Australian Technical Advisory Group on Immunisation (ATAGI)

Information for providers: COVID-19 Vaccination Consent & FAQs

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What has been updated:

Information added about Spikevax (Moderna)

This document contains information on the COVID-19 vaccine Comirnaty (Pfizer), Spikevax (Moderna), and Vaxzevria (AstraZeneca). Information on other vaccines will be added over time.

Aims

This information will assist immunisation providers to gain consent for COVID-19 vaccination and to answer some frequently asked clinical questions. Providers should also be familiar with the content of the following documents:

- *Clinical guidance on the use of COVID-19 vaccine in Australia in 2021*
- *Consent form for COVID-19 vaccination*
- *Information on COVID-19 Pfizer vaccine*
- *Information on COVID-19 Moderna vaccine*
- *Information on COVID-19 Vaccine AstraZeneca*
- *Preparing for COVID-19 vaccination*
- *COVID-19 vaccination – After your Pfizer vaccine*
- *COVID-19 vaccination – After your Moderna vaccine*
- *COVID-19 vaccination – After your AstraZeneca vaccine*

Method of consent

As with all other vaccines, informed consent is needed before each COVID-19 vaccine dose. This can be verbal or written consent. Consent should always be documented, e.g. in a patient's medical record.

The Australian Government has prepared an optional written consent form for providers who choose to use one, at *www.health.gov.au/resources/publications/covid-19-vaccination-consent-form-for-covid-19-vaccination*. The form is provided as an example for vaccination providers to obtain patient consent prior to COVID-19 vaccination.

For further information about valid consent, refer to the Australian Immunisation Handbook – *Preparing for vaccination – Valid consent.*

Suggested discussion points

The following points may assist providers in discussing COVID-19 vaccines with recipients:

- **Benefits of vaccination.**
  The primary benefit of vaccination is protection against illness from COVID-19, and in particular protection against severe illness and death.
  - The short-term vaccine efficacy of Pfizer against symptomatic COVID-19 was approximately 95% from seven days after the second dose in people aged ≥12 years. This was consistent across age groups.
  - The short-term vaccine efficacy of Moderna against symptomatic COVID-19 was estimated to be 94% in people aged ≥18 years, and similarly highly efficacious among adolescents aged 12–17 years.
  - The short-term vaccine efficacy of AstraZeneca against symptomatic COVID-19 was in the range of 62–70%, and efficacy was greater with a longer interval between doses.

  The effectiveness of all three vaccines against symptomatic infection with the Delta strain of SARS-CoV-2 is reduced compared with earlier strains, however protection against hospitalisation is maintained.

- **It is possible that a vaccinated person may still become infected with SARS-CoV-2 and pass on the virus to someone else, regardless of whether they have any symptoms.**
  Pfizer, Moderna and AstraZeneca have been shown to reduce transmission of older strains of SARS-CoV-2 by about 50%, however the efficacy against transmission of the Delta strain is not known.

- **The need for a second dose of the same brand.**
  Pfizer, Moderna and AstraZeneca all require two doses. The first dose provides partial protection, but the second dose is needed to ensure optimal protection. The same vaccine brand should be used to complete the vaccination course. The recommended dose interval varies by brand.
  - The recommended interval between two doses for Pfizer is 21 to 42 days (3 - 6 weeks).
  - The recommended interval between two doses for Moderna is 28 to 42 days (4 - 6 weeks).
    - Longer intervals between the first and second doses of Pfizer or Moderna, e.g. 8-12 weeks, may need to be recommended during program rollout if epidemiological considerations warrant a change.
  - The recommended interval for AstraZeneca is 12 weeks routinely, and 4-8 weeks in outbreak settings.

- **Continue to apply other public health measures.**
  Even after completing vaccination, all people must continue to practise public health measures to reduce their personal risk of infection with SARS-CoV-2 and of passing the virus to others, such as physical distancing, hand washing, wearing a face mask (when recommended), COVID-19 testing and quarantine or isolation as required. As population-level immunity to the virus increases over time following widespread uptake of vaccination, these public health measures may be able to be eased, but only as advised by the local public health authorities.

