

Australian Technical Advisory Group on Immunisation (ATAGI)

Clinical guidance on use of
COVID-19 vaccine in Australia
in 2021.

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This clinical guidance is for COVID-19 immunisation providers and program staff, and is based on currently available data. It provides recommendations on the use of the COVID-19 vaccine Comirnaty (Pfizer). It will be updated as new information and vaccines become available.

Key points

- COVID-19 vaccination is recommended for all people aged ≥ 16 years to protect against COVID-19.
- The aim of Australia's COVID-19 vaccination program is to reduce COVID-19 related harm by preventing serious illness and death, and, as much as possible, disease transmission.
- Initial supply of COVID-19 vaccine will be limited and so the delivery of vaccine will be restricted to priority population groups.
- COVID-19 vaccine should be prioritised initially for the following population groups, as they are at increased risk of exposure to SARS-CoV-2 or of severe COVID-19:
 - quarantine and border workers
 - healthcare workers who are at increased risk of exposure to persons infected with SARS-CoV-2
 - aged care and disability care staff and residents
 - elderly adults, initially focusing on adults aged ≥ 80 years, with progressive vaccine delivery to adults aged 70–79 years, 60–69 years and then 50–59 years
 - adults with underlying medical conditions associated with an increased risk of severe COVID-19
 - Aboriginal and Torres Strait Islander adults
 - critical and high-risk workers, including defence, police, fire, emergency services and others.
- For more information please refer to the [National Rollout Strategy](#) and [ATAGI Preliminary advice](#) on principles of prioritisation for the COVID-19 vaccine.
- Advice on prioritisation of other groups will be available over time.
- There is currently no clinical trial data to support use of the vaccine in children < 16 years.
- Comirnaty (Pfizer Australia Pty Ltd), also known as BNT162b2, is currently the only COVID-19 vaccine provisionally registered and available for use in Australia:
 - Comirnaty is given in a two-dose schedule and has high efficacy (95% against symptomatic COVID-19).
 - Comirnaty has a good safety profile in clinical trials and post-marketing surveillance.
 - Routine co-administration of Comirnaty with other vaccines is not recommended, and a minimum interval of 14 days between the administration of Comirnaty and any other vaccine should be maintained.
- Recording of COVID-19 vaccine administration in the Australian Immunisation Register (AIR) will be mandatory.
- Notification of adverse events following immunisation (AEFI) should be made to the Therapeutic Goods Association (TGA) and through the specified reporting mechanisms for [your state or territory](#).

This advice should be implemented in conjunction with other key guidelines, including:

- COVID-19 Vaccine training – including on the use of Multi-dose vials
- ATAGI immunisation provider guide for obtaining informed consent for COVID-19 vaccination
- Product Information for Comirnaty available at the Therapeutic Goods Administration (TGA) website
- [Shared decision making guides – as available at time of publication](#)

The virus: SARS-CoV-2

The pandemic of coronavirus disease (COVID-19) is caused by the severe acute respiratory coronavirus 2 (SARS-CoV-2), a virus first identified in December 2019. Bats appear to be the reservoir of SARS-CoV-2.¹ SARS-CoV-2 is a single-stranded RNA betacoronavirus in the same subgenus as the severe acute respiratory virus syndrome (SARS) virus, and is more distantly related to the Middle East respiratory syndrome (MERS) virus.²

SARS-CoV-2 contains four main structural proteins:³

- spike (S) glycoprotein
- small envelope (E) glycoprotein
- membrane (M) glycoprotein
- nucleocapsid (N) protein.

The most common target of COVID-19 vaccines is the spike protein. The spike protein contains two subunits: S1 and S2. S1 contains the receptor binding domain, which binds to the angiotensin converting enzyme 2 receptor on host cells.⁴

Several SARS-CoV-2 variant strains of concern have been identified. Some variant strains show higher transmissibility than others, such as 501Y Variant 2 (also known as B.1.1.7⁵). There may be some potential variation in vaccine efficacy against different strains.

