Allergy, Immunodeficiency, Autoimmunity and COVID-19 Vaccination Position Statement

Updated 20 September 2021

This statement has been developed by ASCIA, the peak professional body of clinical immunology/allergy specialists in Australia and New Zealand as a guide for COVID-19 vaccination in people with allergy, immunodeficiency and autoimmune conditions, and will be updated when new information is available.

Introduction

Vaccination is an important method to reduce the risk of developing infectious diseases, including COVID-19, caused by infection with the SARS-CoV-2 coronavirus. Immunisation occurs after the vaccine stimulates the immune system to induce antibodies (immunoglobulins) and cellular immunity to protect from severe COVID-19 disease, and possibly reduce the risk of transmission of infection in the community.

Public health measures and restrictions that have been implemented by the Australian and New Zealand governments since March 2020 have reduced the spread of COVID-19 in our countries. However, the COVID-19 pandemic has been a major cause of illness and deaths worldwide, and local outbreaks continue to occur.

This means that vaccination programs are required throughout the world, including Australia and New Zealand.

COVID-19 vaccines available in Australia and New Zealand

The COVID-19 vaccines listed below are not live-attenuated vaccines and are safe for people with immune system disorders, including allergy, immunodeficiency and autoimmune conditions:

- **Pfizer/BioNTech Comirnaty mRNA-based COVID-19 vaccine** – available in Australia and New Zealand for adults and children 12 years and over.
- **Moderna Spikevax mRNA-based COVID-19 vaccine** – available in Australia for adults and children 12 years and over.
- **AstraZeneca/Oxford viral vector COVID-19 vaccine** – available in Australia for adults 18 years and over.

In Australia the vaccines listed above have all been provisionally approved by the Therapeutic Goods Administration (TGA), which is part of the Australian Government Department of Health.
www.health.gov.au/initiatives-and-programs/covid-19-vaccines

In New Zealand the Pfizer/BioNTech Comirnaty vaccine has been provisionally approved by Medsafe.
www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines

Other brands of COVID-19 vaccines have also been provisionally approved by the TGA and Medsafe, and these may become available in future.

Provisional approval for use of mRNA vaccines in the 12-15 years age group has been made following careful evaluation of the available data supporting safety and efficacy.

Allergic reactions to COVID-19 vaccines

Allergic reactions to COVID-19 vaccines are rare. However, if there is a high risk of an allergic reaction to one of the vaccines, it may be possible to have another vaccine which does not contain the ingredient, subject to availability and medical advice.

With new vaccines it is critical to evaluate the safety after the vaccine has been licensed. Post-licensure information on the safety of mRNA vaccines have demonstrated higher rates of severe allergic reactions (anaphylaxis) than expected. However, rates are extremely low.

Polyethylene Glycol (PEG), also known as macrogol, is an ingredient in mRNA vaccines:

- Different forms of PEG are found in tablets, laxatives, hand sanitiser gels, injectable corticosteroids, medications, cosmetics, bathroom products and colonoscopy preparation products.
- PEG can cause contact dermatitis in some people.
- PEG is recognised as a rare hidden allergen that can trigger anaphylaxis to multiple classes of drugs.

It is uncertain whether PEG or another ingredient may trigger COVID-19 vaccine anaphylaxis.

Polysorbate 80 is chemically related to PEG and is an ingredient in the **AstraZeneca COVID-19 vaccine**.

Widespread use of COVID-19 vaccines suggests that severe allergic reactions to the Pfizer and AstraZeneca vaccines are very rare.

Guide for COVID-19 vaccination in people with allergic conditions

ASCIA has developed the following recommendations, based on the current knowledge regarding allergic reactions to COVID-19 vaccines. These recommendations may change when new information is available.

1. VACCINATE WITHOUT ADDITIONAL PRECAUTIONS

Vaccinate in the community as per national recommendations, with a post-vaccination observation period of **15 minutes**. This includes people with:

- History of allergy, including anaphylaxis to food, drugs, venom, or latex.
- Allergic conditions, including asthma, atopic dermatitis (eczema) or allergic rhinitis (hay fever).

