNATY) (orange cap) COVID-19 Vaccine

(21/09/2023)

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 30 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete.

Learning objectives

At the end of Additional Module 4: Pfizer (COMIRNATY) (orange cap) vaccine, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of Pfizer (COMIRNATY) (orange cap) vaccine.
- Understand the contraindications, warnings, adverse reactions, and co-administration of Pfizer (COMIRNATY) (orange cap) vaccine with other vaccines.
- Demonstrate appropriate storage and handling of the Pfizer (COMIRNATY) (orange cap) vaccine, including handling of vaccines before the time of use, thawing, dilution and storage following dilution.
- Demonstrate appropriate dose preparation including dilution and verification before administration of the Pfizer (COMIRNATY) (orange cap) vaccine.
- Understand the appropriate administration of the Pfizer (COMIRNATY) (orange cap) vaccine.

Topics

1. Introduction and summary
2. Cold chain and thawing
3. Preparation and administration
4. Precautions
5. Adverse events

Topic 1: Introduction and summary

The Pfizer (COMIRNATY) (orange cap) vaccine was provisionally approved by the Therapeutic Goods Administration (TGA) for children aged 5 to <12 years old on 5 December 2021 (TGA, 2021d). This approval is based on the results of a recent clinical trial demonstrating that the vaccine is highly effective and that most side effects are mild and transient. The vaccine is the first COVID-19 vaccine registered for use in children under the age of 12 in Australia (ATAGI, 2021y).

Children who turn 12 after their first dose should complete their primary vaccine course with a BA.4-5-containing bivalent vaccine i.e. Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) or Moderna bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine (ATAGI, 2023d). The recommended interval is 8 weeks.

The Pfizer (COMIRNATY) (orange cap) vaccine is the only COVID-19 vaccine available for children aged 5-11 years. The previously supplied Moderna (SPIEKVAX) (red cap) vaccine was an alternative option for children aged 6-11 years.

COVID-19 vaccines have been approved for people aged 16 years and over for use in Australia since 25 January 2021. On 29 September 2022, the TGA provisionally approved the Pfizer (COMIRNATY) (orange cap) vaccine as a booster dose for children aged 5 to 11 years old (TGA, 2021d).

The **Pfizer (COMIRNATY) (orange cap)** vaccine uses the same mRNA vaccine technology as the other Pfizer (COMIRNATY) vaccines.

It is crucial to note the Pfizer (COMIRNATY) (orange cap) vaccine is a different formulation and has a different recommended use, storage, handling and preparation processes to the Pfizer (COMIRNATY) (maroon cap) and Pfizer (COMIRNATY) (purple cap) vaccines.

The Pfizer (COMIRNATY) (maroon cap) CANNOT be used in individuals 5 years of age and older (TGA, 2022e).

The Pfizer (COMIRNATY) (orange cap) CANNOT be used in individuals 12 years of age and older (TGA, 2022e).

The Pfizer (COMIRNATY) (purple cap) vaccine CANNOT be administered to individuals under the age of 12.

Messenger ribonucleic acid or mRNA is a genetic code (instruction) used by all living cells to produce proteins. The active ingredient in this vaccine is a single-stranded, 5'-capped messenger non-replicating mRNA molecule (Tozinameran). It was created through transcription from the corresponding DNA template of a protein specific to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Pfizer Australia, 2021a; Pfizer Australia, 2021c).

Further information can be found at Therapeutic Goods Administration: COMIRNATY.

ATAGI recommends vaccination with the Pfizer (COMIRNATY) (orange cap) vaccine for all children aged 5 to <12 years. Children aged 5 to <12 years with medical risk factors for severe illness, Aboriginal and Torres Strait Islander children, and children living in crowded conditions or outbreak areas are most likely to benefit from COVID-19 vaccination given their increased risk of severe outcomes and/or exposure (ATAGI, 2021y).

Each vial has an orange cap as shown below and there are 10 vials in each carton (secondary packaging).

Figure 1: Pfizer (COMIRNATY) (orange cap) vaccine vial.

Figure 2: Secondary packaging – A carton of 10x Pfizer (COMIRNATY) (orange cap) vaccine vials.

The vial is a multi-dose glass vial which requires dilution. The vial has a synthetic bromobutyl rubber stopper and a plastic **orange flip-cap** with an aluminium seal. It contains a white to off-white suspension (Pfizer Australia, 2021c).

Each vial contains at least 10 doses of 0.2mL of vaccine when diluted.

Each 0.2mL dose contains 10 micrograms of COVID-19 mRNA vaccine embedded in lipid nanoparticles (Pfizer Australia, 2021c). This is compared to a 0.3mL dose containing 30 micrograms in the Pfizer (COMIRNATY) (purple cap) vaccine for those aged 12 years and older.

The active ingredient in the vial is the BNT162b2 mRNA. Other ingredients include:

- ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
- 2-[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide (ALC-0159)
- Distearoylphosphatidylcholine (DSPC)
- Cholesterol
- Trometamol
- Trometamol hydrochloride
- Sucrose
- Water for injection

(Pfizer Australia, 2021c)

Protection

The Pfizer (COMIRNATY) (orange cap) vaccine has been demonstrated to reduce cases of symptomatic COVID-19 in children 5 to <12 years of age and prevent severe cases of COVID-19 (ATAGI, 2021y). The duration of protection achieved from Pfizer (COMIRNATY) (orange cap) is unknown as this is still being determined through ongoing clinical trials. As with any vaccine, vaccination may not protect all recipients. Individuals may not be fully protected until at least 7 days after their second primary course dose.

The immune response to the vaccine in children was similar to that seen in older age groups. The safety profile in children is also similar to that seen in adults with the observed side effects being mild in the majority of cases.

Among 2186 trial participants aged 5 to 11 years without evidence of prior COVID-19 infection, two doses of 10 micrograms of Pfizer (COMIRNATY) (orange cap) vaccine were 90.7% effective (95% CI [confidence interval]: 67.7 to 98.3%) at preventing laboratory-confirmed symptomatic COVID-19 from day 7 after dose 2 (with an interval of 3 weeks between doses). This was based on 3 observed cases among 1305 Pfizer (COMIRNATY) (orange cap) vaccine recipients compared to 16 cases among 663 placebo recipients reported between July and September 2021. The three cases in the Pfizer (COMIRNATY) (orange cap) vaccine group were mild and without fever, whereas most cases in the placebo group had documented fever. Multiple other symptoms were also observed more frequently among cases in the placebo group. There were no cases of severe COVID-19 in either group (ATAGI, 2021y).

The Pfizer (COMIRNATY) (orange cap) vaccine has been shown to be immunogenic. Neutralising antibody titres after two 10 micrograms doses of the Pfizer (COMIRNATY) (orange cap) vaccine in 264 participants aged 5 to 11 years were comparable to those observed in 253 trial participants aged 16 to 25 years who received two 30 micrograms doses of the adolescent/adult formulation, with a geometric mean ratio of 1.04 (95% CI: 0.93 to 1.18). The proportion achieving seroconversion was 99.2%. Additionally, in a small subset of 34 children studied who received the Pfizer (COMIRNATY) (orange cap) vaccine, the increase in neutralisation titre against the Delta variant strain from pre-vaccination to after dose 2 was similar to the fold-increase observed for the reference strain (29.5- and 36.5-fold, respectively) (ATAGI, 2021y).

As of 9 December 2021, more than 5 million children aged 5 to <12 years had received at least one dose of the Pfizer (COMIRNATY) (orange cap) vaccine in the United States, and more than 2 million had received two doses. Clinical trials were conducted prior to the emergence of the Omicron variant, and the results reflect vaccine efficacy against older strains of SARS-CoV-2. Vaccine efficacy or effectiveness against the Omicron strain is not yet known (ATAGI, 2021y).

More information can be found in the:

- Product Information
- COVID-19 vaccine information,
- ATAGI Clinical guidance for COVID-19 vaccine providers,
- COVID-19 Vaccination: How COVID-19 vaccines work,
- COVID-19 vaccination – Patient resources.

Why is there a different vaccine for children 5 to <12 years of age?

ATAGI recommends using the specific Pfizer (COMIRNATY) (orange cap) vaccine, developed specifically for children aged 5 to <12 years, for the following reasons:

- There is the potential for administration errors leading to under- or over- dose if the adolescent/adult formulation is used to vaccinate children aged 5 to <12 years old.
- Delivering a 10-microgram dose using the Pfizer (COMIRNATY) (purple cap) vaccine would require accurately drawing and administering up 0.1mL, whereas for the Pfizer (COMIRNATY) (orange cap) vaccine the dose volume is 0.2mL.
- Inadvertent administration of a 30-microgram dose to a child aged 5 to <12 years may lead to an increased number or severity of adverse events. In the phase I clinical trial in this age group, the severity of local and systemic adverse events for the 30-microgram dose level were deemed unacceptable to proceed with using this dose.

(ATAGI, 2021y)

Any Pfizer (COMIRNATY) vaccine doses other than the Pfizer (COMIRNATY) (orange cap) given to children aged 5 to <12 years, should be reported as a Vaccine Administration Error (VAE). The Vaccine Operations Centre (VOC) on **1800 318 208** is available to provide advice and guidance to clinicians regarding the management of VAEs. Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Topic 2: Cold chain and thawing

Thawed storage and deliveries

Deliveries of **thawed, undiluted** vaccines will be received at **+2°C to +8°C** and must continue to be stored at **+2°C to +8°C**, unopened, for a single maximum period of up to **10 weeks**, within the **18-month shelf life** (ATAGI, 2021b)**.**

The expiry date **MAY NOT** be printed on each individual vial, only the manufacture date, so it is vital that the outer carton expiry date is checked and noted. The thawed date and use-by date (calculated from the thawed date and within the 18-month shelf life) will be labelled on the carton prior to dispatch from the logistics provider.

Check that the use-by date and thawed date has been labelled on the outer carton when delivered.

All vials must be stored in their original carton to protect them from exposure to light including room and sunlight (Pfizer Australia, 2021c).

Frozen storage and deliveries

Frozen storage and transport of unopened Pfizer (COMIRNATY) (orange cap) vaccine requires ultra-cold chain (UCC) management. The vials can be stored frozen at **-90°C to -60°C** for up to **18 months** (ATAGI, 2021b; Pfizer Australia, 2021c).

Deliveries of frozen vaccines will be received at **-90°C to -60°C**. Once a frozen delivery is received, the vaccines must then be **stored at -90°C to -60°C**; or **thawed** in standard cold chain conditions at **+2°C to +8°C** (Pfizer Australia, 2021c).

Once removed from frozen storage, the unopened vials may be stored refrigerated at +2°C to +8°C for a single period of up to 10 weeks within the 18-month shelf life (ATAGI, 2021b)**.** Upon moving the product to +2°C to +8°C storage, the new use-by date must be written on the outer carton and the vaccine should be used or discarded by the use-by date.

The expiry date MAY NOT be labelled on the outer carton or on the vial for frozen deliveries. Providers are required to check manufacturers expiry date via the Delivery Acceptance forms in the COVID-19 Vaccine Administrative System (CVAS) at health.gov.au/cvas. It is recommended that providers record the expiry dates for each delivery at the time of doing the delivery acceptance.

All vials must be stored in their original carton to protect them from exposure to light including room and sun light (Pfizer Australia, 2021c).

Thermal shippers will be used to deliver the vaccines. Thermal shippers are boxes that contain a Freezer Carton of 60 packs. The carton is submerged in dry ice pellets and can maintain UCC (-75°C ± 15°C) during transport.

Once empty of vials and before sending back, the thermal shipper should be left open in a well-ventilated area where the dry ice will readily sublime (melt from solid to gas) into carbon dioxide gas and dissipate. Dry ice should not be left unattended.

Unpacking frozen deliveries

Proper personal protective equipment (PPE) must be worn when handling dry ice. If you are in a facility with UCC storage. Additional dry ice handling material may be received from the manufacturer. However, state and territory guidelines on dry ice handling should also be followed.

The following information details how to unpack Pfizer (COMIRNATY) (orange cap) deliveries. Most vaccine providers will receive the vaccine thawed from logistics providers so will NOT need to follow the below steps which are for UCC/frozen deliveries only**.**

This information is current as at 1 June 2022 but is subject to change.

Frozen deliveries from DHL:

1. Proceed using PPE gloves and safety goggles and open the thermal shipper.
2. Turn the TempTale Ultra data logger off.
3. Utilise the bag or blue strapping above the dry ice surface and pull the vaccine tray(s) through the dry ice.
4. Place the vaccine trays into your -90°C to -60°C freezer.
5. Please dispose of all dry ice from the thermal shipper. The thermal shipper cannot have any dry ice when returned.
6. Place the temperature device TempTale Ultra and TrackIT device back into the empty thermal shipper.

PDF of packing and unpacking Pfizer (COMIRNATY) (orange cap) deliveries.

Thawing

Prior to a vial being opened and diluted, it must first be thawed. When **thawing from -90°C to -60°C**, the vaccine can be thawed in either **cold chain conditions (+2°C to +8°C) or at room temperature (up to +30°C)** (Pfizer Australia, 2021c).

When frozen vaccines are being moved into standard cold chain conditions **(+2°C to +8°C)**, the current expiry date must be crossed off on the outer carton and a new date, **10 weeks** (within the 18-months shelf life) from the thawed date written in its place. If the current expiry date is in less than 10 weeks, the current expiry date must remain as it cannot be extended (Pfizer Australia, 2021c).

A 10-vial pack may take **4 hours to thaw in cold chain conditions (+2°C to +8°C).** If required, individual vials can be **thawed in room temperatures up to +30°C for 30 minutes**, however, if possible, vials should remain in the carton until dilution (Pfizer Australia, 2021c).

Including thawing time, **unopened vials** may be stored at room temperature, **between +8°C and +30°C for up to 24 hours**. The vial must be used or discarded within this timeframe (ATAGI, 2021y).

If you suspect your vaccines may have been involved in a cold chain breach (CCB), either within the clinical setting or during transit:

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 Vaccine Operations Centre (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.

A quick reference poster guide can be used for CCB management including reporting. Please note the requirement to contact the VOC in the event of a cold chain breach is specific to COVID-19 vaccines, and not stated in the National Vaccine Storage Guidelines.

Please see Appendix 5 for the steps to be followed if a potential CCB occurs.

Once thawed, the vial CANNOT be re-frozen. Thawed vials can be handled in room light conditions (Pfizer Australia, 2021c).

Delivery acceptance (thawed or frozen)

Delivery acceptance reporting must be completed by all sites and completed by the authorised person in charge of accepting deliveries of the vaccine into the COVID-19 Vaccine Administrative System (CVAS). 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.

Stock management reports can be completed by relevant personnel within the administration site who has access to CVAS for that account.

All ordering and stock management should now be submitted through the COVID-19 Vaccine Administrative System (CVAS) at health.gov.au/cvas

- Delivery Acceptance reports must be completed on the day of delivery (as soon as possible).
- Stock Management reports must be submitted no later than 9pm (local time) Friday every week (if your site is unable to submit the report on Friday, please submit on the Wednesday or Thursday prior).

Orders must be placed by 11:59pm Friday for delivery the following fortnight (note that new orders can only be placed if the previous week's stock management report has been completed).

Providers must record and check the manufacturer expiry date and the thaw use-by date at the time of completing the Delivery Acceptance forms in the CVAS at health.gov.au/cvas.

Topic 3: Preparation and administration

After thawing is complete the vial is ready to be diluted and administered. If thawing was completed by placing the vial on the bench, then immediate dilution and administration is required. If thawed in cold chain conditions (+2°C to +8°C), then dilution and administration must occur within 10 weeks. Your facility must record the date and time the vials were removed from the UCC environment and

placed in the fridge and count the expiry date exactly 10 weeks from this time (within the 18-month shelf life).

Some providers will receive the Pfizer (COMIRNATY) (orange cap) vaccine thawed. **Unopened thawed vials** can be stored at **+2ºC to +8ºC** for a maximum of **10 weeks** (within the 18-month shelf life).

Expiry dates must be followed precisely to prevent expired stock being administered. There are two expiry dates that must be observed on Pfizer (COMIRNATY) (orange cap) vaccines, manufacture expiry date and the thawed expiry date. Both must be checked prior to every vaccine administration.

The manufacture expiry date indicates the expiry for the frozen vaccine. The thaw use-by date commences when the vials are removed from the freezer or UCC storage to commence thawing and may be written on either 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**.

To prevent administration errors all sites should clearly label the thawed use-by 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 (VAEs). If vaccines are administered outside of either expiry date, it is considered a VAE. The VOC on **1800 318 208** is available to provide advice and guidance to clinicians regarding the management of VAEs. Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Providers can also check the manufacturers expiry date and the thawed expiry date via the Delivery Acceptance forms in the CVAS at health.gov.au/cvas. It is recommended that providers record the expiry dates for each delivery at the time of doing the delivery acceptance.

Before beginning any dose preparation or administration, double-check you have the correct vaccine brand and formulation: Pfizer (COMIRNATY) (orange cap) and confirm the expiry date.

The storage requirements, dosage, diluent amount and expiry for each vial type are different and great care must be taken to avoid any incorrect administration. It is recommended that facilities store the vaccines and supplies in dedicated containers in separate spaces, such as in clearly labelled shelves (or fridges, if possible) and use colour coding to differentiate between prepared doses for children aged 5 to <12 years and those 12 years and older. Where possible, separate drawing-up spaces may be designated, with separate staff preparing each formulation.

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Dilution

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 (Pfizer Australia, 2021c).

Dilute the Pfizer (COMIRNATY) (orange cap) vaccine by injecting **ONLY** 1.3mL of sterile **sodium chloride (0.9%) for injection** into the vial. Aseptic technique must be maintained as described in Module 4, Topic 2. For a quick review, open the section below:

Gathering and preparing the vial for use:

1. Perform hand hygiene with either soap and water or an alcohol-based rub.
2. Clean and disinfect the separate area for preparation and procedure dish or tray.
3. Collect the required equipment (as outlined earlier in Module 4, Topic 2 in the 'vaccine administration checklist per person').
4. Remove the required vaccine vial (only 1 at a time) from the cold chain storage system used and check the temperature while doing so.
5. Double check you have the correct vaccine before opening the vial, ideally with another health professional if available, and as per your facility and jurisdictional policies.
6. Check the manufacturer expiry date, the thaw use-by date and date and time that the vial was opened. DISCARD the vaccine if it exceeds any expiry date and time. If you are opening the vial for the first time, record the current date and time on the vial, before opening it.
7. Examine the vaccine vial gently and ensure there is no discolouration or turbidity as per the product information by inverting it gently 10 times. If you are unsure of its appearance, **DO NOT** use and seek advice from the VOC on **1800 318 208**.
8. Perform hand hygiene.
9. Open the vial (if applicable) and check the bung (also known as the septum/stopper/diaphragm) integrity.
10. Disinfect the bung using a 70% isopropyl alcohol wipe.
11. Allow to fully dry for 30 seconds.

Brief instructional video as a summary of the above steps:
https://share.viostream.com/bfxgwogd945u5d?t=t-d417yzw

Dilution of the Pfizer (COMIRNATY) (orange cap):

Only thawed vials can be opened and diluted in preparation for administration. The vial should contain white to off-white opaque amorphous particles (Pfizer Australia, 2021c).

