Australian Nursing & Midwifery Federation

ANMF COVID-19 RESOURCE

COVID-19 vaccines: contraindications and precautionary advice

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.

Two safe, effective COVID-19 vaccines are now being rolled out in Australia. Here we summarise the evidence and recommendations regarding contraindications and precautionary advice regarding Australian COVID-19 vaccines.

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Key points

- *COVID-19 vaccines in Australia have been identified as safe and effective for a large majority of the population.*
- *Global consensus on immunisation best practice indicates that very few people should not receive the vaccine. These are:*
  - *People who have experienced anaphylaxis after a previous dose of the name COVID-19 vaccine.*
  - *People who have had an anaphylactic reaction to any component of the COVID-19 vaccines including polyethylene glycol/ PEG (Pfizer/Comirnaty) and polysorbate 80 (Oxford/AstraZeneca).*
  - *Acutely ill people (vaccination should be deferred until recovered).*
- *Routine administration for some groups (e.g. children) is not recommended due to lack of safety and efficacy data.*
- *The Pfizer/Comirnaty vaccine is approved for people aged ≥16 years.*
- *The Oxford/AstraZeneca vaccine is approved for people aged ≥18 years.*
- *In Australia, it has been recommended that the Pfizer/ Comirnaty vaccine be preferable for all adults under 50 years of age.*
- *Where benefits outweigh the risks of thrombosis with thrombocytopenia among adults under 50 years of age, the Oxford/AstraZeneca vaccine may still be administered.*
- *Overall, the benefits associated with COVID-19 vaccine administration (both Pfizer/ Comirnaty and Oxford/AstraZeneca) outweigh a potentially increased risk of thrombosis with thrombocytopenia following Oxford/AstraZeneca vaccination among those aged under 50.*
- *Individuals should consult with their healthcare professional and assess the personal risks and benefits of vaccine administration.*
- *People aged ≥65 years should consider the risk of severe COVID-19 and risk of exposure and consult with their healthcare professional if very frail.*
- *The COVID-19 vaccine is not routinely recommended for pregnant women who do not have related medical risk factors for severe COVID-19 and/or high risk of exposure.*
- *Women who are not at risk of serious COVID-19 infection and/or high risk of exposure may prefer to wait to receive a vaccination until after their pregnancy.*
- *Pregnant women with medical risk factors and/or at high risk of exposure should discuss potential benefits and risks of the vaccine with their health professional.*

- *Experts suggest there is no foreseeable risk for breastfeeding women or the infant, and that those who fall pregnant after receiving the vaccine are at no increased risk of harm.*
- *Pregnancy planning does not need to be delayed following vaccination.*
- *Clinical trials have not yet reported on safety and efficacy in children and adolescents.*
- *The COVID-19 vaccines can be administered to people who have previously contracted COVID-19 (may choose to defer administration for six months following infection).*
- *People with confirmed COVID-19 or recent confirmed exposure should not receive vaccination until they have satisfied self-isolation or quarantine requirements.*
- *The immunocompromised have increased susceptibility to severe COVID-19. Although there is limited data on safety and efficacy within this group, and also those with autoimmune conditions, experts recommend vaccination as the vaccines either do not contain live virus, or are not self-replicating, and are therefore pose minimal risk.*

Introduction

The Australian Government has detailed a national rollout strategy for the delivery of COVID-19 vaccines. In the Phase 1a, vaccines will be available to quarantine and border workers, priority sub-groups of frontline health workers, and aged care and disability care staff and residents.[1]

COVID-19 vaccines have been developed to protect people against the 'severe acute respiratory syndrome coronavirus 2' virus (or 'SARS-CoV-2'). Any COVID-19 vaccine approved for use in Australia may be effective in reducing the severity of illness but may not completely protect against infection or prevent a person from transmitting the virus to others. 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 resource summarises the evidence and recommendations regarding contraindications and precautionary advice regarding Australian COVID-19 vaccines.

The ATAGI identifies a small minority of people who should not receive a particular variant of the vaccine due to known contraindications. For other population groups, such as pregnant women or the immunocompromised, there is not a currently sufficient body of evidence to allow for routine recommendations. Instead, precautionary advice and guidance has been made.[2-4]

Contraindications and precautions prior to vaccination

Evidence and lack of evidence

Although the vaccines in use in Australia have been identified as safe and effective, the evidence regarding their use is continuously evolving and so guidance and recommendations regarding contraindications and precautions may change.

This means that people who are in groups that have been approved for vaccination, should have conversations with a trusted healthcare professional to assess any potential personal risks and benefits to receiving a COVID-19 vaccine.[3]

There are currently two vaccines approved for use in Australia, the Pfizer/BioNtech mRNA based vaccine (Comirnaty),[5] and the Oxford/AstraZeneca (COVID-19 Vaccine AstraZeneca) viral vector vaccine.[*6] These vaccines have been studied since early- to mid-2020.[7,8] For this reason, there are some cases where data on their safety and efficacy are limited.