- **Safety of COVID-19 vaccines**.
  Pfizer, Moderna and AstraZeneca have been studied in tens of thousands of people in clinical trials. As of August 2021, more than 4.5 billion doses of a COVID-19 vaccine have been administered around the world. Most side effects are mild and transient.
  - Reactions at the injection site and some systemic reactions, like headaches, fever, chills and fatigue, are very common within the first 48-72 hours. These side effects are most common after dose 1 of AstraZeneca and dose 2 of Pfizer and Moderna (occurring in approximately two-thirds of people).
  - Very rarely, anaphylaxis has been reported after Pfizer and Moderna, occurring in the USA at a rate of about 5 cases per 1 million doses of Pfizer and 2.5 cases per 1 million doses of Moderna. The rate of anaphylaxis reported after AstraZeneca in Australia is similar to the rate of anaphylaxis for other vaccines.
  - Authorities closely monitor for rare or unanticipated side effects, as for any vaccine or medicine. In early April 2021, a new rare condition called thrombosis with thrombocytopenia syndrome (TTS) (see below) was found to be plausibly linked to AstraZeneca.

- **Thrombosis with thrombocytopenia syndrome (TTS) after AstraZeneca**:
  The AstraZeneca vaccine is associated with a rare condition called 'thrombosis with thrombocytopenia syndrome' (TTS) which involves thrombosis *with* thrombocytopenia. Onset of symptoms occur around 4 to 42 days following vaccination with AstraZeneca. Cases have involved various sites and presentations include cerebral venous sinus thrombosis (CVST) or thrombosis of the splanchnic (abdominal) circulation. Pfizer and Moderna are not associated with a risk of TTS.
  - No medical risk factors for TTS have yet been confirmed.
  - The reported rate of TTS has been higher for younger adults compared to older adults. For this reason, Pfizer and Moderna are the preferred COVID-19 vaccines for people under 60.
  - Pfizer and Moderna are also recommended for people with a past history of CVST, heparin induced thrombocytopenia (HIT), idiopathic splanchnic (mesenteric, portal, splenic) vein thrombosis or antiphospholipid syndrome with thrombosis.

Information on the rare risk of TTS should be provided to recipients as part of the informed consent process for AstraZeneca.
For further information about TTS, refer to *Information for Immunisation Providers on Thrombosis with Thrombocytopenia Syndrome (TTS) following COVID-19 vaccination*.

- **Management of common side effects**.
  Most side effects start within 24 hours of vaccination and will resolve within a few days on their own. To reduce discomfort, paracetamol or ibuprofen can be taken. Some of the expected vaccine side effects overlap with the symptoms of SARS-CoV-2 infection, such as fever. A key differentiating factor, however, is that respiratory symptoms (e.g. cough, runny nose etc.) are not known to be associated with Pfizer, Moderna or AstraZeneca.

- **Isolation or testing after vaccination.**
  Local public health guidance on criteria for SARS-CoV-2 testing should always be followed. People who have typical non-respiratory side effects (e.g. injection side pain, fever, lethargy) within the first 48 hours after vaccination with a complete absence of any respiratory symptoms *may not* need to get a COVID-19 test or isolate. As these vaccines are not known to cause respiratory symptoms (e.g. rhinorrhoea or cough), people with respiratory symptoms should be tested for SARS-CoV-2 as per local testing criteria.

- **Seeking medical attention after vaccination**.
  Vaccine recipients should be advised to seek medical attention if they are concerned about a symptom, have new or unexpected symptoms, or symptoms which have not resolved after several days. See also *Thrombosis with thrombocytopenia syndrome (TTS) after AstraZeneca* above.
  A person with any suggestion of an allergic reaction to vaccination should also seek care, noting that the great majority of (rare) serious allergic reactions present within the first 30 minutes after vaccination.

- **Vaccine safety monitoring**.
  Vaccine recipients may be contacted in the week after vaccination via SMS or email with a brief survey to collect data on any adverse events following the vaccine. This is part of a national adverse events surveillance system called AusVaxSafety.
  Adverse events can also be reported by the recipient or by the immunisation provider to their state or territory health department or to the Therapeutic Goods Administration (TGA). Refer to Question 15 below for further information.

- **Reporting of vaccinations.**
  All COVID-19 vaccinations must be recorded on the Australian Immunisation Register (AIR). This is a mandatory requirement under national legislation. People can obtain a copy of their immunisation history statement online via their Medicare Online account through myGov.

- **Collection of personal details**.
  Please notify patients how their personal details are collected, stored and used. For more information visit *https://www.health.gov.au/using-our-websites/privacy/privacy-notice-for-covid-19-vaccinations*.

Common questions that providers may have regarding COVID-19 vaccine

Vaccines covered in this list of common questions: Comirnaty (Pfizer), Spikevax (Moderna) and Vaxzevria (AstraZeneca).

Questions about COVID-19 vaccines

1. **Is it mandatory to get a COVID-19 vaccine?**

   Vaccination is mandatory for aged care workers and quarantine workers. Exemptions are in place for people who are unable to be vaccinated. Some states and territories have introduced mandates for other occupational groups. Vaccination is otherwise voluntary.