Transmission of SARS-CoV-2 predominantly occurs through droplets via direct and close contact with an infected person. The median incubation period is 5–6 days, with a range of 1–14 days.⁶

The disease: COVID-19

SARS-CoV-2 causes asymptomatic or mild disease in 81% of cases; severe illness (with dyspnoea, hypoxia or >50% lung involvement on imaging within 48 hours) in 14%; and critical illness in 5%.⁷ The most common symptoms are fever and cough.⁸ Other common symptoms include myalgia, headache, dyspnoea, sore throat, diarrhoea and nausea/vomiting. Loss of smell or taste and rhinorrhoea occur in fewer than 10% of cases.

Risk factors for severe COVID-19 (including death) include older age and the presence of certain medical conditions (refer to **Recommendations** section for further information).

Older age is an important risk factor for severe COVID-19, as shown in several international systematic reviews. In comparison with those aged <50 years, the risk of death from COVID-19 progressively increases with every decade of age, from about 2 times for age 50–59 years to >10 times for age ≥80 years.⁹ Findings were similar when results were adjusted for other risk factors.¹⁰ In Australia, the COVID-19 case fatality ratio increased substantially with age, from 0.6% in age 50–64 years to 7.0% in age 65–79 years and 33.8% in age ≥80 years.¹¹

There are certain occupational and environmental settings that may place individuals at higher risk of COVID-19 exposure. These include healthcare facilities; aged care and disability care facilities; border and quarantine facilities; and industries such as meat processing. Refer to **Recommendations** section for further information.

Children and adolescents with COVID-19 are commonly asymptomatic or have mild or moderate symptoms. A systematic review that included data on illness severity in 1,475 children with COVID-19 reported asymptomatic infection in 15%, mild illness in 42%, moderate illness in 39%, severe illness in 2% and critical illness in 0.7%.¹²

A rare but serious condition associated with COVID-19 in children is Paediatric Inflammatory Multisystem Syndrome Temporally associated with SARS-CoV-2 (PIMS-TS), which can present with features similar to those of Kawasaki disease or toxic shock syndrome.¹³

Further information about COVID-19 is available in the [COVID-19 CDNA National Guideline for Public Health Units](#) and information about Australian epidemiology is available on the [Department of Health website](#), including regular epidemiological reports.

COVID-19 vaccination program

The aim of the COVID-19 vaccination program in Australia is to reduce COVID-19 related harm by preventing serious illness and death, and, as much as possible, disease transmission. Information on COVID-19 vaccination program implementation in Australia is available on the [Department of Health website](#).

The epidemiology of COVID-19 is a key determinant in advising on the most appropriate use of COVID-19 vaccines, in addition to the characteristics and availability of COVID-19 vaccines.

In Australia, outbreak control measures (including contact tracing, testing and isolation; border control and quarantine; and physical distancing) have been successful in limiting the spread of COVID-19 in the community.¹⁴ Sporadic disease outbreaks continue to occur following virus introduction from international travellers.

In settings where there is no sustained SARS-CoV-2 community transmission, the initial focus of a vaccine program is to prevent importation of cases and demonstrate reciprocity to critical (particularly frontline) workers.¹⁵ As more vaccine doses become available, older adults should be included, as they are at the highest risk of severe illness or death.

Vaccine, doses and administration

The following COVID-19 vaccine has been provisionally approved for use in Australia. The TGA website provides the product information.

Refer also to Vaccine information section for more details.

Comirnaty (generic name BNT162b2)

Sponsor:	Pfizer Australia Pty Ltd
Approved age for use:	≥16 years
Presentation:	Multi-dose vial without preservative, each vial containing 6 doses in 0.45mL. Requires dilution with 1.8mL of sterile 0.9% NaCl without preservative into each multi-dose vial.
Volume/strength:	0.3mL (30µg) per dose
Schedule:	2 doses at least 21 days apart
Administration route:	Intramuscular injection into deltoid muscle
Ingredients:	Each 0.3mL dose contains 30 mcg mRNA - List of excipients: <ul style="list-style-type: none">○ ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)○ 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)○ Distearoylphosphatidylcholine (DSPC)○ Cholesterol○ Potassium chloride○ Monobasic potassium phosphate○ Sodium chloride○ Dibasic sodium phosphate dihydrate○ Sucrose○ Water for injections

Recommendations

All people aged ≥ 16 years are recommended to receive COVID-19 vaccine.