Follow the below steps to dilute the vial using an aseptic technique:

1. Check the expiry date on the carton and/or vial as applicable.
2. Allow the thawed vial to come to room temperature and gently invert the vial fully 10 times. Do not shake. Prior to dilution, the thawed vaccine may contain white to off-white opaque

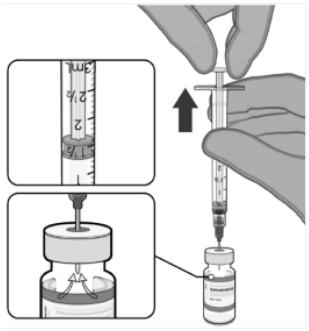
amorphous particles.

(*Image 3: Gently invert the vial 10 times (Pfizer Australia, 2021c*).

3. Pop off the plastic cap, being careful not to touch the rubber bung and maintain aseptic technique. If the rubber bung is touched or contaminated, clean with a 70% isopropyl alcohol wipe thoroughly and allow to dry for 30 seconds prior to use.

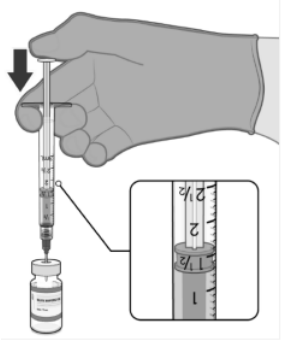
4. Prepare **1.3mL** of sodium chloride (0.9%) solution for injection in a 2mL or 3mL syringe using a 21 gauge or narrower needle.

5. Inject the 1.3mL into the vial carefully.



(*Image 4: Inject 1.3mL of sodium chloride into the vial (Pfizer Australia, 2021c*).

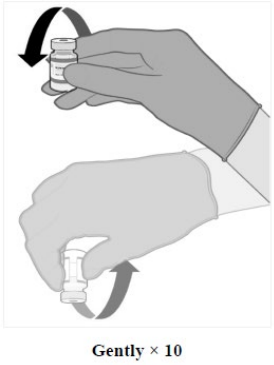
6. Once 1.3mL of sodium chloride is injected into the vial, leave the needle and syringe in and withdraw 1.3mL of air from the vial into the now empty syringe to equalise the pressure in the vial.



(*Image 5: Withdraw 1.3mL of air to equalise the vial pressure (Pfizer Australia, 2021c*).

7. Remove the needle and syringe containing 1.3mL of air and dispose of immediately in a sharps container.

8. Gently invert the diluted vial fully 10 times. Do not shake.



(*Image 3: Gently invert the vial 10 times (Pfizer Australia, 2021c*)).

9. The diluted vial should now contain a suspension with no visible particulates. Do NOT use the vial if particulates or discolouration are present and seek advice from the VOC.
10. **Mark the diluted vial immediately with the new expiry date and time**, 6 hours from the time of dilution If the vial is not used within 6 hours from dilution, the vial must be discarded.

(*Image 6: Record appropriate date and time on the vial immediately (Pfizer Australia, 2021c)*)

11. The open and diluted vial may now be stored in cold chain or room temperature conditions, **in the range of +2°C to +30°C and used within 6 hours from the time of dilution**.

(Pfizer Australia, 2021c).

After dilution, check and ensure that the date and time has been recorded on the vial for safety. DO NOT freeze the diluted vaccine.

Brief instructional video as a summary of the above steps:
https://share.viostream.com/bfxgwogd945wbc?t=t-d417yzw

Dose preparation:

Prior to each vaccination, ensure <u>all</u> relevant expiry dates and times are checked.

The vial should be allowed to come to room temperature before administration if it is taken from the fridge. **Undiluted vials** may be stored at temperatures between 8 °C to 30°C for up to 24 hours, including any time within these temperatures following first puncture.

After initial puncture for dilution, vials can be stored **up to 12 hours** in room temperature **up to +30°C** and must be used within the 12 hours (Pfizer, Australia, 2021c). 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.

Follow all preparation instructions as reviewed in this topic before dilution. Ensure that the vial has not expired and that it has been **less than 6 hours** since the vial was diluted by checking the date and time on the vial. **DO NOT** use if the vial has been opened without a date and time of dilution

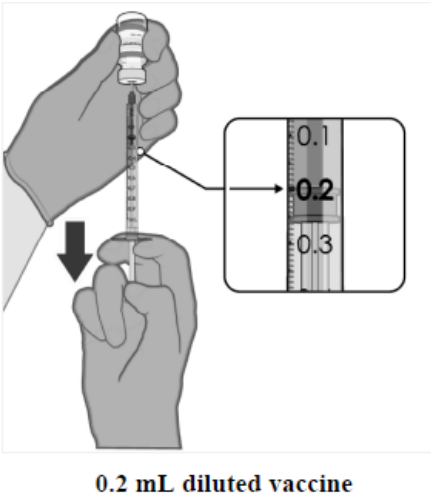
To extract the full 10 doses from the MDV, low dead-volume 1mL Luer-Lock syringes and needles are strongly recommended when available. Standard needles and 1mL syringes can be used if this is the supplied and available stock. The syringe and needle should have a combined dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a tenth dose from a single vial (Pfizer Australia, 2021c).

If a full dose cannot be drawn up from the remaining liquid in an MDV, it must be discarded as doses cannot be drawn from multiple MDVs (Pfizer Australia, 2021c).

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.

A single dose of Pfizer (COMIRNATY) (orange cap) is 0.2mL. Double-check this before administration (Pfizer Australia, 2021c).

Care should be taken to draw up the dose volume exactly (Pfizer Australia, 2021c). When entering the vial multiple times, ensure that each re-puncture occurs as a different site.



(Image 5: Withdraw one dose of diluted vaccine, 0.2mL (Pfizer Australia, 2021c).

Please watch this brief instructional video for a summary of the above steps:
https://share.viostream.com/bfxgwogd945w8i?t=t-d417yzw

Dosing and schedule

Pfizer (COMIRNATY) (orange cap) is administered as an intramuscular (IM) injection containing 0.2mL of the diluted vaccine. This is equal to 10 micrograms.

A total of two primary course doses are required. The recommended schedule for vaccination in this age group is 2 doses, 8 weeks apart (ATAGI, 2021y).

The dose interval for Pfizer (COMINARTY) (orange cap) vaccine can be shortened to a minimum of 3 weeks in special circumstances for higher risk groups such as those with medical risk factors for severe illness, or before international travel (ATAGI, 2021b).

The benefits of earlier protection should be weighed against the benefits of the longer dose interval, such as a slightly lower risk of adverse events and a longer duration of protection (ATAGI, 2021b).

This extended dosing interval of 8 weeks may improve immunogenicity and the effectiveness after the second primary dose. In adult (not directly studied in children) populations, extending the interval (e.g., to 8 weeks or longer) has resulted in higher antibody concentrations, improved vaccine effectiveness and potentially a longer duration of protection compared with the standard interval (ATAGI, 2020z).

Children should receive the appropriate brand and dose of vaccine according to their age on the day of vaccination. Children who turn 12 after their first dose of Pfizer (COMIRNATY) (orange cap) should

complete their primary vaccine course with a BA.4-5-containing bivalent vaccine i.e. Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap) or Modern bivalent BA.4-5 (SPIKEVAX) (PFS) vaccine. The recommended interval is 8 weeks (ATAGI, 2023d).

To reduce the risk of administration error, the paediatric and adolescent/adult formulations of the Pfizer (COMIRNATY) vaccine vials and prepared doses should be stored separately from each other in clearly marked areas, including 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 (ATAGI, 2021g).

Refer to and download the COVID-19 Vaccines in Australia posters for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Vaccine administration errors (VAEs)

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training undertaken to minimise the risk of VAEs occurring (ATAGI, 2022a).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible VAEs, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022a). The VOC on **1800 318 208** is available to provide advice to clinicians regarding the management of VAEs.

Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Please see Appendix 4 for the steps to be followed if a Vaccine administration error occurs.

Administration

Administer as an intramuscular injection (IM), usually into the deltoid. **DO NOT** inject intravascularly, subcutaneously or intradermally (ATAGI, 2021b).

A new sterile syringe and needle must be used for administration to each individual. Do not mix or contaminate the vaccine with any other medication or liquid. If a full dose cannot be extracted from one vial, then that part dose and vial must be discarded (Pfizer Australia, 2021c).

ATAGI is aware of scientific reports proposing that inadvertent injection of a COVID-19 vaccine into a blood vessel may be a contributing cause of serious adverse events following immunisation, such as myocarditis. ATAGI has reviewed the available evidence and considers injection technique highly unlikely to be a contributor to these adverse events, for several reasons:

- The majority of myocarditis cases occur after the second dose of the mRNA vaccines. If intravascular injection were an important contributor, there would not be this differential distribution of cases by vaccine dose.
- Direct injection into a blood vessel is unlikely in recommended injection sites.

(Department of Health and Aged Care [DHAC], 2021k)

Based on a review of the available evidence, ATAGI does not recommend routinely aspirating (drawing back) needles before injection. This practice was rejected some decades ago, due to several disadvantages including prolonging the procedure, potentially associated pain, and increasing the risk of needle-syringe disconnection. Not aspirating is supported by the current advice in the Australian Immunisation Handbook (ATAGI, 2022q).

ATAGI will continue to review emerging evidence on the underlying mechanisms, prevention and treatment of thrombosis with thrombocytopenia (TTS), myocarditis and other serious adverse events of special interest.

COVID-19 vaccines should be prepared by qualified healthcare professionals using aseptic technique to maintain sterility of the doses during required dilution and dose preparation.

The **preferred** extraction method for single or multiple doses of the Pfizer (COMIRNATY) (orange cap) due to the potential loss of volume when changing needles is to use the same needle to draw up and administer the vaccine. An aseptic procedure must be used throughout the procedure as there is a potential for a greater frequency of injection site reactions using this technique. The steps to complete this process are exactly the same as described in Module 4 (and video 3), except the needles are not changed. The needle can be recapped using aseptic technique if not being administered immediately (ATAGI, 2021g). Seek advice from your Public Health Unit (PHU) as to when this may be appropriate.

ATAGI recommends that, when possible, pre-drawn doses kept at room temperature be used within an hour and used within 6 hours if stored in cold chain (+2°C to +8°C) to minimise any remote potential risk of infection (please note these ATAGI recommendations are less than the PI recommendations in cold chain conditions) (ATAGI, 2021b; DHAC, 2021g).

ATAGI recommendations must be followed over product information.

Pre-drawn vaccine doses in syringes are treated differently than diluted or open vials. Please refer to the ATAGI Transport, storage and handling webpage for ATAGI recommendations on diluted or open vials.

After administration, the vaccine dose administered including batch and vial serial number must be entered into the Australian Immunisation Register (AIR) as described in Module 5, Topic 4.

All sharps with syringes still attached (such as after administration) should be discarded in a sharps waste container. The vials and other consumables should be disposed of in accordance with local requirements in the clinical waste bin.

Administration of vaccines under sedation

Procedural guidelines for administration of vaccines under sedation in practice have been developed or are currently being developed in some health services. ATAGI advises that detailed clinical guidance should be developed collaboratively with input from anaesthetic groups, jurisdictional health services and relevant specialists (ATAGI, 2022g).

More information can be found in the ATAGI advice on use of sedation for COVID-19 vaccination.

Home visits – 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 total maximum storage period of **6 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 can be administered as soon as practical and not exceeding the total maximum storage period of 1 hour if at room temperature, and within **6 hours if at 2°C to 8°C**.

More information can be found at the end of the ATAGI recommendations for Transporting, storing and handling COVID-19 vaccines (ATAGI, 2021b).

Disposal and wastage:

Prior to disposal, the outer packaging (carton) should be defaced by striking through at least one panel of the carton with a sharpie or similar marker.

Any unused vaccine or waste material should be disposed of in accordance with local requirements in a clinical waste bin and reported through the COVID-19 Vaccine Administrative System (CVAS).

Surfaces with any spillages of vial contents should be cleaned up immediately using an agent to inactivate the spill (e.g. Ethanol (EtOH)). Health professionals should follow normal procedures for infection control. Spills of the Pfizer (COMIRNATY) (orange cap) vaccine are low-risk.

Incidents of fewer than 10 vials at a time must be reported as minor wastage in the weekly Stock Management Report in CVAS.

Major Wastage (10 or more vials)

From 2 April 2022, a major wastage incident (e.g. damaged vials, expired vaccines or breach of cold chain requirements) is classified as one that includes 10 or more vials at a time.

If more than 10 vials at a time are wasted, providers must submit a Wastage Report through the COVID-19 Vaccine Administrative System (CVAS) within 2 hours of the incident. You are no longer required to call the VOC to additionally report the wastage incident.

Any wastage of fewer than 10 vials in one incident should be reported through the minor wastage section of your weekly Stock Management report in CVAS (due no later than 9pm local time Friday every week).

Additional administration considerations for children 5 to <12 years old

An intramuscular injection (IMI) into the deltoid of a child 5 to <12 years old is not different to injecting a person >12 years of age, except the deltoid area is likely to be smaller. However, several additional considerations should be made when injecting a child.

Working with Children Check (WWCC) - Vaccinators may require a WWCC or state/territory equivalent. Requirements for working with children differ by jurisdiction and based on the circumstances (e.g. vaccination via primary care providers or in mass vaccination clinics) and should be clarified by the Taskforce with their jurisdictional counterparts (ATAGI, 2021y).

Informed consent - Informed consent should be obtained as per usual consent procedures for other vaccinations. As children aged under 12 years are too young to be assessed as mature minors, consent from a parent or guardian is required for vaccination. Verbal consent is acceptable and written consent is not required (ATAGI, 2021y).

A combined information and consent document has been developed for parents/guardians of children aged 5 to <12 years. The consent form requires the parent/guardian to confirm that they have the authority to provide consent on behalf of that child and can be found here.

Consideration should be given to detecting, understanding and addressing parental concerns about COVID-19 vaccination for their children. Information should be provided that addresses parental concerns about the direct and indirect benefits of vaccination and adverse events following vaccination (particularly any data on myocarditis and pericarditis). Resources should be tailored to the 5 to <12 years old population to show that vaccinating this age group have been carefully considered with the direct benefits and risks clearly stated (ATAGI, 2021y).

It is crucial that parents are given an opportunity to discuss their concerns and ask questions if they are hesitant. Delivery via primary care offers parents the opportunity to discuss their concerns with an immunisation provider.

Additional time per child may be required for administering the vaccine, as younger children often require more parental support and a longer time for vaccine administration than older children.

Health practitioners can use TIS National's Free Interpreting Service (FIS) to assist with consultations and obtaining informed consent. You can use your existing TIS client code to request interpreters for Medicare and non-Medicare patients for COVID-19 vaccination. For phone or on-site interpreting, call the Translating and Interpreting Service (TIS) on 13 14 50. TIS provides interpreting support 24 hours a day, 7 days a week, nationwide.

Distraction techniques - Distraction, relaxation and other measures reduce distress and pain after vaccination in young children. Reducing children's distress may encourage parents to present for future vaccinations on time (ATAGI, 2022q). Consider a small reward system for this age group such as the use of stickers, colourful band-aids or lollies.

Distraction could come in the form of a conversation including reassurance with the parent or guardian, or a health professional on one side while another health professional administers the vaccine on the other side. Verbal reassurance and comfort with hand holding may be useful prior and during the administration.

Local anaesthetics and vapocollant sprays - Topical anaesthetics, such as EMLA, are not recommended for routine use. They could be considered in a child with excessive fear or dislike of needles. These products need to be applied 30–60 minutes before an injection (ATAGI, 2022q).

Injecting position – A younger child could be held by the parent or guardian in a straddle position. The carer hugs the child against their chest with the child straddling both of the carer's legs. The carer is holding the child tightly with their left arm and the child's right arm is tucked under the carer's left armpit. The carer is holding the child's left arm at the elbow against the child's body, using their right hand. The deltoid muscle injection side on the child's left arm is exposed for the injection to occur (pictures can be found in the Australian Immunisation handbook).

Consider having a place where children may be able to lie down for their injection rather than sitting down, particularly if there is an excessive fear of needles or anxiety related effects.

Benefits of vaccinating children and adolescents

Vaccinating children and adolescents is anticipated to reduce infections, hospitalisations and deaths from SARS-CoV-2 in this age group. Vaccination may also reduce the risk of paediatric inflammatory

multisystem syndrome temporally associated with SARS-CoV-2 (PIMS-TS). This is a rare but serious condition associated with COVID-19 in children.

Most children and adolescents with SARS-CoV-2 infection are asymptomatic or have a mild illness. Adolescents appear to have similar infection rates to adults. But the frequency of severe illness from COVID-19 is lower in adolescents than in adults, with approximately 4% to 7% of adolescents experiencing severe outcomes.

Adolescents and children are accounting for increasing proportions of COVID-19 cases, in the context of vaccinated older age groups. Overall hospitalisation rates for COVID-19 in the adolescent age group are higher than for other viral respiratory diseases such as influenza. Information on severity of disease in adolescents is mainly from before the Omicron variant began circulating.

Children and adolescents aged ≥5 years in the following groups are most likely to benefit from COVID-19 vaccination because of their increased risk of severe outcomes and/or exposure:

- Those with medical risk factors for severe illness.
- Aboriginal and Torres Strait Islander children and adolescents.
- Those living in crowded conditions or outbreak areas.

Clinical trials have shown that 2 smaller doses of the Pfizer (COMIRNATY) (orange cap) lead to an immune response in children aged 5 to less than 12 years that is equally as strong as the larger doses in people aged 12 years and older (ATAGI, 2022c).

ATAGI advises the following groups should **consider** a 2023 booster dose 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.

- 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.

ATAGI advises that a booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19 and the 2023 booster dose is not a seasonal recommendation.

There is insufficient evidence of severe disease in otherwise healthy children in this age group who have already received two primary doses of a COVID-19 vaccine (ATAGI, 2023a).

A vaccine checklist poster is available showing the different COVID-19 vaccines available for children in Australia and compares their preparation and administration requirements. See COVID-19 Vaccines in Australia.

See Appendix 3 for the Vaccine preparation and Vaccine administration checklist.

Topic 4: Precautions

A pre-screening checklist is required to check for any contraindications or circumstances for which precaution is required before administration. Pre-screening is covered in detail in Module 5 Topic 3.

The precautions discussed below are the same as the ones reviewed in Module 5, Topic 2. Please review these again as required.

Past infection is not a contraindication to vaccination. People with SARS-CoV-2 infection are recommended to be vaccinated **6 months** after the onset of the SARS-CoV-2 infection. People who have received an anti-SARS-CoV-2 monoclonal antibody or convalescent plasma should defer future doses of COVID-19 vaccine for at least **90 days** (ATAGI, 2021b).

Care should be taken in individuals who may have a coagulation disorder or increased risk of bleeding and bruising as this may occur following an IM injection.

For information on temporary medical exemptions for COVID-19 vaccines, view the ATAGI Guidance.