2. VACCINATE WITH PRECAUTIONS*

- Immediate (within four hours) and generalised symptoms of a possible allergic reaction without anaphylaxis to a previous dose of a COVID-19 vaccine.
- Generalised allergic reaction (without anaphylaxis) to one of the ingredients in the COVID-19 vaccine to be administered (Pfizer or Moderna - PEG or AstraZeneca - Polysorbate 80).
- Prior history of anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral) where the ingredients PEG or polysorbate 80 may conceivably be the cause and have not been tolerated since on medication review.
- A history of confirmed Mastocytosis with recurrent anaphylaxis that requires treatment.

*** Precautions:**

- Review or discussion prior to vaccination by a clinical immunology/allergy or vaccinology specialist, to develop a risk/benefit assessment for each patient.
- Skin testing to the vaccine and/or graded doses should be considered in some cases.
- Vaccination in a medical facility equipped for the management of anaphylaxis (such as a medical clinic with multiple doctors available, or a hospital clinic).
- Post-vaccination observation period should be at least **30 minutes**.

3. VACCINATION CONTRAINDICATED

- Documented anaphylaxis to one of the ingredients contained in the COVID-19 vaccine to be administered (Pfizer or Moderna - PEG or AstraZeneca - Polysorbate 80).
- Anaphylaxis to a prior dose of a COVID-19 vaccine.

Note: Anaphylaxis with one type of COVID-19 vaccine may not preclude vaccination with another vaccine, but this should only occur if the precautions listed above are met. If there is a high risk of an allergic reaction to one of the vaccines (such as a known allergy to PEG or Polysorbate 80), it may be possible to have another vaccine which does not contain the ingredient, subject to availability and medical advice.

COVID-19 vaccination and adverse events

Some people will get mild, short-term side effects from vaccination, including injection site reactions, fever, joint pain, muscle aches, fatigue, headaches, or worsened eczema a day after vaccination.

These common side effects indicate the start of an immune response, not an allergic reaction, which are rare. Side effects do not usually require treatment other than paracetamol for fever or discomfort.

Anaphylaxis to vaccines is extremely rare but can be life threatening and should always be treated as a medical emergency, with immediate treatment with **adrenaline (epinephrine)**. Most cases of anaphylaxis to vaccines occur within 20 to 30 minutes of vaccination and respond to one or two doses of adrenaline.

Health professionals administering vaccines in Australia and New Zealand should **all** be trained in the emergency treatment of anaphylaxis, and adrenaline should be readily available in **all** vaccination centres.

ASCIA anaphylaxis e-training and action plans are available at www.allergy.org.au/anaphylaxis

All notifications of adverse events following immunisation should be made through the usual reporting mechanisms. Refer also to the Reporting to immunisation registers section of the Australian Immunisation Handbook https://www.health.gov.au/health-topics/immunisation/health-professionals/reporting-and-managing-adverse-vaccination-events

In New Zealand, notifications of adverse events should be reported to the Centre for Adverse Reactions Monitoring (CARM) https://nzphvc.otago.ac.nz/reporting/

Any unexpected or serious event should be reported, regardless of the causal association with the vaccine.

COVID-19 vaccines and allergy

There is no evidence that people with allergic conditions such as asthma, hay fever (allergic rhinitis), food allergy or insect sting allergy are at any greater risk of vaccine allergy compared to the general population.

People with a known PEG allergy or previous anaphylaxis to multiple medications, should see their clinical immunology/allergy specialist to assess and confirm their allergy. The AstraZeneca vaccine may be a suitable alternative to the Pfizer or Moderna vaccines if PEG allergy is confirmed.

Unlike some other vaccines there is no food, gelatin or latex in the COVID-19 vaccines that are currently available and they are not grown in eggs. If people have had an allergic reaction to another vaccine, this does not mean that they will also be allergic to the COVID-19 vaccine.

Regular medications for allergic rhinitis, atopic dermatitis and asthma should be continued when having the COVID-19 vaccine.