There will be a limited supply of COVID-19 vaccines in the initial phases of the COVID-19 vaccination program. Therefore, vaccine allocation will be determined on the basis of a number of factors, such as timing of supply, priority target groups and logistical considerations.

The following population groups will be prioritised initially:

People with occupational risk of exposure to SARS-CoV-2

People in certain occupations are at increased risk of being infected with SARS-CoV-2 and/or transmitting the virus to vulnerable people who have risk factors for severe illness. These include:

- Healthcare workers at increased risk of exposure to persons infected with SARS-CoV-2: Frontline healthcare workers have seven-fold increased risk of severe COVID-19 compared with non-essential workers (RR 7.42, 95% CI: 5.52–10.00)¹⁶
- Quarantine and border workers
- Aged care and disability care staff
- Critical and high-risk workers, including defence, police, fire and emergency services; certain laboratory staff; meat processing workers; and select others.

Residents of aged care and disability care facilities

Aged care facilities have been the setting for a number of serious COVID-19 outbreaks in Australia.¹⁷

Older adults

Delivery of COVID-19 vaccines to older adults should be prioritised, starting with adults aged ≥ 80 years, and sequentially progressing to lower age groups (70–79, 60–69 and 50–59 years), due to the progressive increase in risk of severe disease and death with increasing age. Older age is by far the strongest risk factor associated with morbidity and mortality from COVID-19.^{7,10,18}

Aboriginal and Torres Strait Islander adults

Aboriginal and Torres Strait Islander adults are at increased risk of severe illness and death from COVID-19 because of multiple factors.¹⁹ These include a high prevalence of underlying chronic health conditions associated with severe COVID-19 and a greater likelihood of living in communities where social distancing cannot be practised.¹⁹

While the impact of COVID-19 on Aboriginal and Torres Strait Islander peoples to date has been mitigated by existing control measures (especially restriction of movement into communities), the factors above warrant prioritisation for vaccination. Precise age cut-offs for vaccination should be decided taking into account logistics and vaccine availability, with the initial focus being on older Aboriginal and Torres Strait Islander adults.

People with medical conditions that increase their risk of severe COVID-19

People aged ≥ 16 years with certain underlying chronic medical conditions, outlined in Box 1, are at increased risk of severe illness with COVID-19 and should be prioritised for vaccination, particularly those who have multiple comorbidities, including older age.^{7,8,18,20}

Box 1: Medical conditions associated with increased risk of severe COVID-19 illness

Individuals at high risk of severe COVID-19 illness

- Organ transplant recipients who are on immune suppressive therapy
- Those who have had a bone marrow transplant in the last 24 months
- Those on immune suppressive therapy for graft versus host disease
- Those who have haematological cancers, for example, leukaemia, lymphoma or myelodysplastic syndrome (diagnosed within the last 5 years)
- Those having chemotherapy or radiotherapy

Individuals at moderate risk of severe COVID-19 illness

- Those with chronic renal (kidney) failure
- Those with heart disease (coronary heart disease or failure)
- Those with chronic lung disease (excludes mild or moderate asthma)
- Those who have a non-haematological cancer (diagnosed in the last 12 months)
- Those who have diabetes
- Severe obesity with a BMI ≥ 40 kg/m²
- Those with chronic liver disease
- Those with some neurological conditions (stroke, dementia, other)
- Those with some chronic inflammatory conditions and treatments
- Those with other primary or acquired immunodeficiency
- Those with poorly controlled blood pressure

Note: More information on the vaccination program for adults aged <50 years who are not covered under any priority groups will be available on the program [website](#).

Considerations for special populations

People who are immunocompromised

COVID-19 vaccine is recommended for people who are immunocompromised because of their increased risk of severe illness with COVID-19.²¹

There are many causes and varying degrees of immunocompromise, and the risk of COVID-19 will vary according to the number and type of underlying conditions, medical management and other factors.