Contraindications

There are only two contraindications to COVID-19 vaccines for children aged 5 to <12 years of age. The contraindications are a hypersensitivity or anaphylaxis reaction to any of the active substances or to any of the other ingredients within the vaccine or to a previous dose of the vaccine (Pfizer Australia, 2021c).

Anaphylaxis is a rare but possible reaction to any medication administration. An anaphylaxis treatment kit and trained health professionals must be available at all sites in case of an anaphylactic reaction following administration of a COVID-19 vaccine. Anaphylaxis doses are based on a person's weight, a chart of appropriate doses and weights should be included within the anaphylaxis or resuscitation kit. The ASCIA acute anaphylaxis management guidelines can be found here for a refresher.

As part of standard observations, all individuals should be kept under close observation for at least 15 minutes following vaccination (ATAGI, 2022q).

Precautions

Previous SARS-CoV-2 infection – Children aged 5 to <12 years who have previously had SARS-CoV-2 infection can receive the Pfizer (COMIRNATY) (orange cap) vaccine 6 months after confirmed SARS-CoV-2 infection (ATAGI, 2022f). This includes children with a past history of paediatric inflammatory multisystem syndrome temporarily associated with SARS-CoV-2 (PIMS-TS) or post COVID-19 condition ('long COVID') (ATAGI, 2021y).

Immunocompromised individuals – Includes individuals receiving immunosuppressant therapy. The efficacy, safety and immunogenicity have not been fully assessed in these individuals and therefore the efficacy may be lower. Early (preprint) evidence suggests a reduced immune response to vaccination with Pfizer (COMIRNATY) vaccines in people with cancer and solid organ transplant recipients (ATAGI, 2021b).

ATAGI highly recommends that these individuals receive the vaccine as normal and there are no specific safety concerns with receiving the vaccine (ATAGI, 2021b). Additionally, ATAGI recommends immunocompromised people aged 5 to <12 years receive a third primary dose of COVID-19 vaccine to optimise their protection. The recommended interval for the third dose is 2 after the second dose of vaccine.

For more information, review ATAGI's COVID-19 vaccination decision guide for people with immunocompromise.

For a comprehensive list of immunocompromising conditions and therapies for which a third primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Ideally, vaccination should occur on a different day to regular infusion treatments, such as immunoglobulin replacement therapy or immunosuppressant infusions (ASCIA, 2021).

Myocarditis and pericarditis –

Myocarditis and pericarditis have been associated with the use of mRNA COVID-19 vaccines. Both are very rare adverse events. The people at highest risk of developing myocarditis and/or pericarditis after mRNA COVID-19 vaccines are males under the age of 30 years (particularly adolescent males) with no other risk factors currently identified (ATAGI, 2021y).

Myocarditis refers to inflammation of the heart muscle, and pericarditis refers to inflammation of the thin sac that surrounds the heart. These conditions can occur separately or together (myopericarditis). Healthcare professionals should be alert to the signs and symptoms of these conditions.

Symptoms typically appear within 1-5 days of vaccination and include chest pain, palpitations (irregular heartbeat), syncope (fainting) or shortness of breath. People who experience any of these symptoms after having an mRNA COVID-19 vaccine should seek prompt medical attention.

Most cases of myocarditis associated with mRNA COVID-19 vaccines in people aged ≥ 16 years have resolved within several weeks. However, some symptoms can persist for a few weeks to months. In an ongoing study conducted by the US CDC, about 50% of these patients reported no symptoms at 10-12 weeks post-vaccination, and about a quarter of patients reported fatigue, palpitations, shortness of breath or chest pain. At 3 months post-vaccination, about 90% of patients were assessed by their healthcare provider to be either 'fully recovered' (74%) or 'probably fully recovered, awaiting additional information' (17%) (ATAGI, 2021y).

The risk of myocarditis or pericarditis after mRNA COVID-19 vaccination in children aged 5 to <12 years is not yet known but appears to be rare based on preliminary data from US surveillance networks. While early reporting in children aged 5 to <12 years in the United States suggests a very low rate of myocarditis following 1st and 2nd doses, further data are expected in the coming weeks (ATAGI, 2021y).

In the absence of direct information for the 5 to <12 years age group, the incidence of myocarditis among adolescents receiving mRNA vaccines in Australia and the USA provides some useful information to infer likely risk. In both countries, the incidence of myocarditis is higher in males than females, and after dose 2 compared to dose 1 (ATAGI, 2021y).

Myocarditis due to other (non-COVID-19) causes is more common in male children than in females and is more common in adolescents than in children aged 5 to <12 years (ATAGI, 2021y).

A longer dosing interval may also reduce the risk of myocarditis and pericarditis after vaccination. In a population-based cohort study evaluating passive vaccine safety surveillance data in Ontario, Canada, rates of myocarditis and pericarditis after the Pfizer (COMINARTY) (purple cap) vaccine in people aged ≥12 years were higher in those with an inter-dose interval of ≤30 days, and were lowest in those with an inter-dose interval of ≥56 days. However, it should be noted that this study did not include children aged 5 to <12 years. An 8-week dosing interval will enable a longer time period for observation of international data regarding potential rare adverse events in this age group, such as myocarditis (ATAGI, 2021y).

Pfizer (COMIRNATY) (orange cap) is recommended for children 5 to less than 12 years of age who do not have any contraindications to the vaccine. The previously supplied Moderna (SPIKEVAX) (red cap) vaccine was an alternative option for children aged 6 to 11 years.

For further information, refer to the Clinical guidance for COVID-19 vaccine providers (ATAGI, 2021b).

Most pre-existing cardiac conditions are **NOT** regarded as contraindications to vaccination. People with a history of any of the following conditions **CAN** receive an mRNA vaccine but should consult a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- Recent (i.e. in the past 3 months) or current inflammatory cardiac illness e.g., myocarditis, pericarditis or endocarditis.
- Acute rheumatic fever or acute rheumatic heart disease.
- Acute decompensated heart failure.

(ATAGI & CSANZ, 2021; ATAGI, 2021b)

Pfizer (COMIRNATY) (orange cap) is recommended for people with a history of most chronic cardiovascular conditions and **CAN** be given to people in the following groups **without any specific precautions**:

- Prior myocarditis, pericarditis, or endocarditis (i.e. > 3 months prior to vaccination).
- Coronary artery disease.
- Myocardial infarction.
- Stable heart failure.
- Arrhythmias.
- Prior history of rheumatic heart disease (RHD).
- Kawasaki disease.
- Congenital heart disease.
- Cardiomyopathy.
- Cardiac transplant.
- People with implantable cardiac devices.

(ATAGI & CSANZ, 2021; ATAGI, 2021b).

People who develop myocarditis or pericarditis attributed to their first dose of Pfizer (COMIRNATY) (orange cap) or the previously available Moderna (SPIKEVAX) (red cap) for children aged 6 to 11 years are advised to defer further doses of an mRNA COVID-19 vaccine and to discuss this with their treating doctor (ATAGI & CSANZ, 2021). Vaccination should be deferred in people with ongoing cardiac inflammation.

For more information, please review the Guidance on myocarditis and pericarditis and Response to ATAGI advice about vaccinating 5 to 11-year-olds against COVID-19 (ATAGI, 2021y).

The manufacturer's recommended schedule is 2 doses, 3 weeks apart. ATAGI recommends a schedule of 2 doses, 8 weeks apart for children 5 to <12 years of age. A longer dosing interval may reduce the risk of myocarditis and pericarditis after vaccination.

Mastocytosis – Confirmed mastocytosis with recurrent anaphylaxis that requires treatment means that the child will need to wait for a 30-minute observation period following vaccination.

Anxiety-related reactions

Anxiety-related reactions include fainting/syncope as a vasovagal, hyperventilation or other stress-related reactions or as a psychogenic response to the needle/injection. Stress-related psychogenic responses are temporary and resolve on their own. Symptoms may include:

- Dizziness.
- Fainting.
- Palpitations.
- Tachycardia or alterations in blood pressure.
- Feeling short of breath.
- Tingling sensations.
- Sweating and/or anxiety.

(Pfizer Australia, 2021c).

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. Vaccination should not be delayed for a minor infection, illness or low-grade fever (Pfizer Australia, 2021c).

Vaccine co-administration

ATAGI supports co-administration of routine childhood and adolescent vaccines with COVID-19 vaccines, given the importance of ensuring protection against other vaccine-preventable diseases and maintaining high vaccine uptake (ATAGI, 2021y).

While there are limited data on the immunogenicity and safety of COVID-19 vaccines co-administered with other vaccines, based on first principles it is unlikely there will be an impact on the immunogenicity or effectiveness of vaccines given on the same day. Expected adverse events such as local reactions and fever may be increased in the setting of co-administration. It is recommended that parents and guardians be made aware of this prior to vaccine administration (ATAGI, 2021y).

Data on the potential for co-administration with other vaccines is currently being reviewed and detailed information on this will be included in the ATAGI Clinical Guidance for COVID-19 vaccine providers (ATAGI, 2021b).

Topic 5: Adverse events

General adverse events have been discussed in Module 6 Topic 2. The Pfizer (COMIRNATY) (orange cap) vaccine was demonstrated to be well tolerated in 5 to <12-year-old children in the phase II/III clinical trial, with most adverse events being mild and transient.

Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side-effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website. For more information, please refer to Core Module 6.

Adverse events following the Moderna (SPIKEVAX) (red cap) may be more common than those following the Pfizer (COMINARTY) (orange cap) vaccine (ATAGI, 2022b; ATAGI, 2022c). Following the second dose of vaccination these are the adverse events seen and the reported incidence (ATAGI, 2022b).

COVID-19 vaccines are well tolerated by children. Children aged 5–11 years are reporting fewer side effects following vaccination with Pfizer (COMIRNATY) (orange cap) dose 1 than older Australians, new COVID-19 vaccine safety data from AusVaxSafety have shown. The following list identifies the frequency of very common adverse events following immunisation (AEFI) in completed clinical trials of those 5 to less than 12 years of age:

- Injection site pain - >80% of individuals.
- Fatigue - >50% of individuals.
- Headache - >30% of individuals.
- Injection site redness and swelling - >20% of individuals.
- Myalgia and chills - >10% of individuals.

(Pfizer Australia, 2021c)

Other symptoms to be aware of include:

- Diarrhoea (common)
- Vomiting (common)
- Arthralgia (common)
- Pyrexia (common)
- Lymphadenopathy (uncommon)
- Hypersensitivity reactions including urticaria, pruritis and rashes (uncommon)
- Decreased appetite (uncommon)
- Nausea (uncommon)
- Pain in extremity (uncommon)
- Malaise (uncommon)
- Anaphylaxis (unknown frequency).

(Pfizer Australia, 2021c)

Expected side effects in the first one to two days after vaccination are less common in children than in teenagers and young adults. Although infrequent, local redness and swelling were more common in children than in young adults. Conversely, systemic adverse reactions after both dose 1 and dose 2 were less frequently observed in 5 to <12 year old children than in 16-to-25-year-olds. Local and systemic adverse events which did occur in the 5 to <12 year age group were milder than in the 16-25 year age group (ATAGI, 2021y).

Consumer medicine information and the COVID-19 vaccination – Patient resources can be given to parents or guardians of children receiving the vaccine which detail what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for your state or territory, please review this website.

Module Summary

- The Pfizer (COMIRNATY) (orange cap) is an mRNA vaccine. The vaccine is distinguishable by its orange cap.
- The Pfizer (COMIRNATY) (orange cap) vaccine is strictly for children aged 5 to less than 12 years. The adult Pfizer (COMINARTY) (purple cap) vaccine should not be administered to patients under the age of 12.
- The Pfizer (COMIRNATY) (orange cap) can **NOT** be given to children aged 12 years and older, even if they received one dose of the Pfizer (COMIRNATY) (orange cap) before they turned 12.
- Frozen vials need to be stored at -90°C to -60°C for a maximum of 18 months. Thawed and unopened vials can be stored in cold chain conditions of +2°C to +8°C for a maximum of 10 weeks before they expire.
- Always check the batch expiry date AND the thawed expiry date prior to opening. The earliest date is considered the use-by date.
- The multi-dose vial contains 10 doses of 0.2mL per dose once thawed and then diluted with 1.3mL of sodium chloride (0.9%) for injection. Write the new vial expiry date on the vial immediately after diluting.
- **Opened and diluted vials can be used for a maximum of 6 hours** in temperatures between +2°C and +30°C. Discard all open vials 6 hours after dilution.
- If available, low dead volume needles and syringes should be used to ensure the full number of doses can be extracted.
- The Pfizer (COMIRNATY) (orange cap) vaccine is given as a 2-dose primary schedule intramuscularly into the deltoid or a 3-dose primary schedule for those who are severely immunocompromised.
- The recommended dose interval between the first primary dose and the second primary dose is 8 weeks. The recommended interval between the second primary dose and the third primary dose, if required, is 2 months.
- Booster doses of Pfizer (COMIRNATY) (orange cap) are approved by the TGA for individuals aged 5-11 years who are at an increased risk of severe disease.
- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

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Multi-choice questions

1. Pfizer (COMIRNATY) (orange cap) must be diluted prior to use. How many millilitres are in a single dose of this diluted vaccine?

    a. 2mL
    b. 0.2mL
    c. 0.3mL

d. 3mL

2. Which of the following statements is CORRECT regarding Pfizer (COMIRNATY) (orange cap) and preparation and administration of a dose?

    a. Dilute the thawed vaccine with 1.3mL of water for injection
    b. Dilute the thawed vaccine with 1.3mL of sodium chloride for injection
    c. Dilute the vaccine, frozen or thawed with 1.3mL of sodium chloride for injection
    d. Dilution is not needed for this vaccine, but it must be thawed prior to use

3. Which of the following statements on expiry dates is INCORRECT?

    a. For thawed deliveries, the use-by date and the thaw date will be labelled on the carton (secondary packaging)
    b. For frozen deliveries, the use-by date and the thaw date should be labelled on the carton (secondary packaging) by the person who removes the carton from UCC storage.
    c. The use-by date should be checked and recorded via the Acceptance Delivery Form on CVAS.
    d. The later of the manufacturers expiry date or thawed-use-by date can be used as the overall expiry date.

4. Put the following dose preparation steps in the correct order. Please note, not all required steps are included below. Click and drag the step descriptions on the left onto each step number on the right:

    a. Check the expiry date on the carton
    b. Open the vial and prepare 1.3mL of sodium chloride for injection into a syringe
    c. Inject the diluent into the vial carefully and withdraw 1.3mL of air
    d. Invert the THAWED and DILUTED vial gently 10 times
    e. Mark the vial with the date and time of dilution

5. Which of the statements regarding COVID-19 Pfizer (COMIRNATY) (orange cap) and Pfizer (COMIRNATY) (purple cap) vaccine is CORRECT?

    a. The Pfizer (COMIRNATY) **(orange cap)** should be used for both doses even if the child turns 12 after their first dose.
    b. The Pfizer (COMIRNATY) (purple cap) should be used for both doses for children who are due to turn 12 before their second dose.
    c. The Pfizer (COMIRNATY) **(orange cap)** should be used for children who are turning 5 that year, even if they have not turned 5 before their first dose.
    d. The Pfizer (COMIRNATY) **(orange cap)** should be used for the first dose for children who are yet to turn 12. If the child turns 12 before the second dose, they should receive the Pfizer (COMIRNATY) (purple cap) for their second dose.

Additional Module 4a: Pfizer (COMIRNATY) (maroon cap)

(21/09/2023)

This module is suitable for healthcare professionals who will be authorised to administer COVID-19 vaccines to children aged 6 months to 4 years.

The recommended time for completing the module is 45 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete.

Learning objectives

At the end of Additional Module 4a: Pfizer (COMIRNATY) (maroon cap) vaccine for children 6 months to 4 years old, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of Pfizer (COMIRNATY) (maroon cap) vaccine for children 6 months to 4 years old.
- Understand the contraindications, warnings, adverse reactions, and co-administration of Pfizer (COMIRNATY) (maroon cap) vaccine for children 6 months to 4 years old.
- Demonstrate appropriate storage and handling of the Pfizer (COMIRNATY) (maroon cap) vaccine for children 6 months to 4 years old, including handling of vaccines before the time of use, thawing, dilution and storage following dilution.
- Demonstrate appropriate dose preparation including dilution and verification before administration of the Pfizer (COMIRNATY) (maroon cap) vaccine for children 6 months to 4 years old.
- Understand the appropriate administration of the Pfizer (COMIRNATY) (maroon cap) vaccine for children 6 months to 4 years old.

Topics

1. Introduction and summary
2. Cold chain and thawing
3. Preparation and administration
4. Precautions
5. Adverse events

Topic 1: Introduction and summary

This module builds on Additional Module 1 (pre-requisite) and Additional Module 4. It will not repeat the information covered in those modules. Please review Additional Modules 1 and 4.

The Pfizer (COMIRNATY) (maroon cap) vaccine for use in children 6 months to 4 years old was provisionally approved by the Therapeutic Goods Administration (TGA) on 29 September 2022 (Therapeutic Goods Administration [TGA], 2021e).

The vaccine recommendations included in this module cover **eligible** children aged 6 months to 4 years.

As per the Australian Technical Advisory Group on Immunisation (ATAGI) advice for COVID-19 vaccines for children, all children aged 5 years and older are recommended to receive a COVID-19 vaccination (Australian Technical Advisory Group [ATAGI], 2022c).
The only vaccine currently available for **children aged 5 to 11 years is the Pfizer (COMIRNATY) (orange cap) 10 mcg vaccine**.

Children who turn 5 years old after their first or second dose of the Pfizer (COMIRNATY) (maroon cap) should receive Pfizer (COMIRNATY) (orange cap) for the remaining dose(s) to complete the 3-dose primary course (ATAGI, 2022c).

The Pfizer (COMIRNATY) (maroon cap) vaccine uses the same mRNA vaccine technology as the other Pfizer (COMIRNATY) vaccines.

It is crucial to note the Pfizer (COMIRNATY) (maroon cap) vaccine has a different formulation and has different recommended use, storage, handling and preparation processes to the Pfizer (COMIRNATY) (orange cap) and Pfizer (COMIRNATY) (purple cap) vaccine.

The Pfizer (COMIRNATY) (maroon cap) CANNOT be used in individuals 5 years of age and older (TGA, 2022e).

ATAGI recommends the **Pfizer (COMIRNATY) (maroon cap)** vaccine for use as a primary course of vaccination against SARS-CoV-2 for children aged 6 months to 4 years with severe immunocompromise, complex or multiple health conditions, or disability with significant or complex health needs (ATAGI, 2022p).

Messenger ribonucleic acid or mRNA is a genetic code (instruction) used by all living cells to produce proteins. The active ingredient in this vaccine is a single-stranded, 5'-capped messenger non-replicating mRNA molecule (Tozinameran). It was created through transcription from the corresponding DNA template of a protein specific to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Pfizer Australia, 2021a; Pfizer Australia, 2021c).

Further information can be found in the Product Information on the Therapeutic Goods Administration website under COMIRNATY.

Each vial has a maroon cap as shown below and there are 10 vials in each carton (secondary packaging).

