Australian Nursing & Midwifery Federation

ANMF COVID-19 RESOURCE

Updated contraindications and precautionary advice for COVID-19 vaccines

***ALERT* Evidence regarding COVID-19 is continually evolving. This resource will be updated regularly to reflect new emerging evidence but may not always include the very latest evidence in real-time.**

Three safe and effective COVID-19 vaccines are now being rolled out in Australia. In this resource, we summarise the evidence and recommendations regarding contraindications and precautionary advice regarding the *Pfizer/Comirnaty*, *AstraZeneca/Vaxzeveria*, and *Moderna/Spikevax* vaccines.

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Introduction

Several COVID-19 vaccines have been developed to protect people against 'severe acute respiratory syndrome coronavirus 2' (or 'SARS-CoV-2'). From late September 2021, three vaccines will be available for administration in Australia. Two are messenger RNA (mRNA) vaccines (*Pfizer/Comirnaty* and *Moderna/Spikevax* and one is a viral vector vaccine (*AstraZeneca/Vaxzeveria*).

COVID-19 vaccination is recommended for all people aged ≥16 years to protect against COVID-19. All COVID-19 vaccines approved by the Therapeutic Goods Administration (TGA) for use in Australia are effective in reducing a recipient's risk of becoming infected, sick, hospitalised, severely ill, being admitted to an intensive care unit, dying, and transmitting the virus, including the Delta variant, to others.[1, 2] The vaccines however do not completely protect a person from harm or prevent transmission. All current official recommendations regarding infection prevention and control should continue to be observed regardless of vaccine status.

To support the rollout and uptake of vaccines, the Australian Government Department of Health publishes recommendations and guidance for administration of the vaccine. In Australia this advice is largely provided to the Government by the Australian Technical Advisory Group on Immunisation (ATAGI).

Contraindications and precautions

This article summarises the evidence and recommendations regarding contraindications and precautionary advice regarding Australian COVID-19 vaccines.

In most cases, the benefits of being vaccinated far outweigh the very small risk of harm and the majority of people can safely receive one of the three available COVID-19 vaccines. As new safety evidence emerges, people who were previously ineligible to receive a vaccine are now recommended to be vaccinated. For example, following publication of clinical trials and ongoing emergence of real-world evidence the Australian mRNA vaccines *Pfizer/Comirnaty* and *Moderna/Spikevax* are now recommended for pregnant and breastfeeding women. People who are unsure about their risk or eligibility to receive a COVID-19 vaccine should discuss their concerns with a trusted member of their healthcare professional team. Australian healthcare professionals who are regulated by the Australian Health Practitioner Regulation Agency (AHPRA) have a professional obligation to only share information that is evidence-based and in line with the best available health advice.

Contraindications

A contraindication is defined as a specific situation in which a drug, procedure, or surgery should not be used because the potential for harm is too high. Specifically, an 'absolute contraindication' is a circumstance in which use of the intervention (e.g. a vaccination) may cause a life-threatening situation and so its use should be avoided.[3]

Based on consensus among health authorities globally there are very few absolute contraindications for the COVID-19 vaccines approved in Australia.[4-7] On the advice of ATAGI, the Australian Government Department of Health identifies the following vaccine contraindications:

- *AstraZeneca/Vaxzeveria*: anaphylaxis to a previous dose or to an ingredient (e.g. polysorbate 80); history of capillary leak syndrome; thrombosis with thrombocytopenia following a previous dose, or any other serious adverse event attributed to a previous dose.
- *Pfizer/Comirnaty* and *Moderna/Spikevax*: anaphylaxis to a previous dose or to an ingredient of an mRNA COVID-19 vaccine (e.g. polyethylene glycol (PEG)); myocarditis and/or pericarditis attributed to a previous dose, or any other serious adverse event attributed to a previous dose.