* Pfizer/BioNtech, or specifically Pfizer Australia PTY Ltd, is the trade name of the company responsible for producing the "Pfizer" vaccine in Australia, the product name of the vaccine itself is Comirnaty and so you may see it referred to in this way. Similarly, the product name of the Oxford/AstraZeneca vaccine is COVID-19 Vaccine AstraZeneca.

For example, while studies are underway, clinical trials have not yet reported on children or adolescents (Pfizer, 2200 participants aged 12 to 15; Oxford/AstraZeneca, 300 participants aged 6 to 17).[9] Because the findings of these studies have not yet been published, there is no evidence to underpin advice regarding vaccination for these groups. Without specific documented evidence on safety and effectiveness, routine recommendations regarding their administration to untested groups cannot be made.

Lack of evidence does not necessarily indicate that specific population groups who currently are not recommended to receive vaccines will always be precluded from receiving a vaccination. To follow from the above example, based on the results of trials in other age groups and current evidence regarding both COVID-19 vaccines and other existing vaccines, experts suggest it is not likely that COVID-19 vaccines would have serious or unforeseen adverse effects on children.[10] As more evidence becomes available, current recommendations and guidance regarding vaccines for this group (and other understudied groups) may change.[3]

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 great. 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.[11] There are limited absolute contraindications to COVID-19 vaccines currently approved for use in Australia.

On the advice of ATAGI, the Australian Government Department of Health identifies the following contraindications to the vaccine. A person should not receive a vaccination if;[3]

- they have experienced anaphylaxis after a previous dose of the same vaccine, or;
- they have previously experienced anaphylaxis to any component of the vaccines, including polyethylene glycol (PEG) for the Pfizer vaccine or polysorbate 80 for the Oxford/AstraZeneca vaccine.

These contraindications are in-line with best practice immunisation guidance.[12] There is an apparent consensus among health authorities globally that the above are the only absolute contraindications in regard to the COVID-19 vaccines approved in Australia.[3, 10, 13, 14]

Anaphylaxis

Anaphylaxis is a severe but relatively rare allergic reaction that can occur due to exposure to certain foods, venom (e.g. bee stings) or medications among some susceptible people. The United States Centre for Disease Control (CDC) reported 21 cases of anaphylaxis resulting from the administration of 1,893,360 doses of the Pfizer vaccine, suggesting a rate of 11.1 cases per million vaccinations. The incidences of anaphylaxis generally occurred within 15 minutes of vaccine administration, were treatable with epinephrine, and there were no deaths.[15]

If a person has a history of anaphylaxis in response to any other antigens such as foods, animal stings and specific medicines, they may still receive a COVID-19 vaccine.[16] 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.[3] This period of observation is also reflected in CDC 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.[10]

Acute illness

Standard practice for COVID-19 and other vaccines is to delay administration until the illness has abated.[12] For those who are currently acutely ill, such as with a febrile illness, 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 or missed.

Precautionary advice and decision guidance for special populations

Elderly people

The Pfizer vaccine has been found to be safe and effective in those over 65 years of age. However, there were few older clinical trial participants in the Oxford/AstraZeneca vaccine and so safety and efficacy data for this vaccine is limited for individuals over 65.[17, 18] A preprint publication analysing data from the United Kingdom, does however suggest that both the Pfizer/Comirnaty vaccine and the Oxford/AstraZeneca vaccine are safe and effective in reducing hospital admissions for people aged 70 and over.[19]

Elderly people 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,[20-22] as well as the increased risk of transmission introduced in close proximity living environments such as nursing homes. The Pfizer vaccine has been found safe and effective in reducing these risks.[7]

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.[23]

Although there are no specific safety concerns regarding vaccine administration to the elderly, and advice suggests there is no cap to the upper age limit of who can receive the Pfizer vaccine, the potential benefit versus the potential risk of the vaccine, including the clinical impact of even mild adverse events in the frail elderly should be carefully considered and discussed with treating health professionals.[23]

Pregnant and breastfeeding women, or those planning a pregnancy

Although studies to assess the safety and efficacy of COVID-19 vaccines in pregnant women are planned,[24] current data is insufficient for routine recommendation of COVID-19 vaccines in pregnant women.[25]

Women who are not at risk of serious COVID-19 infection and/or high risk of exposure may prefer to wait to receive a vaccination until after their pregnancy. Many including the Australian Government and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) encourage pregnant women, particularly those with medical risk factors for severe COVID-19 and/or at high risk of exposure, to consider their personal risks and benefits of vaccination and consult with a healthcare professional. Considerations should include the current level of local community transmission, the individual's personal risk of contracting COVID-19, the risk of COVID-19 to the woman and potentially the unborn baby, efficacy of the vaccine, and side effects of the vaccine. The Australian Government has published a decision guide to aid in this process, and RANZCOG provide guidance here.[2, 25]