Figure 1: Pfizer (COMIRNATY) (maroon cap) vaccine vial.

It is important to note that there may be variations in the cap colour, from the lighter shade (pictured above) to a maroon, depending on where the vials are manufactured. Care should be taken to confirm the vaccine type by the label.

Figure 2: Secondary packaging – A carton of 10x10 Pfizer (COMIRNATY) (maroon cap) vaccine vials. © 2022 Pfizer Inc. All rights reserved.

The vial is a multi-dose glass vial **which requires dilution**. The vial has a synthetic bromobutyl rubber stopper and a plastic **maroon flip-cap** with an aluminium seal. When frozen the vaccine is a white to off-white suspension (TGA, 2022e).

Each vial contains 10 doses of 0.2mL of the vaccine after dilution.

Each 0.2mL dose contains 3 micrograms of COVID-19 mRNA vaccine embedded in lipid nanoparticles (TGA, 2022e). This is distinguished from the Pfizer (COMIRNATY) (orange cap) 0.2mL dose containing 10 micrograms for those 5 to 11 years.

The active ingredient in the vial is the BNT162b2 mRNA. Other ingredients include:

- ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate)) (ALC-0315)
- 2-[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide (ALC-0159)
- Distearoylphosphatidylcholine (DSPC)
- Cholesterol
- Trometamol
- Trometamol hydrochloride
- Sucrose
- Water for injection

(TGA, 2022e)

Protection

Children are often asymptomatic or may have mild symptoms if they contract the COVID-19 virus. However, in some cases, severe disease and death may occur. Those who are immunocompromised, disadvantaged, reside in low socioeconomic conditions or are of a minority ethnic status may be more likely to be hospitalised or have poorer outcomes than other children if they contract the disease.

In the USA, during the stage when the Omicron variant of the virus was predominant, 63% of infants/children who were hospitalised were not immunocompromised. In children < 5 years of age, COVID-19-associated hospitalisation was 1.6 times higher than among children between 12 to 17 years of age and 5.4 times higher than among children 5 to 11 years of age.

Data from the National Notifiable Diseases Surveillance System (NNDSS) in Australia has shown that the hospitalisation rate in children < 5 years of age was more than 1 000 per 100 000 population during the recent peaks of the virus. Currently, the hospitalisation rate is approximately 450 cases per 100 000 population.

As of 8 September 2022, over 450,000 Australian children aged 9 years or under had contracted the COVID-19 virus and there had been 12 deaths in this age group. As of the same date, the USA had recorded 527 COVID-19-associated deaths among children under 5 years of age, with more than half due to the Omicron variant.

A total of 4526 participants aged 6 months to < 5 years of age (1776 participants aged 6 to 23 months, 2750 participants aged 2 to 4 years) were randomised in a 2:1 ratio to receive two doses of 3 microgram vaccine or placebo, 3 weeks apart. For the Phase II/III parts of the study, participants with medical conditions such as stable type 1 diabetes or hypothyroidism, stable and controlled HIV, hepatitis B or C (HBV, HCV) infection and past serological or microbiological evidence of prior (not active) SARS-CoV-2 infection were included.

Descriptive analyses of SARS-CoV-2 variant neutralisation were conducted on the Omicron neutralisation subset. The Phase II/III Study C4591007 included approximately 40 Pfizer (COMIRNATY) (maroon cap) 3 microgram vaccine recipients and 5 placebo recipients randomly selected from the immunobridging subset who had received three doses of study intervention. Each of the paediatric groups were without evidence of prior SARS-CoV-2 infection up to one month post-Dose 3. The median timing of Dose 3 administration after Dose 2 of the Pfizer (COMIRNATY) (maroon cap) vaccine for those in the 6 to 23 months of age group was 11.0 weeks (range: 8.6 to 20.0 weeks) and for the 2 to 4-year-old group, was 10.7 weeks (range: 8.6 to 15.6 weeks). Approximately 33% had received three doses as of the 29 April 2022 data cut-off date.

Among participants aged 2 to < 5 years without prior SARS-CoV-2 infection up to one month post-Dose 2 who received Pfizer (COMIRNATY) (maroon cap) 3 micrograms, the geometric mean ratio (GMR) of neutralising titres against the SARS-CoV-2 wild-type strain was 0.61 (2-sided 95% CI: 0.53, 0.70), when compared to young adults between 16 and 25 years who received Pfizer (COMIRNATY) (purple cap) 30 micrograms. In this population, 96.7% of children and 97.6% of young adults achieved a seroresponse at one month post-Dose 2 with a difference between age groups (children minus young adults) of -0.9% (2-sided 95% CI: -4.3%, 2.3%). Among participants aged 6 months to < 2 years without prior SARS-CoV-2 infection up to one month post-Dose 2 who received Pfizer (COMIRNATY) (maroon cap) 3 micrograms, the GMR of neutralising titres against the SARS-CoV-2 wild-type strain was 1.03 (2-sided 95% CI: 0.90, 1.19), compared to young adults between 16 and 25 years who received Pfizer (COMIRNATY) (purple cap) 30 micrograms. In this population, 98.0% of

children 6 months to < 2 years and 96.2% of young adults 16 to 25 years achieved a seroresponse at one-month post-Dose 2 with a difference between age groups (children minus young adults) of 1.7% (2-sided 95% CI: -1.4%, 5.2%).

The Dose 3 evaluable immunogenicity population included 204 children from 2 to < 5 years of age who received three doses of Pfizer (COMIRNATY) (maroon cap) 3 micrograms and 92 children who received placebo, of whom 143 and 59 participants respectively were without prior evidence of SARS-CoV-2 infection up to one month after Dose 3. The comparator group of young adults 16 to 25 years of age included 183 participants in the Pfizer (COMIRNATY) (purple cap) vaccine 30 microgram group and 45 participants in the placebo group of Study C4591001, of whom 170 and 38 respectively were without prior evidence of SARS-CoV-2 infection up to one month after Dose 2.

Among children 2 to < 5 years of age, the observed Geometric mean titre (GMT) was 20.7 before vaccination and progressively increased with two and three doses of vaccination, to a GMT of 1535 at one month post-Dose 3. The Dose 3 evaluable immunogenicity population included 132 children 6 months to < 2 years of age who received three doses of Pfizer (COMIRNATY) (maroon cap) vaccine 3 micrograms and 67 who received placebo, of whom 82 and 49 participants, respectively, were without prior evidence of SARS-CoV-2 infection up to one month after Dose 3. The comparator group of 16 to 25-year-olds is the same adult group used for immunobridging analysis for the 2 to < 5 years of age group. Similar to older children (2 to < 5 years of age), in younger participants the observed GMT progressively increased with two and three doses of vaccination, to be 1406.5 at one-month post-Dose 3.

Among 34 children from 2 to < 5 years of age without evidence of prior SARS-CoV-2 infection who received three doses of Pfizer (COMIRNATY) (maroon cap) vaccine 3 micrograms, neutralising GMTs prior to vaccination with Dose 3 against Delta (68.0) and Omicron (14.0) were increased at one month post-Dose 3 with respect to both Delta (471.4) and Omicron (82.5).

Correspondingly, increases were also observed for the reference strain from before Dose 3 (70.1) to one month post-Dose 3 (471.4). There was an observed 6.9-fold increase in Delta and a 5.9-fold increase in Omicron neutralising titres from before Dose 3 to one month post-Dose 3. The geometric mean fold rise (GMFR) for the reference strain from before Dose 3 to one month post-Dose 3 was 6.7.

From the currently available data, it can be concluded that a 3-dose Pfizer (COMIRNATY) (maroon cap) vaccine course is efficacious in protecting individuals from 6 months to 4 years of age against symptomatic COVID-19 based on non-inferior immune responses. This is supported by descriptive efficacy analyses. The safety profile is acceptable, and no new safety signals have been identified.

More information can be found in:

- Product Information;
- COVID-19 Vaccination: How COVID-19 vaccines work;
- ATAGI Clinical guidance for COVID-19 vaccine providers; and
- COVID-19 vaccination – Patient resources.

Why should children be vaccinated with a COVID-19 vaccine?

In Australia and internationally there has been a significant number of COVID-19 infections occurring in children aged 6 months to 5 years. Even though the number of infections has been high amongst this age group, studies have shown that severe infections have been low (that is those that require hospitalisation, intensive care admissions or that result in death) (ATAGI, 2022k).

In both healthy and immunocompromised children, severe COVID-19 infection is very rare. Unpublished hospitalisation data from tertiary paediatric hospitals and the Paediatric Active Enhanced Disease Surveillance (PAEDS) network reviewed by ATAGI, have revealed that there has been a low burden of severe disease in children who have been infected with the currently circulating Omicron variants (ATAGI, 2022k).

COVID-19 may be complicated by paediatric inflammatory multisystem syndrome temporarily associated with having COVID-19 (PIMS-TS, also known as MIS-C), a rare and potentially life-threatening syndrome that occurs in ~1 in 3,000 children after COVID-19 infection. With the currently circulating Omicron variants, the rates of PIMS-TS are up to 95% lower and episodes are observed to be milder. Children aged 6 months to 5 years are at a lower risk of PIMS-TS than older children (ATAGI, 2022k). To date, there have been no PIMS-TS associated deaths.

ATAGI recommends COVID-19 vaccination for **children aged 6 months to 4 years** with severe immunocompromise, disability, and those who have complex and/or multiple health conditions which increase the risk of severe COVID-19. These include children with the following or similar conditions:

- Severe primary or secondary immunodeficiency, including those undergoing treatment for cancer or on immunosuppressive treatments as listed in the ATAGI advice on third primary doses of COVID-19 vaccine in individuals who are severely immunocompromised;
- Bone marrow or stem cell transplant, or chimeric antigen T-cell (CAR-T) therapy;
- Complex congenital cardiac disease;
- Structural airway anomalies or chronic lung disease;
- Type 1 diabetes mellitus;
- Chronic neurological or neuromuscular conditions; or
- A disability that requires frequent assistance with activities of daily living, such as severe cerebral palsy or Down Syndrome (Trisomy 21).

(ATAGI, 2022p)

ATAGI does not currently recommend vaccination for children aged 6 months to < 5 years who are **not** in the above risk categories for severe COVID-19 as these children have a very low likelihood of severe illness from COVID-19 (ATAGI, 2022p).

More details on the indirect and direct benefits of COVID-19 vaccination in children are provided here (ATAGI, 2022p).

Topic 2: Cold chain and thawing

Thawed storage and deliveries

Deliveries of **thawed, undiluted** vaccines will be received at **+2°C to +8°C** and must continue to be stored at **+2°C to +8°C**, unopened, for a single maximum period of up to **10 weeks**, within the **12-month shelf life** (ATAGI, 2021b)**.**

The thawed date and new use-by date (calculated as 10 weeks after the thaw date) will be labelled on the carton prior to dispatch from the logistics provider.

Check that the thawed date and use-by date have been labelled on the outer carton when delivered. The label on the carton will reflect the refrigerated thaw use-by date and the manufacturer expiry date. The earlier of these two dates must be applied.

The manufacturer expiry date can also be checked when completing the relevant Delivery Acceptance report in the COVID-19 Vaccine Administrative System (CVAS) at health.gov.au/cvas. Providers must record the expiry dates for each delivery at the time of doing the delivery acceptance in CVAS.

All vials must be stored in their original carton to protect them from exposure to light including room and sunlight (TGA, 2022e).

Frozen storage and deliveries

Frozen storage of unopened Pfizer (COMIRNATY) (maroon cap) vaccine requires ultra-cold chain (UCC) management. The vials can be stored frozen at **-90°C to -60°C** for up to **12 months** (ATAGI, 2021b; TGA, 2022e).

Deliveries of frozen vaccines will be received at **-90°C to -60°C**. Once a frozen delivery is received, the vaccines must then be either **stored at -90°C to -60°C** or **thawed** in standard cold chain conditions at **+2°C to +8°C** (TGA, 2022e).

Once removed from frozen storage, the unopened vials may be stored refrigerated at +2°C to +8°C for a single period of up to 10 weeks within the 12-month shelf life (ATAGI, 2021b; TGA, 2022e)**.** Upon moving the product to +2°C to +8°C storage, the use-by date must be written on the outer carton and the vaccine should be used or discarded by the earliest of both the thaw and manufacturer use-by dates.

All vials must be stored in their original carton to protect them from exposure to light including room and sun light (TGA, 2022e).

Thermal shippers will be used to deliver the vaccines. Thermal shippers are boxes that contain a freezer carton of 60 packs. The carton is submerged in dry ice pellets and can maintain UCC (-75°C ± 15°C) during transport.

Once empty of vials and before sending back, the thermal shipper should be left open in a well-ventilated area where the dry ice will readily sublime (melt from solid to gas) into carbon dioxide gas and dissipate. Dry ice should not be left unattended.

Unpacking frozen deliveries

Proper personal protective equipment (PPE) must be worn when handling dry ice. If you are in a facility with UCC storage, additional dry ice handling material may be received from the manufacturer. However, state and territory guidelines on dry ice handling should also be followed.

The following information details how to unpack Pfizer (COMIRNATY) (maroon cap) deliveries. Most vaccine providers will receive the vaccine thawed from logistics providers so will NOT need to follow the below steps which are for UCC/frozen deliveries only**.**

This information is current as at 1 June 2022 but is subject to change.

Frozen deliveries from DHL:

1. Proceed using PPE gloves and safety goggles and open the thermal shipper.
2. Turn the TempTale Ultra data logger off.
3. Utilise the bag or blue strapping above the dry ice surface and pull the vaccine tray(s) through the dry ice.
4. Place the vaccine trays into your -90°C to -60°C freezer.

5. Please dispose of all dry ice from the thermal shipper. The thermal shipper cannot contain any dry ice when returned.
6. Place the temperature device TempTale Ultra and TrackIT device back into the empty thermal shipper.

Thawing

Prior to a vial being opened and diluted, the vaccine must first be thawed. When **thawing from -90°C to -60°C**, the vaccine can be thawed in either **cold chain conditions (+2°C to +8°C) or at room temperature (up to +30ºC)** (TGA, 2022e).

When frozen vaccines are being moved into standard cold chain conditions, the manufacturer expiry date must be crossed off on the outer carton and the thaw use-by date, **10 weeks** from today written in its place, assuming this date is sooner than the manufacturer use-by date. If the manufacturer expiry date is in less than 10 weeks, the manufacturer expiry date must remain as it cannot be extended (TGA, 2022e).

A 10-vial pack may take **2 hours to thaw in cold chain conditions (+2°C to +8°C).** If required, individual vials can be **thawed in room temperatures up to +30ºC for 30 minutes** (TGA, 2022e).

Including thawing time, **unopened vials** may be stored at room temperature, **between +8ºC and +30ºC for up to 12 hours**. The vial must be used or discarded within this timeframe (TGA, 2022e).

If you suspect your vaccines may have been involved in a cold chain breach (CCB), either within the clinical setting or during transit:

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 Vaccine Operations Centre (VOC) on 1800 318 208, providing as much information and temperature data as possible to aid in the assessment.
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 cold chain breach is specific to COVID-19 vaccines, and not stated in the National Vaccine Storage Guidelines.

Please see Appendix 5 for the steps to be followed if a potential CCB occurs.

Once thawed, the vial CANNOT be re-frozen. Thawed vials can be handled in room light conditions (TGA, 2022e).

Delivery acceptance (thawed or frozen)

Delivery acceptance reporting must be completed by all sites and completed by the authorised person in charge of accepting deliveries of the vaccine into the COVID-19 Vaccine Administrative System (CVAS). 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.

Stock management reports can be completed by relevant personnel within the administration site who have access to CVAS for that account.

All ordering and stock management should now be submitted through CVAS at health.gov.au/cvas

- Delivery Acceptance reports must be completed on the day of delivery (as soon as possible).
- Stock Management reports must be submitted no later than 9pm (local time) Friday every week (if your site is unable to submit the report on Friday, please submit on the Wednesday or Thursday prior).

Orders must be placed by 11:59pm Friday for delivery the following fortnight. (Note that new orders can only be placed if the previous week's stock management report has been completed).

Providers must record and check the manufacturer expiry date and the thaw use-by date at the time of completing the Delivery Acceptance forms in the CVAS at health.gov.au/cvas.

Topic 3: Preparation and administration

After thawing is complete, the vial is ready to be diluted and administered.

Some providers will receive the Pfizer (COMIRNATY) (maroon cap) vaccine thawed. **Unopened thawed vials** can be stored at **+2°C to +8°C** for a maximum of **10 weeks**.

Expiry dates must be followed precisely to prevent expired stock being administered. There are two expiry dates that must be observed on Pfizer (COMIRNATY) (maroon cap) vaccines: the manufacturer expiry date and the thaw use-by date. Both must be checked prior to every vaccine administration.

The manufacture expiry date indicates the expiry for the vaccine when stored frozen. The thaw use-by date commences when the vials are removed from the freezer or UCC storage to commence thawing and may be written on either 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**.

To prevent administration errors all sites should clearly label the thaw use-by date, 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 (VAEs). If vaccines are administered outside either expiry date, it is considered a VAE. The VOC on **1800 318 208** is available to provide advice and guidance to clinicians regarding the management of VAEs. Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Before beginning any dose preparation or administration, double-check you have the correct vaccine brand and formulation: Pfizer (COMIRNATY) (maroon cap) and confirm the expiry date.

The storage requirements, dosage, diluent amount and expiry for each vial type are different and great care must be taken to avoid any incorrect administration. It is recommended that facilities store the vaccines and supplies in dedicated containers in separate spaces, such as in clearly labelled shelves (or fridges, if possible) and use colour coding to differentiate between prepared doses for children aged 6 months to 4 years Pfizer (COMIRNATY) (maroon cap), and other Pfizer (COMIRNATY) vaccine. Where possible, separate drawing-up spaces may be designated, with separate staff preparing each formulation.

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Dilution

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 particles (TGA, 2022e).

Dilute the Pfizer (COMIRNATY) (maroon cap) vaccine by injecting **ONLY** 2.2 mL of sterile **sodium chloride (0.9%) for injection** into the vial. Aseptic technique must be maintained as described in Module 4, Topic 2. For a quick review, read the section below:

Gathering and preparing the vial for use:

1. Perform hand hygiene with either soap and water or an alcohol-based rub.
2. Clean and disinfect the separate area for preparation and procedure dish or tray.
3. Collect the required equipment (as outlined earlier in Module 4, Topic 2 in the 'vaccine administration checklist per person').
4. Remove the required vaccine vial (only one at a time) from the cold chain storage system used and check the temperature while doing so.
5. Double check you have the correct vaccine before opening the vial, ideally with another health professional if available, and as per your facility and jurisdictional policies.
6. Check the manufacturer expiry date, the thaw use-by date and date and time that the vial was opened. DISCARD the vaccine if it exceeds any expiry date and time. If you are opening the vial for the first time, record the current date and time on the vial, before opening it.
7. Examine the vaccine vial gently and ensure there is no discolouration or turbidity as per the product information by inverting it gently 10 times. If you are unsure of its appearance, **DO NOT** use and seek advice from the VOC on **1800 318 208**.
8. Perform hand hygiene.
9. Open the vial (if applicable) and check the bung (also known as the septum/stopper/diaphragm) integrity.
10. Disinfect the bung using a 70% isopropyl alcohol wipe.
11. Allow to fully dry for 30 seconds.