There are no data on the safety and efficacy of COVID-19 vaccination for people who are immunocompromised specifically at the current time. In principle there are no theoretical safety concerns for Comirnaty in people who are immunocompromised, on the basis of a general understanding of vaccine characteristics and because it is a non-live vaccine. However, the immune response to vaccination may be reduced in these people, which may result in lower vaccine effectiveness and protection, compared with that in non-immunocompromised individuals.

COVID-19 vaccine is also recommended for people with HIV. A small number of people (n=120) with stable HIV infection were recruited into the phase II/III trial for Comirnaty, and immunogenicity and safety data for this group are anticipated.²²

Before vaccination, people with immunocompromise should be counselled about the safety and efficacy of COVID-19 vaccine, and lack of data in immunocompromised recipients. People with immunocompromise who have been vaccinated should be advised to continue taking other protective measures against SARS-CoV-2.

Children

COVID-19 vaccines are not currently registered or recommended for use in children aged <16 years. Sufficient data on vaccine safety, immunogenicity and efficacy are not available from clinical trials in this age group. Healthy children have a much lower risk of severe illness from COVID-19 in comparison to adults.¹²

Guidance will be revised when evidence on the efficacy and safety of the use of COVID-19 vaccines in children becomes available.

Women who are pregnant, breastfeeding or planning pregnancy

Use of Comirnaty during pregnancy is not routinely recommended, but is not contraindicated. There are no data on the safety of this vaccine in pregnancy and on pregnancy outcomes. However, on the basis of the mRNA platform technology, there are no theoretical safety concerns regarding the use of Comirnaty in pregnant women, noting that mRNA vaccines are not live vaccines.

Some pregnant women may choose to be vaccinated after considering the benefits and risks of vaccination. In particular, COVID-19 vaccination may be considered in pregnant women who are in a high-risk priority group for vaccination, where the risk of exposure to SARS-CoV2 infection is high, or where the woman has underlying medical conditions that put her at high risk of serious complications from COVID-19. Further information is available in the [COVID-19 Vaccination Decision Guide for women who are pregnant, breastfeeding or planning pregnancy](#).

Women who are breastfeeding or who are planning pregnancy can receive COVID-19 vaccine. There are no theoretical concerns regarding the safety of Comirnaty in these groups.

If Comirnaty is inadvertently administered during pregnancy, routine monitoring for adverse events following immunisation is advised.

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.²³ The risk of preterm delivery is also increased.²³ There is no evidence to suggest that SARS-CoV-2 infection in pregnancy increases the risk for congenital anomalies.²⁴

There were 23 women who participated in the phase II/III trial of Comirnaty and became pregnant shortly after receiving the vaccine.²⁵ These participants and many others who are vaccinated with Comirnaty in programs worldwide are being followed in various studies for pregnancy outcomes.

People with a past history of COVID-19

Past infection with SARS-CoV-2 is not a contraindication to vaccination. Evidence suggests that past infection reduces the risk of reinfection for at least 6 months.²⁶ Individuals who have had PCR-confirmed SARS-CoV-2 infection may wish to defer vaccination for up to six months from the time of their infection.

In the phase II/III trial of Comirnaty, the vaccine was administered to a small number of people with serological evidence of previous SARS-CoV-2 infection. There were no specific safety issues reported among these individuals. A similarly high overall efficacy was shown when participants who have had previous SARS-CoV-2 infection were also included for analysis, but a separate estimate of efficacy for these individuals was not reported.

Serological testing or other testing to detect current or previous infection with SARS-CoV-2 before vaccination is neither necessary nor recommended before vaccination.

Timing of administration of influenza vaccine

Routine administration of a COVID-19 vaccine and influenza vaccine on the same day is not currently recommended, given the current absence of data on the immunogenicity and safety of these vaccines when co-administered.

This advice may change as further information becomes available.