2. **How much does it cost to get a COVID-19 vaccine?**

   The COVID-19 vaccine is free for people residing in Australia, including visa holders. More information can be found in *Australia's COVID-19 Vaccine and Treatment Strategy*.

3. **How long does it take for COVID-19 vaccines to work after receiving them?**

   Partial protection against COVID-19 may be achieved as soon as two weeks after the first dose of Pfizer or Moderna, and 22 days after the first dose of AstraZeneca. However, this protection is likely to be short lived unless a second dose is given, and all people are recommended to receive the second dose to provide optimal protection.

4. **What if a person does not get the second dose of a COVID-19 vaccine?**

   A single dose of COVID-19 vaccine will provide only partial protection against COVID-19 and this protection is likely to be of shorter duration unless the second dose is given. For optimal protection against COVID-19, two doses are required.

5. **Why are multi-dose vials being used?**

   Multi-dose vials (MDVs) contain more than one dose of a vaccine in a single glass vial. Each dose is extracted and given via an individual syringe. Given the huge demand for COVID-19 vaccines worldwide, there are not enough vials available globally for single-use prefilled syringes to be used in the first stages of the global vaccination effort. MDVs are the most efficient way to distribute a new vaccine to the maximum number of people and are being used world-wide for all COVID-19 vaccines. It is expected that COVID-19 vaccines will only be available in MDVs in 2021. Providers must follow guidance on how to safely handle and administer vaccines supplied in MDVs. Refer to *Training materials for immunisation providers* for the COVID-19 vaccination program in Australia.

6. **Why do vaccine recipients still need to practise public health measures (e.g. physical distancing) after completing vaccination?**

   It is not yet known to what extent COVID-19 vaccines protect against transmission of SARS-CoV-2 at the individual or population level. This means that although a fully vaccinated person will obtain strong protection against becoming ill with COVID-19, it is possible they may still get infected with the SARS-CoV-2 virus and pass it on to others, even if they do not have any symptoms. This is also true for other vaccine preventable diseases (including influenza, pertussis and rotavirus) and does not necessarily mean that vaccines will not be highly effective in reducing the impact of COVID-19. It will take time to gain more data to answer these questions.

   To prevent transmission of SARS-CoV-2, it is essential to continue practising COVID-19 prevention measures like physical distancing, handwashing, wearing a face mask, COVID-19 testing and quarantine or isolation as required.

Questions about the safety of COVID-19 vaccines

7. What are the common side effects of Pfizer?

The side effects from Pfizer are generally mild and short-lived, with onset mostly within 1 day after vaccination and a duration of approximately 1–2 days.

In clinical trials, the most commonly reported adverse events in the first week after vaccination were[1]:

- pain at the injection site (in about 84%)
- tiredness (in about 62%)
- headache (in about 52%)
- muscle pain (in about 37%)
- chills (in about 35%)
- joint pain (in about 22%)
- fever (in about 16%)
- diarrhoea (in 10%).

Clinical trial participants also rarely (0.3%) reported mild and transient lymphadenopathy (predominantly axillary or cervical) following vaccination, which may be related to the immune response to the vaccine.

Adverse events such as respiratory symptoms, vomiting and diarrhoea were no more common in the first week after vaccination in vaccine as compared with placebo recipients, meaning such symptoms are unlikely to be attributable to vaccination.

The adverse events described above were slightly more common after the second dose, and slightly less common in people over 55 years of age than in younger adults.

8. What are the common side effects of Moderna?

In the clinical trial, side effects from Moderna generally started the day of vaccination or the day after vaccination, and self-resolved within 3 days. The side effects were generally mild and occurred more commonly after the second dose of the vaccine than the first dose.

Common side effects within 7 days from vaccination were:

- pain at the injection site (in about 88%)
- tiredness (in about 65%)
- headache (in about 59%)
- muscle pain (in about 58%)
- chills (in about 44%)
- joint pain (in about 43%)
- nausea and/or vomiting (in about 19%)
- fever (in about 16%)
- axillary lymph node swelling (in about 14%).

These adverse reactions were less common in people aged 65 years or over than in younger people.

Delayed-onset injection site reactions, occurring from day 8 after vaccination onwards, such as pain, redness or swelling, occurred in 0.8% of recipients after the first dose and 0.2% after the second dose. These reactions generally resolve after 4 to 5 days.

Respiratory symptoms such as cough and sore throat were not more common after vaccination with Moderna than placebo and are therefore unlikely to be attributable to the vaccine.