Dilution of Pfizer (COMIRNATY) (maroon cap) vaccine:

Only thawed vials can be opened and diluted in preparation for administration. The vial should contain white to off-white opaque amorphous particles (TGA, 2022e).

Follow the below steps to dilute the vial using an aseptic technique:

1. Check the expiry date on the carton and/or vial as applicable.
2. Allow the thawed vial to come to room temperature and gently invert the vial fully 10 times. Do not shake. Prior to dilution, the thawed vaccine may contain white to off-white opaque amorphous particles.

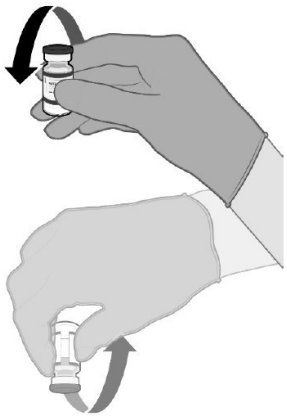

Image 1: Gently invert the vial 10 times (TGA, 2022e).

3. Pop off the plastic cap, being careful not to touch the rubber bung and maintain aseptic technique. If the rubber bung is touched or contaminated, clean with a 70% isopropyl alcohol wipe thoroughly and allow to dry for 30 seconds prior to use.
4. Prepare **2.2mL** of sodium chloride (0.9%) solution for injection in a 3mL syringe using a 21 gauge or narrower needle.
5. Inject the 2.2mL into the vial carefully.

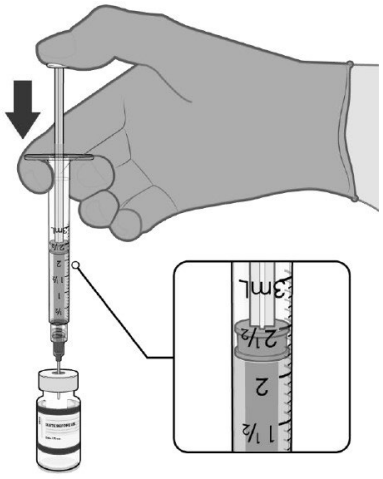

Image 2: Inject 2.2mL of sodium chloride into the vial (TGA, 2022e).

6. Once 2.2mL of sodium chloride is injected into the vial, leave the needle and syringe in and withdraw 2.2mL of air from the vial into the now empty syringe to equalise the pressure in the vial.

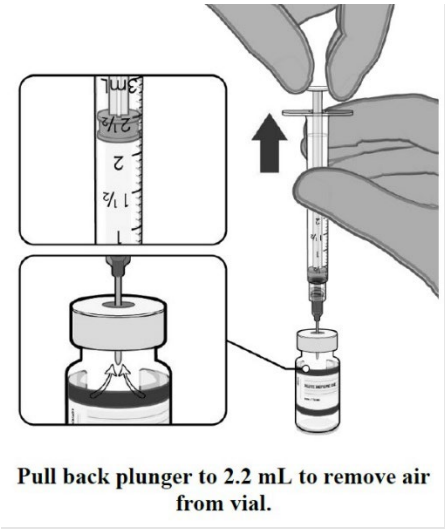

Image 3: Withdraw 2.2mL of air to equalise the vial pressure (TGA, 2022e).

7. Remove the needle and syringe containing 2.2mL of air and dispose of immediately in a sharps container.

8. Gently invert the diluted vial fully 10 times. Do not shake.

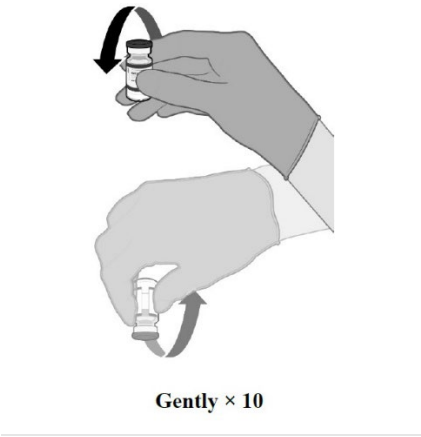

Image 4: Gently invert the vial 10 times (TGA, 2022e).

9. The diluted vial should now contain a white to off white dispersion with no visible particulates. DO NOT use the vial if particulates or discolouration are present and seek advice from the VOC.

10. **Mark the diluted vial immediately with the new expiry date and time** and use within 6 hours from the time of dilution. If the vial is not used within 6 hours from dilution, the vial must be discarded.

Image 5: Record appropriate date and time on the vial immediately (TGA, 2022e)

11. The open and diluted vial may now be stored in cold chain or room temperature conditions, **in the range of +2°C to +30°C and used within 6 hours from the time of dilution**.

(TGA, 2022e).

After dilution, check and ensure that the date and time have been recorded on the vial for safety. DO NOT freeze the diluted vaccine.

Dose preparation:

Prior to each vaccination, ensure <u>all</u> relevant expiry dates and times are checked.

The vial should be allowed to come to room temperature before administration if it is taken from the fridge. **Undiluted vials** can be stored for **up to 12 hours** (including thawing time) at room temperature. **Diluted vials** can be stored for **up to 6 hours** at **+2°C to +30°C.**

Follow all preparation instructions as reviewed in this topic before dilution. Ensure that the vial has not expired and that it has been **less than 6 hours** since the vial was diluted by checking the date and time on the vial. **DO NOT** use if the vial has been opened without a date and time of dilution.

To extract the full 10 doses from the MDV, low dead-volume 1mL Luer-Lock syringes and needles are strongly recommended when available. Standard needles and 1mL syringes can be used if this is the supplied and available stock. The syringe and needle should have a combined dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a tenth dose from a single vial (TGA, 2022e).

If a full dose cannot be drawn up from the remaining liquid in an MDV, it must be discarded as doses cannot be drawn from multiple MDVs (TGA, 2022e).

A single dose of Pfizer (COMIRNATY) (maroon cap) is 0.2mL. Double-check this before administration (TGA, 2022e).

Care should be taken to draw up the dose volume exactly (TGA, 2022e). When entering the vial multiple times, ensure that each re-puncture occurs as a different site.

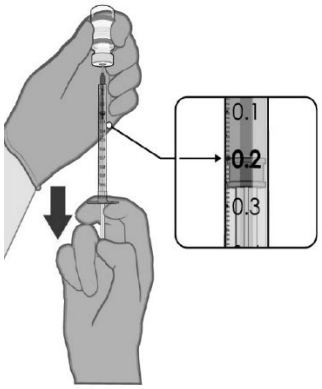

Image 6: Withdraw one dose of diluted vaccine, 0.2mL (TGA, 2022e).

Dosing and schedule

Pfizer (COMIRNATY) (maroon cap) is administered as an intramuscular (IM) injection containing 0.2mL of the diluted vaccine. This is equal to 3 micrograms.

A total of three primary course doses are required. The recommended schedule for vaccination in this age group is three doses, 8 weeks apart (ATAGI, 2022p).

Children who turn 5 years old after their first or second dose of the Pfizer (COMIRNATY) (maroon cap) should receive a Pfizer (COMIRNATY) (orange cap) dose of the vaccine for the remaining dose(s) to complete the 3-dose primary course (ATAGI, 2022c).

To reduce the risk of administration errors, the paediatric and adolescent/adult formulations of the Pfizer (COMIRNATY) vaccine vials and prepared doses should be stored separately from each other in clearly marked areas, including in dedicated containers in separate spaces (e.g. in 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 (ATAGI, 2021g).

Refer to and download the COVID-19 Vaccines in Australia posters for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Vaccine administration errors (VAEs)

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training undertaken to minimise the risk of VAEs occurring (ATAGI, 2022a).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible VAEs, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022a). The VOC on **1800 318 208** is available to provide advice to clinicians regarding the management of VAEs.

Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Please see Appendix 4 for the steps to be followed if a vaccine administration error occurs.

Administration

Administer the vaccine as an intramuscular injection (IMI). The recommended site for infants **<12 months** is the vastus lateralis muscle in the anterolateral thigh. **DO NOT** use the deltoid muscle for infants <12 months (ATAGI, 2022q). **DO NOT** inject intravascularly, subcutaneously or intradermally (ATAGI, 2021b).

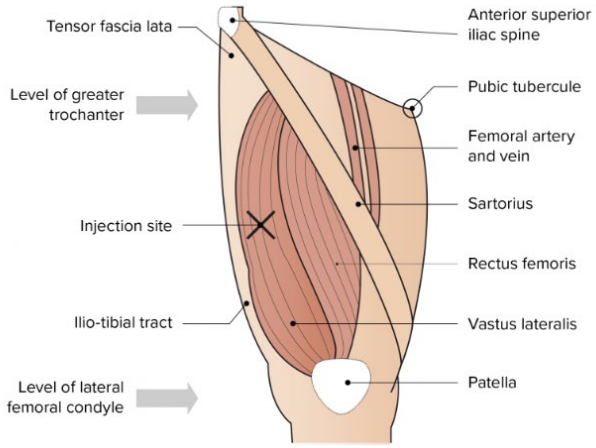

Image 7: Anatomical markers used to identify the vastus lateralis injection site on the anterolateral thigh for infants <12 months

For children **>12 months** administer the vaccine as an intramuscular injection (IMI) in the deltoid muscle. **DO NOT** inject intravascularly, subcutaneously or intradermally (ATAGI, 2021b).

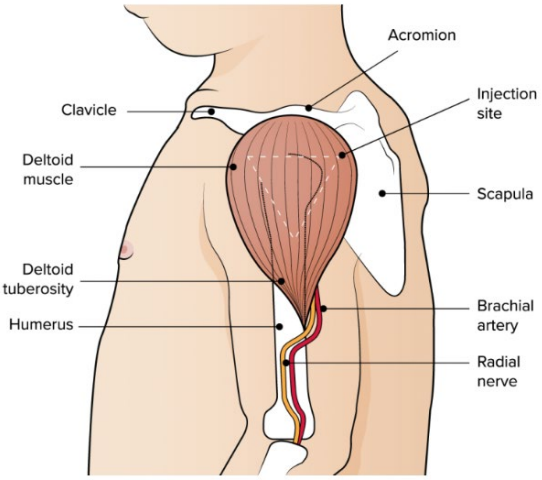

Image 8: Anatomical markers used to identify the deltoid injection site

A new sterile syringe and needle must be used for administration to each individual. Do not mix or contaminate the vaccine with any other medication or liquid. If a full dose cannot be extracted from one vial, then that part dose and vial must be discarded (TGA, 2022e).

Based on a review of the available evidence, ATAGI does not recommend routinely aspirating (drawing back) needles before injection. This practice was rejected some decades ago, due to several disadvantages including prolonging the procedure, potentially associated pain, and increasing the risk of needle-syringe disconnection. Not aspirating is supported by the current advice in the Australian Immunisation Handbook (ATAGI, 2022q).

COVID-19 vaccines should be prepared by qualified healthcare professionals using aseptic technique to maintain sterility of the doses during required dilution and dose preparation.

The **preferred** extraction method for single or multiple doses of the Pfizer (COMIRNATY) (maroon cap) is to use the same needle to draw up and administer the vaccine, to avoid the potential loss of volume when changing needles. An aseptic procedure must be used throughout the procedure as there is a potential for a lower frequency of injection site reactions using this technique. The steps to complete this process are exactly as described in Module 4 (and video 3), except the needles are not changed. The needle can be recapped using aseptic technique if not being administered immediately (ATAGI, 2021g). Seek advice from your **Public Health Unit (PHU)** as to when this may be appropriate.

ATAGI recommendations must be followed over product information.

Storing vials and vaccine doses

After initial puncture for dilution, vials can be stored **up to 12 hours** at **+2°C +30°C** and must be used within the 12 hours (Pfizer, Australia, 2021c). 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 re-freeze 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.

Pre-drawn vaccine doses in syringes are treated differently from diluted or open vials. Please refer to the ATAGI Transport, storage and handling webpage for ATAGI recommendations on diluted or open vials.

After administration, the vaccine dose administered, including batch and vial serial number, must be entered into the Australian Immunisation Register (AIR) as described in Module 5, Topic 4.

All sharps with syringes still attached (such as after administration) should be discarded in a sharps waste container. The vials and other consumables should be disposed of in the clinical waste bin in accordance with local requirements.

Topic 4: Precautions

ATAGI will closely monitor data that may become available regarding the use of the Pfizer (COMIRNATY) (maroon cap) vaccine in children from both overseas and within Australia and will continue to update recommendations based on the latest available evidence (ATAGI, 2022p).

Adverse events following immunisation (AEFI) report should be submitted to the TGA or your state/territory health department using established mechanisms as discussed in Additional Module 1. All AEFI reports are reviewed by the TGA.

Any error of administration, including 0.2mL/10 microgram Pfizer (COMIRNATY) (orange cap) vaccine dose given to a child aged 6 months to 4 years of age, must be reported as a Vaccine Administration Error (VAE) to your local public health unit (PHU) or public health authority of your state/territory or

to the Vaccine Operations Centre (VOC) on **1800 318 208** (check with your employer about your organisation's processes for reporting VAEs). Refer to Additional Module 1 and *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Anaphylaxis – As per Additional Modules 1 and 4.

Previous SARS-CoV-2 infection – As per Additional Modules 1 and 4.

Immunocompromised individuals

ATAGI recommends COVID-19 vaccination for **children aged 6 months to 4 years** with severe immunocompromise, disability, and those who have complex and/or multiple health conditions which increase the risk of severe COVID-19. These include children with the following or similar conditions:

- Severe primary or secondary immunodeficiency, including those undergoing treatment for cancer, or on immunosuppressive treatments as listed in the ATAGI advice on third primary doses of COVID-19 vaccine in individuals who are severely immunocompromised;
- Bone marrow or stem cell transplant, or chimeric antigen T-cell (CAR-T) therapy
- Complex congenital cardiac disease;
- Structural airway anomalies or chronic lung disease;
- Type 1 diabetes mellitus;
- Chronic neurological or neuromuscular conditions; or
- A disability that requires frequent assistance with activities of daily living, such as severe cerebral palsy or Down Syndrome (Trisomy 21).

(ATAGI, 2022p)

ATAGI does not currently recommend vaccination for children aged 6 months to < 5 years who are **not** in the above risk categories for severe COVID-19 as these children have a very low likelihood of severe illness from COVID-19 (ATAGI, 2022p).

More details on the indirect and direct benefits of COVID-19 vaccination in children are provided here (ATAGI, 2022p).

Myocarditis and pericarditis – As per Additional Modules 1 and 4.

Further detail regarding myocarditis and pericarditis following administration of mRNA vaccines is available here.

Concurrent illness – As per Additional Modules 1 and 4.

Vaccine co-administration - ATAGI recommends that where possible a minimum interval of 7-14 days is recommended between a Pfizer (COMIRNATY) (maroon cap) vaccine and other vaccines in children aged 6 months to 4 years, to minimise the risk of adverse events such as fever (ATAGI 2022c).

Data on the potential for co-administration with other vaccines are currently being reviewed and detailed information will be included in the ATAGI clinical guidance for COVID-19 vaccine providers (ATAGI, 2021b).

Topic 5: Adverse events

General adverse events have been discussed in Module 6 Topic 2. The Pfizer (COMIRNATY) (maroon cap) vaccine was demonstrated to be well tolerated in 6 months to 4-year-old children in the phase II/III clinical trial, with most adverse events being mild and transient.

Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side-effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website. For more information, please refer to Core Module 6.

COVID-19 vaccines are well tolerated by children. The following list identifies the frequency of very common AEFI in completed clinical trials of those 6 months to less than 4 years of age:

- Injection site pain – 26.7% of individuals.
- Fatigue – 24.5% of individuals.
- Headache - 4.9% of individuals.
- Injection site redness and swelling – 2.7%-10.9% of individuals.
- Myalgia and chills - 2.0%-3.3% of individuals.

(TGA, 2022e)

Other symptoms to be aware of include:

- Diarrhoea (common)
- Vomiting (common)
- Arthralgia (common)
- Pyrexia (common)
- Lymphadenopathy (uncommon)
- Hypersensitivity reactions including urticaria, pruritis and rashes (uncommon)
- Decreased appetite (uncommon)
- Nausea (uncommon)
- Pain in extremity (uncommon)
- Malaise (uncommon)
- Anaphylaxis (unknown frequency).

(TGA, 2022e)

Consumer medicine information and the COVID-19 vaccination – Patient resources can be given to parents or guardians of children receiving the vaccine which detail what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for your state or territory, please review this website.

Module Summary

- The Pfizer (COMIRNATY) (maroon cap) is a mRNA vaccine. The vaccine vial is distinguishable by its maroon cap.

- The Pfizer (COMIRNATY) (maroon cap) vaccine is strictly for **eligible** children aged 6 months to 4 years. The Pfizer (COMINARTY) (orange cap) vaccine should not be administered to children under the age of 5.
- Thawed and unopened vials can be stored in cold chain conditions of +2°C to +8°C for a maximum of 10 weeks (within the 18-month shelf life) before they expire.
- Always check the manufacturer expiry date AND the thaw use-by date prior to opening. The earlier date must be used.
- The multi-dose vial contains 10 doses of 0.2mL per dose once thawed and then diluted with 2.2mL of sodium chloride (0.9%) for injection. Write the new vial expiry date on the vial immediately after diluting.
- **After initial puncture** for dilution, vials can be stored **up to 12 hours** at **+2°C +30°C** and must be used within the 12 hours. 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.
- If available, low dead volume needles and syringes should be used to ensure the full number of doses can be extracted.
- The Pfizer (COMIRNATY) (maroon cap) vaccine is given as a **3-dose primary** schedule intramuscularly into the vastus lateralis muscle in the anterolateral thigh for infants <12 months and into the deltoid muscle for children >12 months.
- The recommended dose interval between doses is 8 weeks.
- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

References

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Multi-choice questions

1. What is the ATAGI recommended dose and interval of Pfizer (COMIRNATY) (maroon cap) **3-dose schedule** for infants/children aged between 6 months and 4 years?

    a. 0.2mL/10 micrograms 3 weeks apart
    b. 0.2mL/3 micrograms 8 weeks apart
    c. 0.2mL/10 micrograms 8 weeks apart
    d. 0.2mL/3 micrograms 4 weeks apart

2. Which of the statements regarding Pfizer (COMIRNATY) (maroon cap) dosing is CORRECT?

    a. The 6 months to 4-year-old dosing of Pfizer (COMIRNATY) (maroon cap) is recommended to be used for all primary doses, even if the child turns 5 after their first dose.
    b. The 5 to <12-year-old Pfizer (COMIRNATY) (orange cap) dosing should be used for all primary doses for children who are due to turn 5 before their third primary dose is due.
    c. The 6 months to 4-year-old Pfizer (COMIRNATY) (maroon cap) dosing can be used for children who have already turned 5 years old.
    d. **The 6 months to 4-year-old Pfizer (COMIRNATY) (maroon cap) dosing can only be used for infants/children who are <5 years old. If the child turns 5 before their primary course is completed, it is advised for them to receive the same age-appropriate brand of vaccine which was used for their first dose.**

3. Pfizer (COMIRNATY) is provided in three presentations. How is the correct multi-dose vial identified for infants and children aged 6 months to 4 years?

    a. 30 micrograms/0.3mL multi-dose vials WITH A GREY Cap
    b. 3 micrograms/0.2mL multi-dose vial WITH A MAROON Cap
    c. 10 micrograms/0.3mL multi-dose vials WITH A PURPLE Cap
    d. 10 micrograms/0.2mL multi-dose vials WITH AN ORANGE Cap

4. Which of the following statements on the site of administration is INCORRECT for infants aged <12 months?

    e. The Pfizer (COMIRNATY) (maroon cap) vaccine should be administered as an intramuscular injection.
    f. The recommended site for infants <12 months is the vastus lateralis muscle in the anterolateral thigh.
    g. The deltoid muscle MUST NOT be used for infants <12 months old.

h. The Pfizer (COMIRNATY) (maroon cap) vaccine can be injected intravascularly, subcutaneously or intradermally in children aged 6 months to 4 years.