The preferred minimum interval between receipt of Comirnaty vaccine and an inactivated influenza vaccine is 14 days. Co-administration or near administration (e.g., within days) of two or more vaccines can sometimes lead to a higher frequency of mild to moderate adverse events or make the attribution of potential adverse events to vaccination more challenging.

There are circumstances where shortening the intervals between or co-administering a dose of influenza vaccine and COVID-19 vaccine on the same day may be justified, such as:

- if adherence to the preferred minimum interval (14 days) will likely lead to an individual or a target population for either of these vaccines missing the opportunity to receive vaccine doses.
- there is an imminent need to administer either of these vaccines because of the prevailing local epidemiological situation, for example, for protection from influenza or COVID-19.

If inadvertent co-administration of an influenza vaccine and COVID-19 vaccine occurs, revaccination is not required for either vaccine. The patient should be informed of the possibility of an increased likelihood of common adverse effects and be asked to [report any untoward adverse events](#).

Timing of administration of other vaccines

Routine co-administration of a COVID-19 vaccine on the same day as another vaccine is not recommended. (For specific guidance on influenza vaccine, refer to **Timing of administration of influenza vaccine** section above.)

There should be a minimum interval of 14 days between receipt of Comirnaty and any other vaccine. Although immune interference is unlikely between vaccines that do not contain common antigens, there are currently no immunogenicity or safety data on co-administration of Comirnaty and other vaccines.

If a COVID-19 vaccine has inadvertently been administered on the same day or within 14 days before or after other vaccines, no vaccine doses need to be repeated.

An individual risk–benefit assessment is necessary to consider shortening of the interval between, or offer same day administration of, a COVID-19 vaccine with another vaccine. This may be considered when a high risk of imminent exposure to the diseases is to be prevented, or it is highly likely that the opportunity of receiving either vaccine will be missed. If same day or reduced-interval vaccination is proposed, patients should be counselled about the possible adverse events from each vaccine and advised to [report any adverse events](#).

Co-administration of antipyretics/analgesics

Prophylactic use of paracetamol or ibuprofen is not recommended before receiving Comirnaty. Antipyretics and analgesics can be taken after vaccination for management of vaccine-related side effects such as fever and myalgia, if required.

Variation of schedule and interchangeability between COVID-19 vaccines

The recommended interval between two doses of Comirnaty is at least 21 days.

It is recommended to complete the two-dose course within 6 weeks. This allows time for logistical considerations, including supply and timing of access to vaccine at the individual and clinic levels.

Although Comirnaty may provide partial protection against COVID-19 as soon as 12 days after the first dose, this protection is likely to be short lived. A two-dose course is recommended for all individuals for optimal protection.

Longer intervals between first and second doses may need to be recommended during program rollout if epidemiological considerations warrant a change (e.g., during an outbreak response to ensure available doses are provided as first doses to as many people as possible).

If the second dose of Comirnaty is administered later than the recommended interval, no vaccine doses need to be repeated.

Minimum interval between doses

The minimum acceptable interval between the two doses of Comirnaty is 19 days. Shortening of the minimum acceptable interval may result in a sub-optimal immune response. If two doses have inadvertently been given at a shorter than the minimum acceptable interval, it is not currently recommended that a vaccine dose is repeated. This is because there are no data on administration of more than two vaccine doses and there is still a likelihood of good protection in that individual.

Interchangeability of vaccines

On the basis of currently available information, Comirnaty and other COVID-19 vaccines are not considered interchangeable. The two-dose course should be completed with the same vaccine. There are no data yet on the efficacy of mixed schedules.

Repeat vaccination

Additional or booster doses beyond the two-dose course are not recommended.

Data on the real-world effectiveness and duration of protection from Comirnaty will be gathered over coming months and years, and will need to be assessed to inform future recommendations.

Contraindications and precautions

Anaphylaxis or severe allergic reaction to a COVID-19 vaccine

The only absolute contraindications to Comirnaty are:

- anaphylaxis after a previous dose
- anaphylaxis to any component of the vaccine, including to polyethylene glycol (PEG)

Comirnaty may be given to people with a history of severe allergy or anaphylaxis to food, insect stings and specific medicines.