It is recommended that allergen immunotherapy (AIT) or venom immunotherapy (VIT) injections should not be given within 48 hours of the COVID-19 vaccine injection. This avoids confusion about the cause of side effects or allergic reactions, if they occur in response to the COVID-19 vaccine or immunotherapy.

COVID-19 vaccines, immunodeficiency and autoimmune conditions

There is no evidence that people with primary or secondary immunodeficiencies and autoimmune conditions are at any greater risk of vaccine allergy than the general population. People with certain pre-existing medical conditions have been identified as one of the initial priority groups for COVID-19 vaccines. This includes people with immunodeficiencies and autoimmune conditions.

It is important that treatments for immunodeficiencies and autoimmune conditions are continued, because stopping these treatments can place patients at greater risk from COVID-19.

Vaccination should occur on a different day (if possible) from regular infusion treatments, such as immunoglobulin replacement therapy or immunosuppressant infusions.

For example, people on monthly intravenous immunoglobulin (IVIg) may be advised by their specialist to be vaccinated two weeks after an IVIg infusion. This avoids confusion about the cause of side effects or allergic reactions, if they occur in response to the COVID-19 vaccine or the infusion treatment.

People with immunodeficiencies and autoimmune conditions should follow the advice from their clinical immunology/allergy specialist or rheumatologist regarding COVID-19 vaccines.

Current recommendations for patients with immunosuppression from the Australian Rheumatology Association (ARA) https://rheumatology.org.au/ or the American College of Rheumatology (ACR) www.rheumatology.org/ may be used by clinical immunology/allergy specialists and rheumatologists to guide decisions regarding COVID-19 vaccination. Each patient with immunosuppression requires shared decision making between patient and prescriber that is based on these recommendations and specific clinical circumstances, including disease activity, co-morbidities and risk of COVID-19 infection.

COVID-19 vaccines, other medical conditions and vaccinations

COVID-19 vaccines have initially been tested in healthy adults, before being tested on more vulnerable people, to provide confidence that the vaccine is safe for use in the general population.

If a patient is being treated for other medical conditions or is in a clinical trial, they should ask their doctor for advice regarding the COVID-19 vaccine.

Surgery guidelines recommend that people do not have major surgery and vaccines within one week of each other. This is because both surgery and the vaccine can cause a fever.

It is recommended not to have the influenza vaccine and a COVID-19 vaccine on the same day.
The preferred minimum interval between an influenza vaccine and a COVID-19 vaccine is seven days.

COVID-19 vaccines and new variants of the SARS-CoV-2 coronavirus

Clinical trials have shown that the vaccine stimulates the immune system to make antibodies (immunoglobulins) that are able to respond to a variety of mutations.

Technology used in vaccine development is adaptable to change if mutations occur, in the same way that the influenza vaccine ingredients change each season. Developments in this area are being closely monitored.

Other measures to prevent COVID-19

It is not yet known how long the antibodies (immunoglobulins) or cellular immunity lasts, which are induced in response to having the COVID-19 vaccine, or after having COVID-19.

There is limited information from COVID-19 vaccine clinical trials regarding whether vaccination reduces the rate of transmission of infection.

Therefore, it is important that the following measures continue to be followed, even if people are vaccinated or have had COVID-19:

- **Hand hygiene -** Regular, thorough hand washing with soap and water is vital to prevent infections, especially after using the bathroom and before eating. Hand sanitiser may be used if soap and water are unavailable.
- **Respiratory hygiene -** Physical distancing and covering the mouth and nose with a bent elbow or tissue when coughing or sneezing, then disposing of the used tissue immediately, can prevent infections.
- **Stay home if you are unwell -** If anyone has a fever or cough, they should stay home, seek medical attention (call in advance), and follow health authority instructions, including isolation.
- **Follow government advice and restrictions -** This includes the measures listed above.

ASCIA has also developed a Frequently Asked Questions (FAQ) about Allergy, Immunodeficiency, Autoimmunity and COVID-19 Vaccination, for patients, consumers and carers.

To access the FAQ and further information go to www.allergy.org.au/members/covid-19

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