9. What are the common side effects of AstraZeneca?

In clinical trials, adverse events following AstraZeneca were generally mild or moderate. They were most commonly reported on day 1 after vaccination, and generally resolved within a few days. The most common systemic adverse events at day 7 were fatigue, headache and malaise.

Common side effects reported after AstraZeneca in clinical trials included[2]:

- tenderness at the injection site (in about 64%)
- pain at the injection site (in about 54%)
- headache (in about 53%)
- tiredness (in about 53%)
- muscle pain (in about 44%)
- feeling unwell, also called malaise (in about 44%)
- chills (in about 32%)
- nausea (in about 22%)
- fever (in about 8%)

Clinical trial participants also rarely (0.3%) reported mild and transient lymphadenopathy following vaccination, which may be related to the immune response to the vaccine.

Adverse reactions were milder and less frequent after the second dose, and were milder and less frequent in older adults (≥ 65 years old) compared to younger adults.

10. Are there any serious safety risks associated with Pfizer?

As with any vaccine, rare serious adverse events have been reported after Pfizer, including anaphylaxis and myopericarditis.

No cases of anaphylaxis were seen in the phase II/III study of Pfizer. However, anaphylaxis has been very rarely reported in US recipients of Pfizer at a rate of around 5 cases per million doses administered (as of January 2021). In case series, most of the recipients who experienced anaphylaxis after Pfizer had symptom onset within 30 minutes. The majority had a past history of a known allergy. The exact cause of anaphylaxis in these patients (e.g. if it was a particular component of the vaccine, such as polyethylene glycol) is still being investigated. No other serious adverse events have been confirmed to be directly linked to Pfizer.

Very rarely, myocarditis and pericarditis have been reported following vaccination with Pfizer and other mRNA COVID-19 vaccines. Most reported cases have been mild, self-limiting and have recovered quickly, although longer-term follow-up of these cases is ongoing. Cases have been reported predominantly after the second dose and predominantly in younger males (aged < 30 years).

In the phase II/III clinical trial of Pfizer there were four cases of Bell's palsy (idiopathic lower motor neuron seventh nerve palsy, leading to weakness of one side of the face) in the vaccine group compared to zero cases in the control group. This was still very rare and occurred at a rate consistent with the expected background rate of Bell's palsy. Therefore, the numerical imbalance in the trial may have been coincidental. This and a range of other adverse events of special interest are being monitored in post-market vaccine safety surveillance to determine, although very unlikely, if vaccination is linked with any unwanted rare or unexpected health outcomes.

11. Are there any serious safety risks associated with Moderna?

An anaphylactic reaction (a severe allergic reaction) was observed in two participants of the Moderna phase III clinical trial (one in the placebo arm and one in the vaccine arm). Since provisional registration, the rate of anaphylaxis after Moderna vaccination in the US is estimated to be 2.5 cases per 1 million doses of Moderna. Anaphylaxis started between 1 to 45 minutes after administration of Moderna, with the majority (84%) starting within 15 minutes. The majority of patients (84%) had a past medical history of an allergy, with one quarter having a history of prior anaphylaxis. The exact cause of anaphylaxis in these patients is still under investigation.

In addition, in the clinical trial for Moderna, two participants experienced facial swelling within two days from vaccination. Both cases had a history of dermal filler injection prior to vaccination, and both cases of facial swelling resolved.

Similar to Pfizer, rarely, myocarditis and pericarditis have been reported following vaccination with Moderna. These cases were mostly mild and self-limiting, although longer term follow-up is ongoing. Myocarditis and pericarditis after Moderna vaccination is predominantly observed in younger males (aged < 30 years).

12. Are there any serious safety risks associated with AstraZeneca?

Thrombosis with thrombocytopenia syndrome (TTS) is a rare condition that has been reported following administration of AstraZeneca, almost exclusively after the first dose. See above section *Thrombosis with thrombocytopenia syndrome (TTS) after AstraZeneca*, and refer also to the *Information for Immunisation Providers on Thrombosis with Thrombocytopenia Syndrome (TTS) following COVID-19 vaccination*.

There has not been a higher overall rate of relatively common types of blood clots (including deep vein thrombosis and pulmonary embolism) reported after COVID-19 vaccination.

The first dose of AstraZeneca 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, for which a causal association has not yet been confirmed. These are Guillain Barre syndrome and capillary leak syndrome.