Anaphylaxis

Anaphylaxis is a severe but very rare allergic reaction that can occur due to exposure to certain foods, venom (e.g. bee stings) or medications among some susceptible people. The risk of experiencing anaphylaxis following COVID-19 vaccination is around one in 100,000 doses. In the United States, the rate of anaphylaxis following *Pfizer/Comirnaty* administration was 4.7 cases per million doses in early 2021. During the same period, the rate of anaphylaxis following *Moderna/Spikevax* administration was 2.5 cases per million doses. In almost 70 percent of cases, anaphylaxis occurred within 30 minutes following vaccination.[8]

If a person has a history of anaphylaxis in response to any other antigens such as foods, animal stings, or specific medicines, they may still receive a COVID-19 vaccine.[9] It is recommended that these people be observed for 30 minutes post vaccination as opposed to the 15 minute observation for people without history of anaphylaxis.[5] This period of observation is also reflected in United States recommendations that suggest a period of extended observation is necessary for any individual who has experienced an allergic reaction of any severity to a previous dose of an mRNA vaccine.[6]

Precautionary advice

There are a number of precautions that should be considered when deciding on which vaccines should be administered and to whom. Precautions do not preclude the administration of a vaccine and are rather evidence-informed indications to inform and enhance the safety of vaccination among different populations (e.g. clinical presentations and age groups) and in varying contexts (e.g. localities with uncontrolled community spread).

Pregnant and breastfeeding women, or those planning a pregnancy

Due to the emergence of new evidence regarding COVID-19 vaccine safety, pregnancy, breastfeeding, and planning pregnancy are no longer conditions that preclude vaccination.

In Australia, women at any stage of pregnancy are a priority group for vaccination in Australia and *Pfizer/Comirnaty* and *Moderna/Spikevax* the preferred vaccines for this group. Breastfeeding women can also be safety administered one of the COVID-19 vaccines with the mRNA vaccines the recommended option. For women who have already received one dose of *AstraZeneca/Vaxzeveria*, *Pfizer/Comirnaty* and *Moderna/Spikevax* are preferred for the second dose, however *AstraZeneca/Vaxzeveria* can be administered if the risk of harm from COVID-19 is greater than the risk of vaccine administration for the individual woman.

The Australian Government has published a decision guide to aid women and health professionals to make the best decision for them regarding vaccine administration. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has also published guidance here.[10, 11]

Pregnant women are a priority population because they have a potentially greater risk of experiencing complications and severe COVID-19.[12] Pregnant women who experience severe COVID-19 are at increased risk of preterm birth and pregnancy loss.[13]

Experts do not consider COVID-19 vaccines to pose a risk to breastfeeding women or babies, and also note that there is no evidence to suggest that women who become pregnant after receiving the vaccine are at any increased risk of harm. There is no need for pregnancy to be delayed after receiving a COVID-19 vaccine.[11]

Acute illness

Standard practice for all vaccines including those for COVID-19 is to delay administration until the illness has resolved.[14] For those who are acutely ill including febrile illness (axillary temperature ≥38.5°C) at the planned time of vaccination, administration should be deferred to ensure that any adverse reaction to the vaccine does not exacerbate the illness and so that symptoms of the illness are not incorrectly identified as a vaccine reaction or missed.

Elderly people

Older age (e.g. ≥60 years and ≥80 years) is a known risk factor for experiencing worse disease-related outcomes of COVID-19 infection, so older people have been among the priority groups to receive vaccinations in Australia. The benefits of COVID-19 vaccination greatly outweigh the risks of COVID-19 infection as well as the rare risks that can be encountered related to vaccination.

Although some countries have reported deaths in elderly people following vaccination, no causal link between administration of the vaccine and the deaths has been established. The deaths were recorded among frail individuals, with very short life expectancies and in some circumstances palliative care had already begun prior to vaccination.[15]

Older adults and their proxy decision makers may consider both the risks and benefits of receiving the vaccine when deciding whether they will receive a vaccination or not. The Australian Government has provided a decision guide for frail older people which notably states their increased risk of contracting severe COVID-19 and death,[16-18] as well as the increased risk of transmission introduced in close proximity living environments such as nursing homes.

Children and adolescents

Healthy children have a much lower risk of severe COVID-19-related illness when compared to adults.[19] In Australia, ATAGI currently recommends that the following children aged 12-15 years be prioritised for vaccination:

- Children with specified medical conditions that increase their risk of severe COVID-19 (e.g. specified immunocompromising conditions including various cancers, inflammatory conditions, chronic disease and conditions, and disability).
- All Aboriginal and Torres Strait Islander children aged 12-15 years
- All children aged 12-15 in remote communities, as part of broader community outreach vaccination programs that provide vaccines for all ages (≥12 years).