Additional Module 5: COVID-19 Vaccine Novavax (NUVAXOVID)

(21/09/2023)

This module is suitable for all healthcare professionals administering COVID-19 vaccines.

The recommended time for completion is 30 minutes. Each topic must be worked through in order and there are multi-choice questions to pass before this module is complete.

Learning objectives

At the end of this module, it is expected that you will be able to:

- Understand the appropriate dosing and schedule for administration of the Novavax (NUVAXOVID) vaccine.
- Understand the appropriate dose preparation and administration of the Novavax (NUVAXOVID) vaccine.
- Understand the contraindications, warnings, adverse reactions, and recommendations for co-administration with other vaccines for the Novavax (NUVAXOVID) vaccine.
- Understand the appropriate storage and handling of the Novavax (NUVAXOVID) vaccine.

Topics

1. Introduction and summary
2. Cold chain storage and disposal
3. Preparation and administration
4. Precautions and contraindications
5. Adverse events

Topic 1: Introduction and summary

The Novavax (NUVAXOVID) vaccine was provisionally approved by the Therapeutic Goods Administration (TGA) in Australia on 20 January 2022. A booster dose of the Novavax (NUVAXOVID) vaccine, has also been provisionally approved by the TGA on 9 June 2022. The vaccine is registered for use in **people aged 18 years and over.** On 28 July 2022, the TGA provisionally approved Novavax (NUVAXOVID) for use as a primary course for adolescents aged 12 to 17 years (TGA, 2021d; TGA, 2022; Novavax, 2022a; ATAGI, 2022l).

The vaccine name is NUVAXOVID SARS-CoV-2 rS (NVX-CoV2373) (Novavax, 2022a).

This vaccine uses a recombinant spike (rS) protein which is produced using recombinant DNA technology in an insect cell of the *Spodoptera frugiperda* species using a baculovirus. The baculovirus encodes the full SARS-CoV-2 spike gene producing trimeric spike proteins.

The vaccine is adjuvanted with Matrix-M. Matrix-M adjuvant contains Quillaja saponaria saponins fractions A and C. The two vaccine components elicit B and T lymphocyte immune responses to the spike protein (Novavax, 2022a).

The Novavax (NUVAXOVID) vaccine **CANNOT** cause COVID-19 or any other disease.

This vaccine is NOT a live-attenuated vaccine and therefore live vaccine precautions are NOT required for this vaccine.

Vaccination with Novavax (NUVAXOVID) will not affect a polymerase chain reaction (PCR) swab test used to detect COVID-19. Results may be altered for serum antibody tests if they detect the spike protein antibodies.

Each multi-dose vial (MDV) contains **ten 0.5mL doses containing** 5 micrograms of SARS-CoV-2 rS protein and 50 micrograms of Matrix M adjuvant per dose. There are 10 MDVs in a pack (outer packaging) (Novavax, 2022a).

Figure 1. *Example of Novavax* (NUVAXOVID) *outer packaging*.

Figure 2. Example of Novavax (NUVAXOVID) 5mL vial

The MDV contains liquid which appears as colourless to slightly yellow and clear to mildly opalescent. There are no visible particles within the MDV (Novavax, 2022a).

The ingredients in Novavax (NUVAXOVID) include:

- Dibasic sodium phosphate heptahydrate
- Monobasic sodium phosphate monohydrate
- Sodium chloride
- Polysorbate 80
- Sodium hydroxide (for adjustment of pH)
- Hydrochloric acid (for adjustment of pH)
- Water for injections
- Matrix M adjuvant
    - Quillaja saponaria saponins fraction A
    - Quillaja saponaria saponins fraction C
    - Cholesterol
    - Phosphatidyl choline
    - Monobasic potassium phosphate
    - Potassium chloride

(Novavax, 2022a)

The vial is made of type I glass with a bromobutyl or chlorobutyl rubber stopper, aluminium overseal and blue plastic flip-cap.

Protection

It is essential to follow Department of Health and Aged Care (DHAC) and jurisdictional infection prevention and control guidelines for COVID-19 regardless of vaccination status.

Two phase III trials, conducted in the USA/Mexico and in the UK, assessed the efficacy of Novavax (NUVAXOVID) vaccine. Across these trials approximately 27,000 participants received the full 2 doses of vaccine, and approximately 17,000 received a placebo. A phase II trial conducted in South Africa included over 4000 participants and provided data on vaccine efficacy against the Beta variant of SARS-CoV-2 (Australian Technical Advisory Group on Immunisation [ATAGI], 2022a).

Vaccine efficacy (VE) against PCR-confirmed symptomatic mild, moderate or severe COVID-19 in serologically negative adults, with onset at least 7 days after 2nd dose was 90.4% (95% CI 82.88 - 94.62) in the US/Mexico trial, and 89.7% (95% CI 80.2 - 94.6) in the UK trial. The estimated VE against moderate or severe COVID-19 was 100% (95% CI 80.9 - 100) in the USA/Mexico trial, and 86.9% (95% CI 73.7 - 93.5) in the UK trial. In the South African phase II trial, VE among HIV-negative adults was 60.1% (95% CI 19.9 – 80.1) overall, and specifically against the Beta variant was estimated at 51% (95% CI -0.6 to 76.2). The significant difference in VE estimates between the American/UK trials and the South African trial has been attributed to the prevalence of the Beta variant in South Africa during the study period. However, other contributory factors cannot be excluded (ATAGI, 2022a).

A study is ongoing that involves adolescents aged 12 to 17 years. These adolescents received the same formulation of the Novavax (NUVAXOVID) vaccine that is authorised for use in adults aged 18 years and older. Among 1,799 trial participants aged 12 to 17 years without evidence of previous SARS-CoV-2 infection, the Novavax (NUVAXOVID) vaccine was 79.5% effective (95% CI: 46.8–92.1) at preventing laboratory-confirmed symptomatic COVID-19 from day 7 after dose 2 (with an interval of 3 weeks between doses).

The duration of protection is unknown and is still being determined in ongoing clinical trials. Individuals may not be fully protected until 7 days after their second dose (Novavax, 2022a).

In November 2021, the World Health Organisation (WHO) declared the Omicron variant as a Variant of Concern and a dominant strain globally. The effectiveness of currently available COVID-19 vaccines against the Omicron variant is not yet known. Laboratory studies suggest that a booster dose of an mRNA COVID-19 may be required to induce adequate neutralising antibody titres against this variant.

More information can be found in the:

- Product Information,
- COVID-19 vaccine information,
- ATAGI Clinical guidance for COVID-19 vaccine providers, and
- COVID-19 Vaccination: How COVID-19 vaccines work

Topic 2: Cold chain storage and disposal

Deliveries

Delivery acceptance reporting must be completed by all facilities and completed by the authorised person in charge of accepting deliveries of the vaccine. The delivery acceptance process is to notify the Department of Health and Aged Care of acceptance and any potential issues. This also allows the Commonwealth to meet key obligations.

Stock management reports can be completed within the COVID-19 Vaccine Administrative System (CVAS) by relevant personnel who have access to the CVAS for that account.

All ordering and stock management must be submitted through the CVAS at health.gov.au/cvas.

- Delivery Acceptance Reports must be completed on the day of delivery (as soon as possible).
- Stock Management Reports must be submitted no later than 9pm (local time) Friday every week (if your site is unable to submit the report on Friday, please submit on the Wednesday or Thursday prior).
- Orders must be placed by 11:59pm Friday for delivery the following fortnight (note that new orders can only be placed if the previous week's Stock Management Report has been completed).

Providers must record and check the manufacturer expiry date at the time of completing the Delivery Acceptance forms in the CVAS at health.gov.au/cvas.

Cold chain storage

Standard cold chain (+2°C to +8°C) procedures should be followed for all transport, storage and handling of the Novavax (NUVAXOVID) vaccine. For a review of the cold chain procedures please refer to Module 2 and also the *Strive for 5* guidelines (Department of Health and Aged Care [DHAC], 2019a).

The MDVs should be stored in their original outer packaging (pack) to protect them from light until ready for use.

The Novavax (NUVAXOVID) vaccine can be **stored** in cold chain conditions of **+2°C to +8°C** for a **maximum of 9 months**.

The TGA has approved a shelf-life extension of Novavax (NUVAXOVID) from 6 months to **9 months from manufacture date, provided that approved storage conditions have been maintained.**

Please be aware that the packaging associated with the above batch has not been amended to reflect the extended expiry dates. It is expected that all future batches will have the correct expiry date printed on the packaging and vials.

Store in the outer carton to protect the vials from light. **DO NOT FREEZE the vaccine.**

Unopened vials have been shown to be stable for up to **12 hours at +25°C**, however storage at +25°C is **not** the recommended storage or shipping condition.

After initial puncture, vials can be stored up to 12 hours at +2°C to +25°C (TGA, 2022d). 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 for the Novavax (NUVAXOVID) vaccine, 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.

ATAGI recommendations must be followed over product information.

Cold chain breach (CCB)

If you suspect your vaccines may have been involved in a cold chain breach (CCB), either 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 Vaccine Operation Centre (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.

A quick reference poster guide can be used for CCB management including reporting. Please note the requirement to contact the VOC in the event of a cold chain breach is specific to COVID-19 vaccines, and not stated in the National Vaccine Storage Guidelines.

Please see Appendix 5 for the steps to be followed if a potential CCB occurs.

Waste and disposal

All sharps with syringes still attached (such as after administration) should be discarded in a sharps waste container. The vials and other consumables should be disposed of in accordance with local requirements in the clinical waste bin.

Prior to disposal, the outer packaging (carton) should be defaced by striking through at least one panel of the carton with a Sharpie or similar marker.

The Novavax (NUVAXOVID) vaccine contains genetically modified organisms (GMOs). As a result, any unused vaccine or waste material should be disposed of in accordance with local requirements in a clinical waste bin and reported through the COVID-19 Vaccine Administrative System (CVAS) .

Incidents of fewer than 10 vials at a time must be reported as minor wastage in the weekly Stock Management Report in CVAS.

Major Wastage (10 or more vials)

A major wastage incident (e.g. damaged vials, expired vaccines or breach of cold chain requirements) is classified as one that includes 10 or more vials at a time. If more than 10 vials at a time are wasted, providers must submit a Wastage Report through the COVID-19 Vaccine Administrative System (CVAS) within 2 hours of the incident. You are no longer required to call the VOC to additionally report the wastage incident.

Any wastage of fewer than 10 vials in one incident should be reported through the minor wastage section of your weekly Stock Management report in CVAS (due no later than 9pm local time Friday every week).

Surfaces with any spillages of vial contents should be cleaned up immediately using a spill kit similarly to spills of other viral vaccines as per the National Health and Medical Research Council (NHMRC) *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (2019). Spills of the Novavax (NUVAXOVID) vaccine are relatively low risk as the protein subunit is unable to replicate (Office of the Gene Technology Regulator [OGTR], 2021).

A spill kit should contain the safety equipment and all items required to clean up a spill including gloves, masks, paper towels and a disposal bag etc. (NHMRC, 2019).

If a spill kit is not available, then the spilt contents can be decontaminated with an appropriate virucidal disinfectant.

Dose preparation

Prior to each vaccination, ensure all relevant expiry dates and times are checked.

Do **NOT** mix or contaminate the vaccine with any other medication or liquid.

Do **NOT** dilute the vaccine as the vial comes ready to use (Novavax, 2022a).

Each multidose vial contains a colourless to slightly yellow, clear to mildly opalescent suspension free from visible particles. The MDV must be inspected prior to preparation to ensure integrity of the sample as discussed in Topic 1. This is done to ensure that the contents of the vial do not contain any visible particulate matter and/or discolouration prior to administration. Do not administer the vaccine if either are present (Novavax, 2022a).

Once inspected, **gently swirl the multidose vial before and in between each dose withdrawal**. Do **NOT** shake (Novavax, 2022a).

If you are concerned about the appearance of the vial, label as **DO NOT USE** and seek advice from the Vaccine Operation Centre (VOC) on **1800 318 208**.

Ensure that the vial has not expired and that it has not reached the maximum time since opening (needle first penetrated the bung). If the vial has been opened and there is no clear indication of the

date and time of opening, the vial must be disposed of and accounted for in the weekly Stock Management Report in CVAS.

There is available space on the MDV to record the date and time first opened.

A sterile 19 to 21 gauge, bevelled drawing up needle is preferred for drawing-up. To extract the full 10 doses from the MDV, care should be taken to draw up the **0.5 mL** individual dose volume exactly. A 2 mL or 3 mL syringe is recommended for doses of 0.5 mL or greater such as with the Novavax (NUVAXOVID) vaccine, if stock is available. Otherwise a 1 mL syringe can be used.

Multiple doses can be drawn up at once. Each filled syringe must be stored with a capped administration needle and appropriately labelled as well as stored at the appropriate temperature. If doses are not planned to be administered one after another, then each dose should only be withdrawn as required.

Data on the stability of pre-drawn doses in syringes is not available for Novavax (NUVAXOVID) and therefore storing pre-drawn doses of this vaccine in syringes is not preferred. However, if pre-drawn doses are used the Australian Technical Advisory Group on Immunisation (ATAGI) advise that each drawn-up dose should be administered:

- as soon as practicable and within **1 hour** if stored at room temperature, or
- within **6 hours** if stored at **+2ºC to +8ºC**.

(DHAC, 2021g; ATAGI, 2021b).

Pre-drawn vaccine doses in syringes are treated differently than open vials. Please refer to the ATAGI Transport, storage and handling webpage for ATAGI recommendations on open vials.

Some liquid remaining within the vial after removing all doses is normal. If low dead-space syringes and/or needles are used an extra 0.5 mL dose may be drawn up.

When entering the vial multiple times, ensure that each re-puncture occurs at a different site on the bung. **Gently swirl the multidose vial before and in between each dose withdrawal.**

If a full dose cannot be drawn up from the remaining liquid in the MDV, it must be discarded as doses cannot be drawn from multiple MDVs and combined (Novavax, 2022a).

When handling the vaccine vial, ensure you do not shake the vial (Novavax, 2022a).

Home visits

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

- Preferably, transport the vial at +**2ºC to +8ºC** and not exceeding the total maximum storage period of **6 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 can be administered as soon as practical and not exceeding the total maximum storage period of **1 hour if at room temperature**, and within **6 hours if at 2°C to 8°C**.

More information can be found at the end of the ATAGI recommendations for Transporting, storing and handling COVID-19 vaccines (ATAGI, 2021b).

Topic 3: Preparation and administration

Dosing and schedule

The Novavax (NUVAXOVID) vaccine is administered as an intramuscular (IM) injection containing **0.5mL of vaccine**. Double-check the details of the vaccine and dose before administration, ideally with another health professional as described in Module 4.

ATAGI recommends a primary dosing schedule of Novavax (NUVAXOVID) of 2 doses, 8 weeks apart. The extended dosing interval of 8 weeks has been selected to be consistent with recommendations for other COVID-19 vaccines. Evidence from other COVID-19 vaccines has suggested that a longer dosing interval may improve vaccine effectiveness (ATAGI, 2021b).

The dosing interval can be shortened to a minimum of 3 weeks. This shorter interval can be used in specific circumstances for higher-risk groups (such as older people of those with medical risk factors for severe illness), or before international travel. Shortening of the recommended dose interval may result in a suboptimal immune response (ATAGI, 2021b).

ATAGI prefers the use of the same COVID-19 vaccine for the 2 doses of the primary course. An alternative vaccine brand for dose 2 should be used if there are specific medical contraindications or precautions, or the same vaccine brand is not available in Australia. It is preferable to use the same brand for both doses of the primary course, but an alternative brand can be used for the second dose for other reasons. Examples include if a person is unable to access the same brand or does not accept a second dose of the same brand. Emerging data support the safety and efficacy of mixed schedules (ATAGI, 2021b).

Refer to and download the COVID-19 Vaccines in Australia poster for further information on the key differences between each COVID-19 vaccine approved for use in Australia as per the ATAGI guidelines.

Severely immunocompromised individuals

A third primary dose of COVID-19 vaccine is recommended for all people aged 6 months or older with severe immunocompromise who are receiving a 2-dose primary course. The third dose should be given from 2 months after the second vaccine dose. A minimum interval of 4 weeks may be considered in exceptional circumstances (e.g., anticipated intensification of immunosuppression; outbreaks). People who have received a second dose more than 6 months ago should receive a third dose as soon as feasible (ATAGI, 2021w).

The third dose is intended to address the risk of lowered response or non-response to the standard 2-dose schedule. For more details on vaccine effectiveness in people who are immunocompromised, see COVID-19 vaccine information.

Individuals who currently are not severely immunocompromised but who will commence significant immunosuppressive therapy 2 or more weeks after their second dose do not require a third dose, as it can be expected that an adequate response to 2 primary doses will be achieved (ATAGI, 2021w).

For a comprehensive list of immunocompromising conditions and therapies for which a third primary dose is recommended please review the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

An age-appropriate formulation of an mRNA COVID-19 vaccine or the Novavax (NUVAXOVID) is recommended for the third dose. Most studies of third doses of COVID-19 vaccine in immunocompromised people have used mRNA vaccines.

There is very limited evidence of the efficacy of Novavax (NUVAXOVID) in immunocompromised people.

Booster doses

ATAGI **recommends** 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:

- 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.

ATAGI advises the following groups should **consider** a 2023 booster dose 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.

ATAGI advises that a booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19 and the 2023 booster dose is not a seasonal recommendation.

Development of seasonal immunisation policy to manage COVID-19 is limited as the evolution as well as duration and strength of protection against serious SARS-CoV-2 illness is uncertain at this time.

(ATAGI, 2023a)

Booster doses are not currently recommended for children aged under 5 years, or for children and adolescents aged 5 to 17 years who are not at increased risk of severe disease as defined above. Severe COVID-19 in children is uncommon and the primary course of COVID-19 vaccines generates a strong immune response. The benefit from additional doses of vaccine is likely to be small. Current evidence does not suggest that booster doses are needed at this time.