Additional precautions are recommended at this time for individuals with a history of anaphylaxis to any antigen (including food, insect stings, medicines), and those who have been prescribed an adrenaline autoinjector (e.g., EpiPen). These individuals should be observed for 30 minutes following administration of a COVID-19 vaccine dose. All other vaccine recipients should be observed for at least 15 minutes following administration of the vaccine at the clinic site in accordance with the current recommendations in the Australian Immunisation Handbook.

For individuals who are suspected to have had an allergic reaction to their first dose of Comirnaty, providers should seek expert advice through the specialist immunisation service of their state/territory to discuss the need for specialist assessment and make a decision regarding the second dose.

As with all vaccines, COVID-19 vaccine recipients may rarely develop anaphylaxis shortly after vaccination. The early observed rate of anaphylaxis after Comirnaty administration in the United States of America (the USA) was 5.0 cases per million doses. 90% of cases occurred within 30 minutes of vaccination (refer to **Adverse events** section for more information).²⁷ The majority (80%) of cases had a history of allergy to a range of substances, and 24% had a history of prior anaphylaxis. Comirnaty contains polyethylene glycol (PEG), and it is possible that this component could be implicated in anaphylaxis.²⁸ People with a confirmed or possible history of PEG allergy should seek expert advice on COVID-19 vaccination before being vaccinated. It is important to note that anaphylaxis following PEGs is reported to be extremely rare (37 case reports between 1977 and 2016).²⁹

Before and during each vaccination session, providers should check that up-to-date protocols, equipment, medicines and trained staff to manage anaphylaxis are available. Refer to the [“Preparing for vaccination”](#) section of the Australian Immunisation Handbook.

As part of routine care, all vaccine recipients should be given information on adverse events following immunisation and when to seek medical attention.

Acute illness

Vaccination should be deferred in people with an acute illness, including febrile illness (axillary temperature $\geq 38.5^{\circ}\text{C}$). This is a general precaution for all vaccines and will also avoid potential misattribution of symptoms from the acute illness as being due to the vaccine or vice-versa.

People with bleeding disorders

People with bleeding disorders and people who are receiving anticoagulant therapy may develop haematomas at intramuscular injection sites. Prior to vaccination, the recipient and/or guardian should be informed about this risk. Comirnaty should be administered by intramuscular injection. Subcutaneous administration of Comirnaty is not recommended, as no data are available on the safety or immunogenicity of Comirnaty given via this route.

When administering an intramuscular injection to an individual with a bleeding disorder, a 23 or 25 gauge needle should be used, and firm pressure applied to the site without rubbing for at least 2 minutes.³⁰

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For detailed information on how to safely administer vaccines intramuscularly vaccines to people with bleeding disorders, refer to [Vaccination for people with bleeding disorders](#) section in the Australian Immunisation Handbook.

Adverse events

Comirnaty

In the phase II/III trial, adverse events reported within 7 days following vaccination were very common but generally mild to moderate and well tolerated.

Injection site reactions were very common, particularly pain at the injection site (refer to Table 1). Injection site pain was reported with similar frequency after dose 1 and dose 2, but occurred slightly more frequently in the younger people aged 16 to 55 years (83% post dose 1 and 78% post dose 2) than in older adults aged >55 years (71% and 66 %, respectively). Injection site redness and swelling occurred in <10% of all participants. These local reactions were generally mild to moderate, had a median time of onset on the day after vaccination and resolved within 1 to 2 days.

Systemic adverse events reported after Comirnaty vaccination were more common following the second dose (refer to Table 1). The median onset of systemic adverse events was 1–2 days after vaccine receipt, with resolution in a median of 1 day.²⁵ Adverse events were generally milder and less frequent in adults aged >55 years than in those aged 16–55 years. Most adverse events were of mild to moderate severity and did not affect daily activities. The reported rates of diarrhoea and vomiting did not differ between vaccine and placebo recipients.