Recommendations for use in all other children aged 12-15 years will be made in updated advice within the coming weeks. In Australia the *Pfizer/Comirnaty* vaccine has been authorised for use among children and adolescents aged ≥12 years.

Persons previously or currently infected, or recently exposed to COVID-19

Past infection with SARS-CoV-2 is not a contraindication or precaution for subsequent vaccination; however, it is recommended that vaccination be deferred for up to six months after the acute illness in those who have had PCR-confirmed SARSCoV-2 infection. Previous infection with COVID-19 appears to reduce the risk of reinfection for approximately six months.[20, 21]

Vaccination is not recommended for those who are currently infected or for those who have been recently exposed to COVID-19.[5, 6] These recommendations are because of the low likelihood that the body will develop a sufficient immune response within the incubation period, and also the risk of exposing others to COVID-19 at the time of vaccination.[6, 22]

Persons with autoimmune conditions or the immunocompromised

COVID-19 vaccine is recommended for people who are immunocompromised because of their increased risk of severe illness with COVID-19. Persons with autoimmune conditions or the immunocompromised should consult with a healthcare professional ahead of receiving the vaccine.[5, 23] The Australian Government has published a decision guide for this group.

Although there is limited available data on vaccination of those with autoimmune conditions or the immunocompromised, guidance indicates that those who have either should receive a vaccine.[5, 6, 23, 24]

The Australasian Society of Clinical Immunology and Allergy (ASCIA) notes there is no evidence that those with either primary or secondary autoimmune conditions or immunodeficiency are at any greater risk of vaccine allergy than the general population.[23] Further, the Centers for Disease Control and Prevention finds that there were no resulting inconsistencies between individuals with autoimmune conditions that were vaccinated in clinical trials of mRNA vaccines (*Pfizer/Comirnaty*), and those who received a placebo.[6]

For the immunocompromised, recommendations for vaccination are made more specifically because of the increased risk of severe illness for immunocompromised people who contract COVID-19.[25] Expert opinion also suggests that the vaccines are not a risk given the mRNA vaccine does not contain any live virus, and the viral vector vaccine (*AstraZeneca/Vaxzeveria*) is non-replicating.[5]

People aged under 60 years

Most people aged under 60 years can safely receive one of the COVID-19 vaccines, as the benefits of every vaccine generally outweigh the risks. Very rare instances of blood clots with low platelet counts (thrombosis with thrombocytopenia (TTS)) have been reported among people who have received the *AstraZeneca/Vaxzeveria*. The TGA carefully reviews all Australian reports of TTS following vaccination and updates their advice accordingly. People who have had the first dose of the *AstraZeneca/Vaxzeveria* vaccine without any serious adverse effects should have the second dose. This includes people aged under 60 years.

The *AstraZeneca/Vaxzeveria* vaccine can be used in adults aged under 60 years where the benefits clearly outweigh the risk for that individual (e.g. due to individual conditions or local outbreak situation) and the person has made an informed decision based on an understanding of the risks and benefits. People aged 18-59 years can choose to receive the *AstraZeneca/Vaxzeveria* vaccine following an appropriate assessment of suitability by a qualified health professional and after verbal or written consent. Otherwise, *Pfizer/Comirnaty* (≥12 years) and *Moderna/Spikevax* (≥18) are the preferred vaccines.

As a precaution, people with a history of any of the following conditions are recommended to receive (when eligible) a *Pfizer/Comirnaty* vaccine over a *AstraZeneca/Vaxzeveria* vaccine:

- Cerebral venous sinus thrombosis (CVST)
- Heparin-induced thrombocytopenia (HIT)
- Splanchnic vein thrombosis
- Antiphospholipid syndrome (APLS) with thrombosis and/or miscarriage.

The preferred minimum interval between receipt of a COVID-19 vaccine and any other vaccine, including influenza vaccine, is 7 seven days. In some scenarios such as the increased risk of COVID-19 or another vaccine-preventable disease or logistical issues resulting in difficulty scheduling visits to maintain the seven-day interval, an interval of less than seven days, including co-administration is acceptable.

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