Although the comparative number of severe COVID-19 cases in pregnant women is small, in comparison with other women in the same age group, pregnant women have a potentially greater risk of experiencing complications and severe COVID-19.[26] Pregnant women who experience severe COVID-19 are at increased risk of preterm birth and pregnancy loss.[27]

Experts do not consider COVID-19 vaccines to pose a risk to breastfeeding women or the infant, 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 the vaccine.[25]

Children and adolescents

Healthy children have a much lower risk of contracting severe COVID-19 when compared to adults.[28] As with pregnant women initial clinical trials are not typically undertaken on children and adolescents. In Australia the Pfizer/Comirnaty vaccine has been authorised for use in adolescents aged 16 and 17 years old, however the Oxford/AstraZeneca vaccine has only been approved for those over the age of 18 years old.[29, 30]

Expert guidance suggests there is no theoretical reason as to why the vaccine would be harmful to children and so this advice may change dependent on the outcome of clinical trials in this younger age group. These trials are currently underway.[31]

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

Previous infection with COVID-19 appears to reduce the risk of reinfection for approximately six months.[32, 33] For this reason, individuals do not necessarily require vaccination for a period of six months after contracting COVID-19. Clinical trials of the Pfizer vaccine did not indicate any specific safety issues for the individuals in their study who showed evidence of previous COVID-19 infection.[7]

The Australian Government suggests those who have had PCR-confirmed SARS-CoV-2 infection may choose to defer their vaccination for up to six months from the time of their infection. This is not mandated however, and vaccination is encouraged amongst those who have previously contracted the disease. Testing for evidence of previous COVID-19 infection is not necessary or recommended prior to vaccination.[3]

Vaccination is not recommended for those who are currently infected or for those who have been recently exposed to COVID-19.[3, 10] 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.[10, 34]

Persons with autoimmune conditions or the immunocompromised

Persons with autoimmune conditions or the immunocompromised should consult with a healthcare professional ahead of receiving the vaccine.[3, 35] 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.[3, 10, 35, 36]

In clinical guidance the Australian government does not provide specific advice for those with an autoimmune condition, however 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.[35] Further, the CDC finds that there were no resulting inconsistencies between individuals with autoimmune conditions that were vaccinated in clinical trials of mRNA vaccines (Pfizer), and those who received a placebo.[10] 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.[37] 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 is non replicating.[3] Importantly, immune responses for immunocompromised people may be limited, so vaccine efficacy may be reduced in this population.[3, 36]

People aged under 50 years

Very rare instances of blood clots with low platelet counts (thrombosis with thrombocytopenia) have been reported among people who have received the Oxford/AstraZeneca vaccine.[38,39] To date, one case of thrombosis with thrombocytopenia has been reported in Australia and assessed by the Vaccine Safety Investigation Group (VSIG).[40] As yet, there is insufficient evidence to confirm that the clot was caused by the vaccine, however emerging evidence suggests a likely association. The European Medicines Agency (EMA) has found a possible link between the AstraZeneca COVID-19 vaccine and thrombosis with thrombocytopenia with most case reports in women under 60 years of age, within 2 weeks of vaccination.38 The TGA is carefully reviewing all Australian reports of blood clots following the AstraZeneca vaccine and will update any advice accordingly.[41]

In Australia, it has been recommended that the Pfizer/Comirnaty vaccine be preferable for all adults under 50 years of age (i.e. all adults regardless of sex assigned at birth).[40] Where benefits outweigh the risks of thrombosis with thrombocytopenia among adults under 50 years of age, the Oxford/AstraZeneca vaccine may still be administered.[40] Overall, the benefits associated with COVID-19 vaccine administration (both Pfizer/Comirnaty and Oxford/AstraZeneca) outweigh a potentially increased risk of thrombosis with thrombocytopenia following Oxford/AstraZeneca vaccination among those aged under 50.[38,40] People who have received the first dose of the Oxford/AstraZeneca vaccine with no serious adverse effects (including people under 50) should still receive the second dose.[40]

Globally, many groups are continuously monitoring even very rare and minor adverse events. Even an extremely small number of cases of blood clots among vaccine recipients is being taken seriously and investigated. It is important to consider that among non-vaccinated people, blood clots are relatively common (millions of cases every year worldwide).[42] There are many and varied risk factors that increase a person's risk of blood clots including some common medications (e.g oral contraceptives), hospitalisation and medical treatments (major surgery), pregnancy and postpartum, increasing age, male biological sex, and personal and familial history).[42]

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