Booster dose: vaccine preference recommendations

Any age-appropriate COVID-19 vaccine, including original (ancestral virus-based) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer lasting protection against severe disease.

However, bivalent mRNA vaccines are preferred over other vaccines for people aged 12 years and older. These include:

- Pfizer bivalent BA.4-5 (COMIRNATY) (grey cap), for people 12 years and older.

- Moderna bivalent BA.4-5 (SPIKEVAX) (PFS), for people 12 years and older.
- Pfizer bivalent BA.1 (COMIRNATY) (grey cap), for people 18 years and older.
- Moderna bivalent BA.1 (SPIKEVAX) (blue cap, green label), for people 18 years and older.

Although not preferred, Novavax (NUVAXOVID) vaccines can be used as a booster dose in people aged 18 years and older in the following circumstances:

- people who have a contraindication to mRNA vaccines (including those who have had a serious adverse event following mRNA vaccines, such as a history of anaphylaxis or myocarditis attributed to an mRNA vaccine)
- people who do not prefer an mRNA vaccine.

Although not TGA-registered as a booster in this age group, Novavax (NUVAXOVID) can be used as a booster in people aged 12 years or older if no other COVID-19 vaccine brand is suitable for that person.

Pfizer (COMIRNATY) (orange cap) can be used in children aged 5 to 11 years.

Administration of a 2023 COVID-19 booster dose should aim to occur prior to June 2023 and at a time of 6 months or greater following the most recent COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (ATAGI, 2023a).

The evidence underpinning booster dose recommendations will continue to be reviewed and this clinical guidance may be refined. For more details see: COVID-19 vaccine information.

Vaccine administration errors (VAEs)

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidance. Immunisation providers should ensure that best practice is followed, and training undertaken to minimise the risk of VAEs occurring (ATAGI, 2022c).

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible VAEs, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered (ATAGI, 2022c). The VOC on 1800 318 208 is available to provide advice to clinicians regarding the management of VAEs.

Refer to *ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors* for further information.

Please see Appendix 4 for the steps to be followed if a Vaccine administration error occurs.

Administration

Pre-administration

Prior to administering the first dose of Novavax (NUVAXOVID), ensure that it is definitely the first dose the individual will receive. At the timing of the second dose, and prior to administration, ensure that the first dose given was the same COVID-19 vaccine brand to be used for the second dose. This can be done by looking up the individual's immunisation history through the Australian Immunisation Register (AIR), your clinical system (if integrated with the AIR), or the individual's My Health Record. Double check this information with the individual for accuracy.

It is recommended that all individuals who have received a Novavax (NUVAXOVID) dose receive the batch number for adverse event reporting. It is expected that ALL adverse events experienced

following immunisation (AEFI) are reported by the individual after receiving a COVID-19 vaccination. More information is covered in Module 6.

If required refer to the *COVID-19 – ATAGI immunisation provider guide to obtaining informed consent for COVID-19 vaccine.*

Administration

Do **NOT** mix or contaminate the vaccine with any other medication or liquid.

Do **NOT** dilute the vaccine as the vial comes ready to use (Novavax, 2022a).

Inspect the vial and **gently swirl the multidose vial before and in between each dose withdrawal**. Do **NOT** shake (Novavax, 2022a).

A new sterile syringe and needle must be used for administration to each individual.

In certain mass vaccination situations, it is acceptable to use the same needle to draw up and administer the vaccine. An aseptic procedure must be used throughout the procedure as there is a potential for a greater frequency of injection site reactions using this technique. Steps to complete this process are exactly the same as described in Module 4, except the needles are not changed. In this case only an administration needle is used to both draw up and administer the vaccine (ATAGI, 2021a). Seek advice from your Public Health Unit (PHU) when this may be appropriate.

A dose that has just been withdrawn from a vial which has a capped administration needle on it may be transported from the vaccine preparation area to the administration area. The room temperature should be below 25°C.

A sterile 22 to 25 gauge, 25mm length needle is recommended for administration, except for individuals with obesity when a 38mm length needle is recommended. Safety needles are also strongly recommended if available. Refer to Module 4 for more information.

Administer intramuscularly (IM), preferably into the deltoid using aseptic technique. **DO NOT** inject intravenously, subcutaneously or intradermally (Novavax, 2022a).

Based on a review of the available evidence, ATAGI does not recommend routinely aspirating (drawing back) needles before injection. This practice was rejected some decades ago, due to several disadvantages including prolonging the procedure, potentially associated pain, and increasing the risk of needle-syringe disconnection. Not aspirating is supported by the current advice in the Australian Immunisation Handbook (ATAGI, 2022q).

ATAGI will continue to review emerging evidence on the underlying mechanisms, prevention and treatment of Thrombosis with Thrombocytopenia, myocarditis and other serious adverse events of special interest.

Administration of vaccines under sedation

Procedural guidelines for administration of vaccines under sedation in practice have been developed or are currently being developed in some health services. ATAGI advises that detailed clinical guidance should be developed collaboratively with input from anaesthetic groups, jurisdictional health services and relevant specialists (ATAGI, 2022g).

More information can be found in the ATAGI advice on use of sedation for COVID-19 vaccination.

Post administration

A minimum 15-minute observation period must be completed post administration to monitor for adverse events.

After administration, the Novavax (NUVAXOVID) vaccine dose administered including batch number must be entered into the Australian Immunisation Register (AIR) as described in Module 5 Topic 4 to facilitate traceability (Novavax, 2022a).

Co-administration:

COVID-19 vaccines can be co-administered (i.e. on the same day) with an influenza vaccine. COVID-19 vaccines can also be co-administered with other vaccines if required. However, given the current limited evidence on the concomitant use of COVID-19 vaccines with other vaccines, providers need to balance the opportunistic need for co-administration with giving the vaccines on separate visits. There is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time. Co-administration or near administration (e.g. within days) with another vaccine may also make the attribution of potential adverse events more challenging (ATAGI, 2021b).

Data on the potential for co-administration with other vaccines is currently being reviewed and detailed information on this will be included in the ATAGI Clinical Guidance for COVID-19 vaccine providers (ATAGI, 2021b).

See Appendix 3 for the Vaccine preparation and Vaccine administration checklist.

Topic 4: Precautions and contraindications

A pre-screening checklist must be completed to check for any contraindications or circumstances for which precaution is required before administration (covered in Module 5 Topic 3). The precautions relating to Novavax (NUVAXOVID) are the same as those reviewed in Module 5 Topic 2. Please review these - as required and also refer to the COVID-19 vaccine contraindications and precautions website.

Further clinical studies are planned to evaluate long-term effectiveness and safety, as well as effectiveness in the wider population, including use in pregnant women, individuals under 18 years of age and individuals who are immunocompromised.

Individuals who have previously had COVID-19 are able to safely receive the Novavax (NUVAXOVID) vaccine. All people are recommended to defer COVID-19 vaccination for 6 months after a confirmed SARS-CoV-2 infection. The next scheduled dose should then be given as soon as possible. All recommended doses should still be received, and no doses should be omitted from the schedule. (ATAGI, 2021b).

There is only one true contraindication to receiving the Novavax (NUVAXOVID) vaccine:

- An anaphylactic or hypersensitivity reaction to a **previous** Novavax (NUVAXOVID) vaccine dose **OR** to any of its contained ingredients as listed in Topic 1 including Polysorbate 80.

If an individual has a contraindication following a first dose of a COVID-19 vaccine, an alternative brand should be considered for the second dose, the recommended interval for administration of a second dose is 4 to 12 weeks after the first dose. A longer interval is acceptable if the second dose cannot be administered during this time window. People should be made aware of the risks and

benefits of receiving an alternative vaccine brand for the second dose. For more information, please review the ATAGI Clinical recommendations for COVID-19 vaccines.

Precautions

As with other vaccinations, administration of the Novavax (NUVAXOVID) vaccine should not be delayed for a minor infection, illness or low-grade fever (<38.5°C). Vaccination should be delayed in individuals experiencing an acute severe febrile illness with a temperature ≥ 38.5°C (Novavax, 2022a).

Past infection is not a contraindication to booster doses. ATAGI recommends that booster doses should be deferred for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19 (ATAGI, 2023a).

People who have received an anti-SARS-CoV-2 monoclonal antibody or convalescent plasma should defer future doses of COVID-19 vaccine for **at least 90 days** (ATAGI, 2021b).

Waiting for a 6-month period after infection before COVID-19 vaccination is intended to optimise protection for that person. A longer gap between infection and vaccination is likely to lead to a better immune response and result in longer protection from reinfection (ATAGI, 2022f).

Infection with certain SARS-CoV-2 variants has previously been shown to reduce the risk of reinfection with a variant other than Omicron for at least 6 months. However, recent evidence shows that people with prior infection with a variant other than Omicron are likely to be reinfected with the SARS-CoV-2 Omicron variant more often than with other variants, such as Delta.

The risk of reinfection with Omicron after an Omicron infection is not yet known, but it is likely the reinfection rates will be lower in this context for a period of time, as compared with prior infection with a variant other than Omicron.

Testing using polymerase chain reaction (PCR) or rapid antigen testing (RAT) to detect current or past infection with SARS-CoV-2 before vaccination is neither necessary nor recommended.

Individuals who have prolonged symptoms from COVID-19 beyond 4 months can be vaccinated on a case-by-case basis. People with a past COVID-19 infection should receive a standard primary schedule and booster if 16 years and over (ATAGI, 2021b).

Children– The safety and efficacy of the Novavax (NUVAXOVID) vaccine has not been tested in those under 12 years of age and therefore has not been established (Novavax, 2022a). If individuals under the age of 12 present for vaccination, they should not be given a Novavax (NUVAXOVID) vaccine.

Adolescents– ATAGI has evaluated data on immunogenicity, safety, efficacy and international recommendations of the Novavax (NUVAXOVID) vaccine and has stated that individuals aged 12 to 17 years can receive the Novavax (NUVAXOVID) vaccine for their primary course of the COVID-19 vaccine (ATAGI, 2022l).

Significant co-morbidities and older adults – Novavax (NUVAXOVID) has been given to people from 18 to 95 years old in clinical trials to date. The vaccine efficacy was consistent between the older adults (≥65 years old) and younger individuals (18 to 64 years old). The vaccine efficacy was 88.9% (95% CI 20.2 – 99.7) in older adults, and about 91% (95% CI 70.4 – 95.9) in adults with a comorbid medical condition (Novavax, 2022a).

The decision to immunise an elderly patient should be decided on a case-by-case basis with consideration of age, co-morbidities and their environment taking into account the benefits of

vaccination and potential risks. Further information from ongoing clinical trials and post-market monitoring is expected in the coming months. Additional details can be found in the Product Information and the *Australian Public Assessment Report (AusPAR)*.

The Novavax (NUVAXOVID) vaccine is available for use in all individuals over 12 years. However, if someone is very frail or close to the end of life you may choose not to give them the vaccine. As the over 65 group are at most risk of severe disease and death due to COVID-19, they are also the most likely to benefit from vaccination. There is currently no evidence to suggest that the Novavax (NUVAXOVID) vaccine is less effective at preventing severe illness or death compared with other vaccines currently approved for use in Australia.

The potential benefits should be assessed against the risks at an individual level, especially if the person is frail. The COVID-19 vaccination decision guide for frail older people, including those in residential aged care facilities can be used by the older adult to make an informed decision. Additionally, a new decision guide is now available for people receiving palliative care and/or end-of-life care.

Immunocompromised individuals – Immunocompromised individuals are at higher risk of severe COVID-19 disease and are highly recommended to have the vaccine. This includes people who are on immunosuppression medication, on high-dose steroids or are immunodeficient. Being immunocompromised does not increase potential adverse risks. However, it is not known if individuals with an impaired immune system exhibit the same response as immunocompetent individuals (Novavax, 2022a).

There are limited data on the safety and immunogenicity of Novavax (NUVAXOVID) vaccine in people with immunocompromise. In the South African phase II trial, among 2684 participants, 6% were HIV positive. When including all participants, vaccine efficacy was 49.4% (95%CI 6.1 - 72.8). However, when HIV positive participants were excluded, vaccine efficacy was 60.1% (95%CI 19.9 - 80.1). Neutralising antibody geometric mean titres were comparable in HIV-positive and HIV-negative participants. No safety concerns were highlighted for the HIV-positive participants (ATAGI, 2022a).

The Novavax (NUVAXOVID) vaccine can be used for the third dose for people who have received Novavax (NUVAXOVID) for their first 2 doses, or if there are contraindications to mRNA COVID-19 vaccines.

ATAGI recognises that a substantial proportion of vaccinated individuals among some groups with severe immunocompromise conditions show suboptimal response to COVID-19 vaccine, and that this is likely to place them at ongoing increased risk of SARS-CoV-2 infection despite vaccination. ATAGI considers it important to offer a third primary dose to provide a higher level of protection for these individuals, aiming to attain a level as close as possible to that seen in healthy individuals. Provision of a third primary course dose to severely immunocompromised individuals does not guarantee equivalent protection to immunocompetent individuals, therefore ongoing risk mitigation measures are warranted. Antibody testing is not recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination, including in immunocompromised individuals after a second or third dose. There are no serological assays that provide a definitive correlate of immunity to SARS-CoV-2 (ATAGI, 2021w).

For more information, review ATAGIs COVID-19 vaccination decision guide for people with immunocompromise.

Bleeding risk – Caution is advised with individuals who may have thrombocytopenia, a coagulation disorder, or are receiving anticoagulation therapy because of the IM injection breaking the skin and therefore, increasing the risk of bleeding and bruising (Novavax, 2022a).

Allergies - The precautions relating to the Novavax (NUVAXOVID) vaccine are the same as the ones reviewed in Module 5 Topic 2. Please review these as required.

Consultation with a clinical immunology, allergy or vaccinology specialist is recommended prior to administering a COVID-19 vaccine to an individual who has had a generalised reaction (without anaphylaxis) to a previous dose of COVID-19 vaccine or one of the ingredients of the Novavax (NUVAXOVID) vaccine. The Australasian Society of Clinical Immunology and Allergy (ASCIA, 2021) position statement can be read for more specific details here. ATAGI also have some advice on allergy precautions here.

For specialist advice and assistance, please contact your local public health unit (PHU).

Pregnancy, fertility and breastfeeding

There is limited experience with its use in pregnant or breastfeeding women, who were excluded from trials. There are no theoretical safety concerns relating to its use; however,

- The novel adjuvant Matrix-M has also not previously been used in pregnancy or breastfeeding.
- Animal studies do not indicate direct or indirect harmful effects relating to pregnancy or embryonic/foetal development

(ATAGI, 2022a)

Pregnancy (Category B1) – bivalent mRNA vaccines are the recommended COVID-19 vaccines for pregnant women. This is based on the growing body of evidence supporting the safety of mRNA vaccines in pregnancy, whereas there are still very limited data on the safety of Novavax (NUVAXOVID) in pregnancy. However, people who cannot access an mRNA vaccine can consider vaccination with Novavax (NUVAXOVID) if the benefits to the individual outweigh the potential risks.

Pregnant women with COVID-19 have a higher rate of hospitalisation, intensive care unit admission and mechanical ventilation, but not death, than age-matched non-pregnant women. The risk of preterm delivery is also increased. There is no evidence to suggest that SARS-CoV-2 infection in pregnancy increases the risk for congenital anomalies (ATAGI, 2021b).

Fertility – It is not known whether the Novavax (NUVAXOVID) vaccine affects fertility as there are no human data available. From a developmental and reproductive toxicity study on female rats, no vaccine-related adverse effects on female fertility, pregnancy/lactation, or development of the embryo/foetus and offspring through post-natal Day 21 were observed (Novavax, 2022a).

Breastfeeding – It is recommended that women who are breastfeeding or who are planning pregnancy receive a bivalent mRNA vaccine.

There are no data on the safe use of the vaccine with breastfed newborns and infants and it is not known if Novavax (NUVAXOVID) is excreted in breast milk. Therefore, a risk cannot be excluded (Novavax, 2022a).

For further information, refer to the COVID-19 vaccination – Shared decision making guide for women who are pregnant, breastfeeding, or planning pregnancy.

Topic 5: Adverse events

General adverse events have been discussed in Module 6 Topic 2.

Information about how to report suspected AEFIs associated with a COVID-19 vaccine is available on the TGA website.

Individuals and healthcare workers can report side-effects directly to the TGA.

In some jurisdictions, health professionals are required under public health legislation to notify AEFIs to the relevant health department. For a review of AEFI reporting and the process for your state or territory, please review this website. For more information, please refer to Core Module 6.

Safety data from the three phase II-III clinical trials included approximately 34,000 participants. Safety monitoring was conducted after each vaccine dose with a median follow-up period of around 70 days.

The following list identifies the frequency of very common adverse events following immunisation (AEFI) in completed clinical trials:

- Injection site tenderness (75%) and injection site tenderness pain (62%)
- Headache (50%).
- Fatigue (53%).
- Myalgia (51%).
- Malaise (41%).
- Arthralgia/joint pain (24%).
- Nausea and/or vomiting (15%).

(Novavax, 2022a)

Adverse reactions were usually mild to moderate in severity with a median duration of less than or equal to 2 days for local events and less than or equal to 1 day for systemic events following vaccination (Novavax, 2022a). The adverse reaction profile was generally similar in 12 to 17 year olds to that among adults.

Common and uncommon symptoms to be aware of include:

- Injection site redness and swelling (common).
- Pyrexia (common).
- Chills (common).
- Pain in the extremity (common).
- Lymphadenopathy (uncommon).
- Hypertension (uncommon).
- Rash and erythema (uncommon).
- Pruritus (general and injection site) and urticaria (uncommon).

(Novavax, 2022a)

Adverse reactions including anaphylaxis, pericarditis, hypoaesthesia and paraesthesia have been spontaneously reported during post-authorisation use of Novavax (NUVAXOVID). As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered unknown.

Local and systemic adverse reactions were more frequently reported after Dose 2 than Dose 1. Overall, there was a higher incidence of adverse reactions in younger age groups: the incidence of injection site tenderness, injection site pain, fatigue, myalgia, headache, malaise, arthralgia, and nausea or vomiting was higher in adults aged 18 to less than 65 years than those aged 65 years and above (Novavax, 2022a; ATAGI, 2022a). Pyrexia, including grade 3 pyrexia, was more common among adolescents aged 12 to 17 years than among adults.

There are currently no data on safety of third doses of vaccine in relation to adverse events. ATAGI will continue to monitor the evidence around safety of additional doses of COVID-19 vaccine (ATAGI, 2021w).

Studies suggest that the common mild and transient side effects after booster doses are comparable to those following primary vaccine doses. However, there are limited data on the incidence of rare but potentially serious adverse events following booster doses (ATAGI, 2021x).

Rare events

Serious adverse events were rare (ATAGI, 2022a).

A total of 3 cases of myocarditis were reported in the two phase III trials, of which 2 occurred in the vaccine group and 1 in the placebo group. Based on this very small number of cases with limited information and the overall number of trial participants, which was inadequate for detection of very rare adverse events such as myocarditis, it is not possible to determine if there is a causal relationship or to estimate the risk of myocarditis associated with this vaccine (ATAGI, 2022a).