The median duration of follow-up for adverse events was 2 months after the second dose. Lymphadenopathy, though uncommon (<1%), was more common in vaccine recipients than in placebo recipients (64 cases [0.3%] versus 6 cases [<0.1%]) and is likely related to the expected immune response to the vaccine. The cases of lymphadenopathy were generally mild to moderate and resolved after a median time of 10 days. There were four cases of Bell's palsy (acute peripheral facial paralysis) in the vaccination group (with onset at 3, 9, 37 and 48 days after a dose), respectively, and no cases in the placebo group.²⁵ However, this observed frequency was consistent with the expected background rate of Bell's palsy in the general population and thus may not have a causal relationship to vaccination.

There were no substantive differences in the frequency of adverse events overall observed in the clinical trial by age, sex, race, ethnicity or baseline SARS-CoV-2 status subgroups. There was no evidence of enhanced COVID-19 disease in vaccinated individuals who developed SARS-CoV-2 infection after completing vaccination, with only one severe case in the eight vaccine failures.³¹

Anaphylaxis after Comirnaty has been reported rarely. Refer to **Contraindications and precautions: Anaphylaxis or severe allergic reaction to a COVID-19 vaccine** section for further information.

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty (30µg per dose) in phase II/III trial (the US Food and Drug Administration, 2020)

	16–55 years of age		>55 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	83.1%	77.8%	71.1%	66.1%
Fever	3.7%	15.8%	1.4%	10.9%
Fatigue	47.4%	59.4%	22.6%	50.5%
Headache	41.9%	51.7%	25.2%	39%
Chills	14.0%	35.1%	6.3%	22.7%
Muscle pain	21.3%	37.3%	13.9%	28.7%
Joint pain	11.0%	21.9%	8.6%	18.9%
Required paracetamol	27.8%	45%	19.9%	37.7%

Reporting adverse events

All notifications of adverse events following immunisation should be made through the usual reporting mechanisms [in your state or territory](#). Refer also to the “[Reporting to immunisation registers](#)” section of the Australian Immunisation Handbook.

The safety of COVID-19 vaccines will be actively monitored by the TGA as well as state and territory governments.

Vaccine information

A phase II/III trial of Comirnaty is ongoing with >43,000 individuals aged ≥12 years enrolled. An interim analysis, with a duration of observation of 2 months post dose 2, reported vaccine efficacy (VE) of 95.0% (95% CI: 90.3–97.6) in preventing symptomatic laboratory-confirmed COVID-19 in people aged ≥16 years (median age 52 years, range 16–89 years for vaccine recipients) without evidence of prior infection with SARS-CoV-2. Sub-group analyses demonstrated similarly high efficacy in adults aged ≥65 years (VE 94.7 [95% CI: 66.7–99.9]) and in adults with at least one medical comorbidity or obesity (VE 95.3 [95% CI: 87.7–98.8]).

In this interim analysis, short-term efficacy after a single dose was 52.4% (95% CI: 29.5–68.4), with protective effect observed starting 12 days after dose 1. There is also evidence of efficacy against severe illness, although the estimate is imprecise due to the lower number of people overall who developed severe disease (VE 88.9% after first dose (95% CI: 20.1–99.7)).³¹ No data are currently available to assess efficacy for prevention of asymptomatic infection, although serological data are awaited. The duration of protection has not been determined.

This ongoing phase II/III trial also includes participants with well-controlled chronic medical conditions. An interim sub-analysis of those with some specified medical conditions showed a similar vaccine efficacy to those without such conditions (95.3% [95% CI: 87.7–98.8] versus 94.7% [95% CI: 85.9–98.6])³².

Data on the safety and efficacy of Comirnaty in children aged <16 years are not yet available. Children aged ≥12 years were enrolled in the phase II/III trial of Comirnaty, and safety and immunogenicity of the vaccine in adolescents aged 12–15 years will be reported in the final analysis. Data on safety, immunogenicity or efficacy of Comirnaty in people living with HIV (who were included in the clinical trial if stable) have not yet been published.