The occurrence of these cases is not necessarily attributable to this vaccine. It is recommended that all COVID-19 vaccine recipients should be aware of the potential signs and symptoms of myocarditis or pericarditis and should be counselled about when to seek medical attention. For more information see ATAGI guidance on Myocarditis and Pericarditis (ATAGI, 2022a).

ATAGI will continue to evaluate further data on the safety and efficacy of the Novavax (NUVAXOVID) vaccine as it emerges, including in special populations and as a booster vaccine, and will provide updated recommendations as required (ATAGI, 2022a).

All immunisers are strongly encouraged to report **ALL** adverse events following administration of Novavax (NUVAXOVID) that are serious, unexpected or require medical attendance. The batch number should also be included in this reporting to monitor any potential issues with manufacturing, transport or storage. Refer to Module 5 for national and jurisdictional reporting requirements and pathways.

Anaphylaxis can occur after administration of any medicine. As with all vaccines, immunisation providers must be prepared to respond to an individual developing anaphylaxis. The anaphylaxis rate in Australia appears similar to any other vaccine (DHAC, 2021h). Follow all management steps outlined in Module 6 Topic 3.

The Novavax (NUVAXOVID) vaccine has no or limited effects on the ability to use machines and drive. However, if experienced, some of the AEFI may temporarily affect an individual's ability to drive or use machines (Novavax, 2022a).

Consumer medicine information can be given to individuals receiving the vaccine which detail what to expect and how to monitor for adverse effects.

For a review of adverse events reporting and the process for your state or territory, please review this website.

Module Summary

- The Novavax (NUVAXOVID) vaccine uses a recombinant spike (rS) protein which is produced using recombinant DNA technology spike protein that comes ready to use.
- The MDVs contain 5mL of vaccine which equates to 10 doses of 0.5mL.
- Novavax (NUVAXOVID) can be given to people aged 12 years and over.
- The **unopened** (unpunctured) vials can be stored at **+2°C to +8°C** for up to **9 months**. Check the expiry date on the MDV before use.
- **After initial puncture**, vials can be stored up to 12 hours at +2°C to +25°C 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 for the Novavax (NUVAXOVID) vaccine, so storing pre-drawn doses of this vaccine in syringes is not preferred.
- The Novavax (NUVAXOVID) vaccine is given as a 2-dose primary schedule intramuscularly into the deltoid, or as a 3-dose primary schedule for people who are severely immunocompromised if an mRNA vaccine is not available or suitable.
- ATAGI recommends a primary dosing schedule of Novavax (NUVAXOVID) vaccine of 2 doses, 8 weeks apart. The dosing interval can be shortened to a minimum of 3 weeks. The recommended dose interval for the third primary dose, if required, is 2 months after the second primary dose.
- Booster doses can be administered 6 months after the last COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (whichever is the most recent). Bivalent mRNA COVID-19 vaccines are preferred for booster doses.
- All adverse events must be reported as this is a novel vaccine.
- Prior to each vaccination, ensure all relevant expiry dates and times are checked.

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Multi-choice Questions

1. Which of these statements about storage and preparation for the Novavax (NUVAXOVID) vaccine is **CORRECT**?

    a. The unopened MDVs can be stored in cold chain storage (+2°C to +8°C) for a maximum of 9 months.
    b. An opened MDV can be left at room temperature (up to 25°C) for a maximum of 12 hours.
    c. The vaccine must be administered within 24 hours of being drawn up into the syringe.
    d. The opened vaccine can be used for a maximum of 12 hours if stored in cold chain (+2°C to +8°C).

2. What are the vaccine recommendations for a person 18 years of age or older receiving Novavax (NUVAXOVID) who has no precautions?

    a. 2-dose primary course a minimum 3 weeks apart and recommended 8 weeks apart.
    b. 2-dose primary course a minimum 3 weeks apart and recommended 4 weeks apart.
    c. 3-dose primary course a minimum 3 weeks apart and recommended 8 weeks apart.
    d. 3-dose primary course a minimum 4 weeks apart and recommended 4 weeks apart.

3. Which of these sentences regarding the dose and administration of the Novavax (NUVAXOVID) is CORRECT?

    a. A single dose is 0.5 mL and is recommended to be drawn up in a 1 mL, 2 mL or 3 mL syringe. Each MDV contains 10 doses.
    b. A single dose is 0.3 mL and is recommended to be drawn up in a 2 mL or 3 mL syringe. Each MDV contains 6 doses.

c. A single dose is 0.5 mL and is recommended to be drawn up in a 1 mL or 2 mL syringe only. Each MDV contains 10 doses.
d. A single dose is 0.5 mL and is recommended to be drawn up in a 2 mL syringe only. Each MDV contains 10 doses.

4. Which of these people should be routinely recommended to receive Novavax (NUVAXOVID) as their COVID-19 vaccine schedule?

a. Children aged 5 to 11 years of age.
b. Adolescents and adults aged 12 years and above.
c. A person with a past anaphylactic reaction to a medication containing Monobasic sodium phosphate monohydrate.

Appendix 1 – Handling and Storage: Pfizer Packaging Demo

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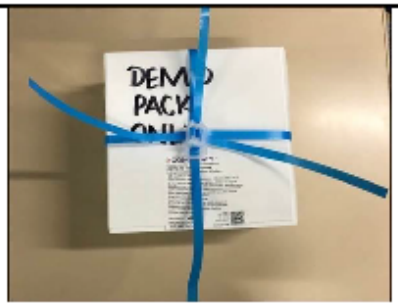
COVID-19 VACCINATION

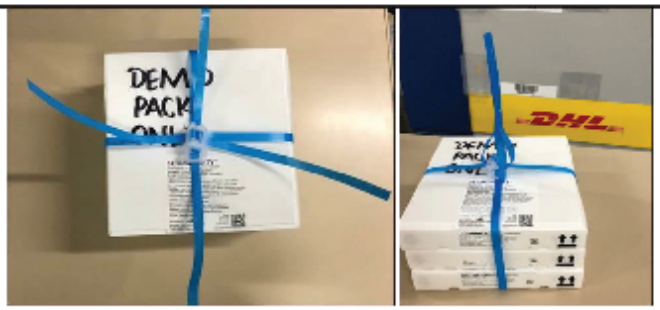
COVID-19 Vaccine Module 2

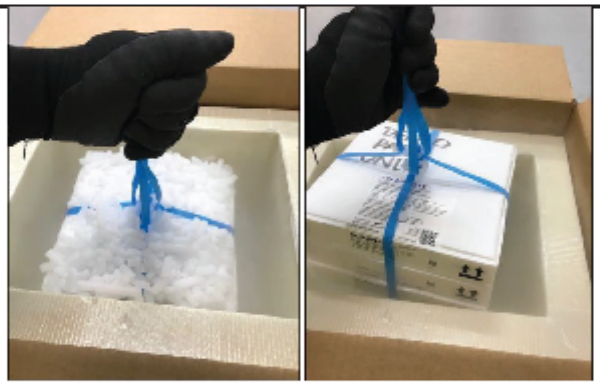
Handling and Storage: Pfizer Packaging Demo

Demo of DHL packs Pfizer A2 trays utilising straps and buckles instead of plastic bags.

Step 1. 3 x Pfizer frozen trays (585 units) 4 x straps (at least 130cm long)	
Step 2. Add 2 x clips and tighten	

1

Step 3. Staple the 4 ends together with a minimum of 2 staples	
Step 4. Place around 3kg of dried ice to the bottom of the package Put the bundle of 3 x trays into the A2 on top of the dried ice (Note: TempTale Ultra Probe not used for demo)	

Step 5. Add 21kg dry ice over the bundle as per packing process Allow the straps to stand out of the dried ice for easy access Seal package	
Step 6. Open package with care Remove top layer of dry ice Carefully lift the 3 x trays by utilising the stapled straps	

Appendix 2 - Storage Rack for ULT25NEU

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Storage Rack for ULT25NEU

For transferring vaccine vials from Pfizer 'pizza' boxes it is necessary to transfer the vaccine vials from the pizza boxes into the storage trays of the rack within the shuttle.

1. Have the rack assembly in the shuttle and operating at set temperature of -80degC
2. When ready to transfer vials, remove the rack from the shuttle by lifting up the assembly.
3. Ensure freezer lid is closed to preserve temperature
4. Remove one drawer from the rack
5. Remove the rear panel of the drawer by lifting it up (see Fig 1)
6. Flatten the pizza box by unlocking the tabs
7. Scoop up the vials into the drawer (see Fig 2)
8. Re-insert the rear panel
9. Replace the drawer in the rack
10. When all trays filled, rack assembly can be placed back into the freezer.

Fig 1 – rear panel

Fig 2

Demonstration Videos

Transfer demonstration - ULT26NEU portable freezer
https://www.youtube.com/watch?v=cZJN4ETX3ws

Stirling Ultracold – Vaccine storage handling
www.stirlingultracold.com/vaccine-storage-handling

COVID-19 VACCINATION

Keep up to date at
health.gov.au/covid19-vaccines.

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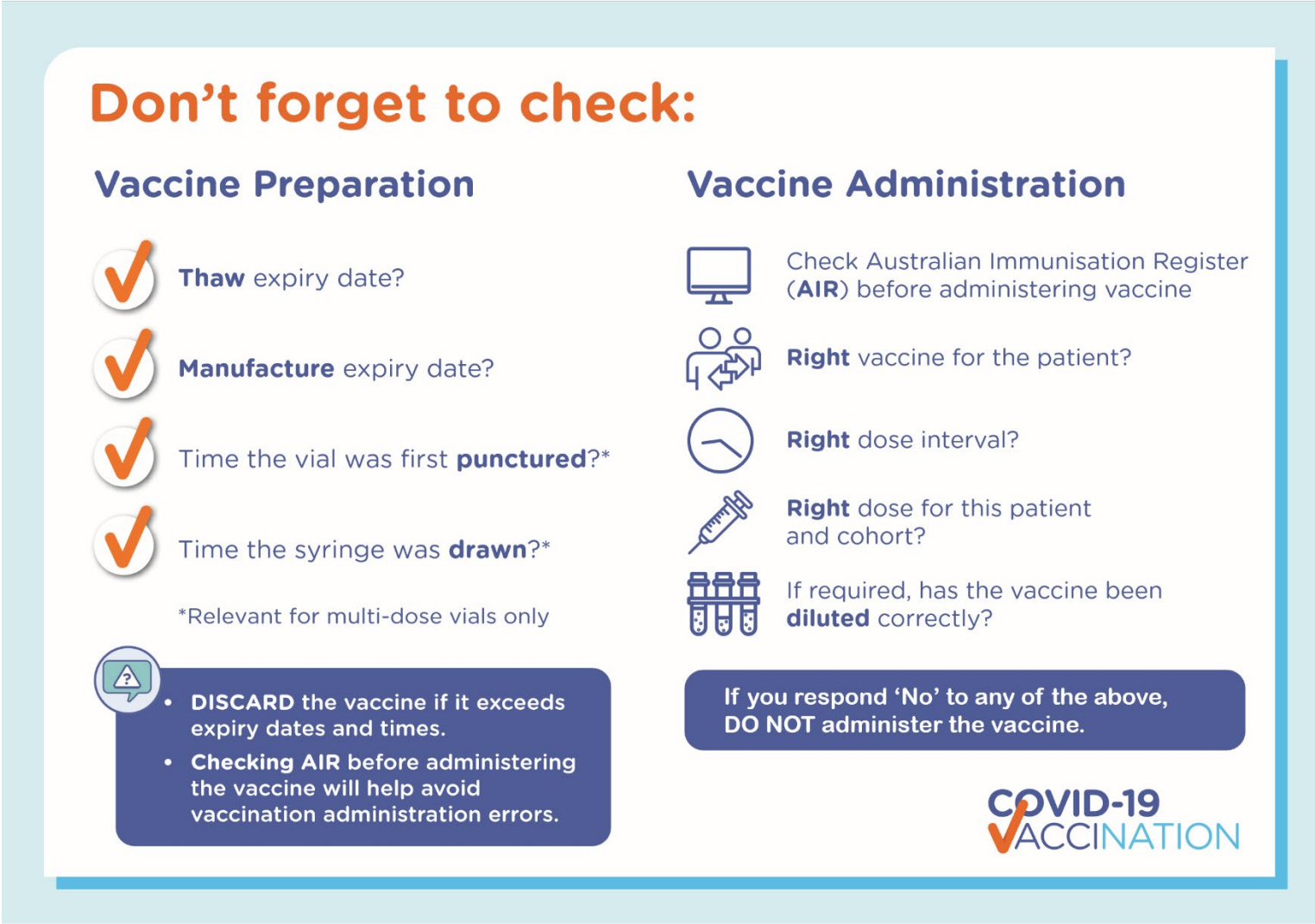
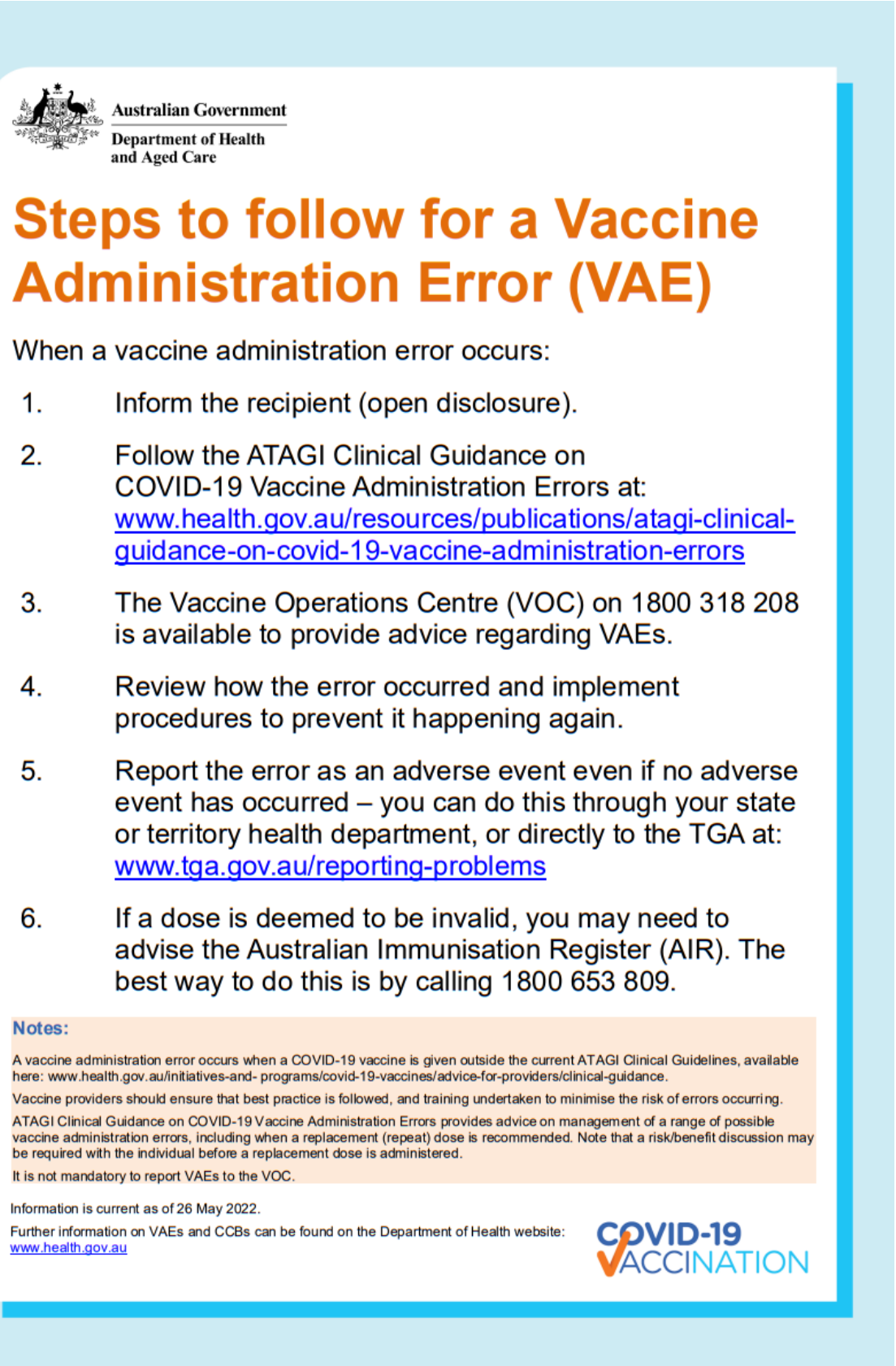
Appendix 3 – Vaccine Preparation and Administration Checklist



Appendix 4 - Steps to follow for a Vaccine Administration Error (VAE)



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Steps to follow for a Vaccine Administration Error (VAE)

When a vaccine administration error occurs:

1. Inform the recipient (open disclosure).
2. Follow the ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors at: www.health.gov.au/resources/publications/atagi-clinical-guidance-on-covid-19-vaccine-administration-errors
3. The Vaccine Operations Centre (VOC) on 1800 318 208 is available to provide advice regarding VAEs.
4. Review how the error occurred and implement procedures to prevent it happening again.
5. Report the error as an adverse event even if no adverse event has occurred – you can do this through your state or territory health department, or directly to the TGA at: www.tga.gov.au/reporting-problems
6. If a dose is deemed to be invalid, you may need to advise the Australian Immunisation Register (AIR). The best way to do this is by calling 1800 653 809.

Notes:

A vaccine administration error occurs when a COVID-19 vaccine is given outside the current ATAGI Clinical Guidelines, available here: www.health.gov.au/initiatives-and- programs/covid-19-vaccines/advice-for-providers/clinical-guidance.

Vaccine providers should ensure that best practice is followed, and training undertaken to minimise the risk of errors occurring.

ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors provides advice on management of a range of possible vaccine administration errors, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual before a replacement dose is administered.

It is not mandatory to report VAEs to the VOC.

Information is current as of 26 May 2022.

Further information on VAEs and CCBs can be found on the Department of Health website: www.health.gov.au

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Appendix 5 – Steps to follow for a Cold Chain Breach (CCB)

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Steps to follow for a Cold Chain Breach (CCB)

If your vaccines have been involved in a potential CCB, either within the clinical setting or during transit:

1. Place any affected vaccines in quarantine, secured within the appropriate cold chain storage requirements.
2. Mark stock as 'Do not use Do not discard'
3. Report the PCCB to the Vaccine Operations Centre (VOC) on 1800 318 208, providing as much information and temperature data as possible to aid in the assessment*
4. Wait for the outcome of the assessment and advice on whether the vaccines are safe to use.

Notes:

All staff involved in the monitoring or administration of COVID-19 vaccines should be familiar with and regularly review cold chain management processes.

The National Vaccine Storage Guidelines 'Strive for 5', provides information and advice for vaccine storage management for Australian immunisation service providers: www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5

It is critical that cold chain requirements are maintained, and the National Vaccine Storage Guidelines 'Strive for 5'are always followed. This ensures patients are receiving safe and effective vaccines.

*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.

Information is current as of 26 May 2022.

Further information on VAEs and CCBs can be found on the Department of Health website: www.health.gov.au

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