Women who were pregnant or breastfeeding; people with conditions with high risk of severe COVID-19 (including residents in a long-term care facility) or with immunocompromising conditions; or those taking immunosuppressive therapy were excluded from the trial.³² Data on the safety of Comirnaty vaccination in these populations will be available in the future from additional clinical trials and post-marketing studies.

Transporting, storing and handling vaccines

Comirnaty

Comirnaty vaccine vials have a shelf life of 6 months at -90°C to -60°C. Frozen vials should be thawed at 2°C to 8°C. For a carton of 195 vials, this requires 3 hours. Frozen vials can also be thawed at room temperature (up to 30°C) for 30 minutes, for immediate use. Once thawed the vaccine should not be re-frozen. Refer to the product information for more detailed guidance regarding thawing of vials.

After thawing, the shelf life is 5 days at 2°C to 8°C. Undiluted vaccine vials can be stored at up to 30°C for 2 hours (including thawing time). After dilution, vials must be kept at 2°C to 30°C and used within 6 hours from the time of dilution (not including the 2-hour maximum window for storage of an undiluted vial at up to 30°C). Do not freeze the diluted vaccine.

Comirnaty is presented in a multi-dose vial containing 0.45mL of undiluted vaccine and must be reconstituted by diluting with 1.8mL of sterile 0.9% sodium chloride. The vaccine does not contain a preservative. Do not use bacteriostatic 0.9% sodium chloride. The total quantity after dilution will be 2.25mL. Do not shake the vial. It is preferable to administer vaccine doses immediately after dilution.

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

For additional information refer to the National Vaccine Storage Guidelines [‘Strive for 5’](#)

Recording vaccination

Recording of administration of each and every dose of COVID-19 vaccine on AIR is mandatory.

This will assist in ensuring that the correct vaccine and interval is used for the second dose, and to identify patients who are due for a second dose. This will also allow verification or provision of evidence of completion of COVID-19 vaccination, if required.

For more information, refer to the Services Australia website: [AIR for health professionals](#).

Serological testing for immunity

Testing for anti-spike antibodies or neutralising antibodies to demonstrate immunity against SARS-CoV-2 in vaccinated individuals is not recommended. An immune correlate of protection has not yet been established for SARS-CoV-2 infection or COVID-19 in humans.³³

Impact of vaccination on future COVID-19 testing

Receipt of a COVID-19 vaccine will not affect the results of nucleic acid testing or rapid antigen testing for diagnosis of SARS-CoV-2 infection.

Since the Comirnaty COVID-19 vaccine encodes the spike protein of SARS-CoV-2, it may affect any subsequent serological diagnostic testing and result in detection of antibody to the spike protein, but will not affect the results of anti-nucleocapsid antibody testing.

Isolation or testing for COVID-19 following adverse events

Testing for SARS-CoV-2 infection or implementing (non-medically recommended) isolation of someone who develops symptoms of fever, headache, fatigue or other systemic symptoms within and lasting for <48 hours after receipt of a COVID-19 vaccine is not necessarily required. If a vaccine recipient develops the type of vaccine-related adverse events (refer to **Adverse events** section above) and there is complete absence of respiratory symptoms (including loss of smell), it is more likely that they have an expected vaccine response.

For **Comirnaty**, the median time of onset of systemic adverse events was 1–2 days after vaccine receipt, with resolution in a median of 1 day.

Local public health guidance on criteria for SARS-CoV-2 testing varies depending, in part, on local epidemiology and outbreak management, and should be followed irrespective of a history of vaccination, unless otherwise directed.

Post-exposure prophylaxis

COVID-19 vaccines are not recommended for post-exposure prophylaxis use, as no data are available to support such a use. The median incubation period for SARS-CoV-2 is 5–6 days (with a range of 1 to 14 days in most people) and vaccination after exposure is unlikely to generate sufficient immunity within this period to prevent infection in a previously unvaccinated exposed individual.

However, local public health authorities may recommend prioritising COVID-19 vaccination for certain populations related to local outbreaks or settings with community transmission of COVID-19. For latest information refer to the CDNA [National guidelines for public health units](#) on COVID-19.

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