In clinical trials of AstraZeneca, one participant had a new diagnosis of multiple sclerosis 10 days after vaccination, however MRI findings suggested that the onset of the multiple sclerosis lesions pre-dated vaccination. A likely case of 'short segment inflammatory myelitis' also occurred in the vaccine group, with onset 14 days after vaccination. However, a causal association between the vaccine and these two cases cannot be concluded.

The reported rate of anaphylaxis following AstraZeneca in Australia appears to be similar to the known rate of anaphylaxis for other vaccines.

13. When and where should vaccine recipients seek medical care after vaccination?

Vaccine recipients should seek medical care after vaccination if they:

- think they are having an allergic reaction – if the reaction is severe, the patient should seek emergency medical care immediately by calling 000
- have an expected vaccine side effect which has not resolved after a few days
- are worried about a potential side effect or have new or unexpected symptoms, particularly around 4 to 42 days after vaccination, such as a headache that persists beyond 48 hours after vaccination, or appears later than 48 hours after vaccination.

Vaccine recipients should seek medical care from their regular health care provider (usually their GP), unless it is an emergency. Mild, temporary, anticipated side effects do not require follow up.

14. Can vaccine recipients take paracetamol or ibuprofen to reduce the side effects of vaccination?

Yes, paracetamol or ibuprofen can be taken after vaccination for a short time (e.g. 1–2 days) if required. However, they should not be taken prophylactically prior to vaccination.

15. How is the safety of COVID-19 vaccines monitored in Australia?

Vaccine safety is monitored in a number of ways in Australia. In passive safety surveillance, immunisation providers, members of the general public, and pharmaceutical companies can report adverse events from a vaccine (refer to Question 16 below for further information). This is called passive vaccine safety surveillance because it relies upon people reporting any concerns.

Australia also has an active safety surveillance system called AusVaxSafety, which collects information directly from people who have been vaccinated. This information is collected by SMS surveys sent out from the vaccine clinics to people who receive vaccines (or their parents or guardians) to ask if they had

any reactions after receiving a vaccine. The de-identified data is used to monitor the safety of a vaccine program in close to real time, and would enable rapid detection of potential vaccine safety issues. The AusVaxSafety data is available here: *https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines*

Researchers and pharmaceutical companies also actively study the safety and effectiveness of vaccines after they are licensed.

The TGA and state and territory health departments' expert panels will regularly review all reported safety data, even more frequently than usual for other vaccines.

16. How should providers or vaccine recipients report an adverse event?

All immunisation providers are encouraged to report adverse events following immunisation (AEFIs). Providers practising in New South Wales, Western Australia, Queensland, Northern Territory, Australian Capital Territory and South Australia are required under public health legislation to report AEFIs to their state or territory health department. Members of the general public can also report AEFIs.

Mild, short-lived symptoms that are expected following vaccination do not need to be reported.

There are multiple ways to report an AEFI:

- *Report to local state or territory health department.*
- Providers and recipients can report to the *Therapeutic Goods Administration* (TGA). Reports can be made via *online form*, email (*adr.reports@tga.gov.au*) or by phone (1800 020 653).
- Providers and recipients can report to the NPS MedicineWise Adverse Medicine Events line on 1300 134 237 (9am–5pm, Monday–Friday).
  Visit *www.tga.gov.au/reporting-problems* for further details.

17. Can vaccine recipients get COVID-19 disease from the vaccine?

Pfizer and Moderna are not live vaccines, and it is not possible to get COVID-19 from the vaccine.

AstraZeneca does not contain the SARS-CoV-2 virus. It contains an unrelated harmless 'common cold' virus (an adenovirus), which has been modified so that it cannot replicate after entering cells. It therefore does not behave like a 'live vaccine' and cannot spread to other cells or cause infection.

Questions about the Australian Immunisation Register (AIR)

18. Is it mandatory to record COVID-19 vaccine doses on the AIR? Why is health information reported to AIR, and how will it be used?

The AIR is a whole of life, national immunisation register that records vaccines given to all people in Australia.

It is mandatory to record all COVID-19 vaccine doses given in Australia on the AIR. Vaccine doses administered overseas can also be recorded on the AIR.

A person does not need to have a Medicare number for their vaccine data to be included on the AIR.

The AIR is used:

- to monitor the effectiveness of vaccines and vaccination programs, including adverse events
- to identify any parts of Australia at risk during disease outbreaks
- to inform immunisation policy and research
- as proof of vaccination for entry to child care and school, and for employment purposes
- to monitor vaccination coverage across Australia.

Providers can use the AIR to check their patient's immunisation history, including the brand and timing of any previous COVID-19 vaccine doses that a recipient may have recorded.

Vaccine recipients can access their immunisation history statement via their Medicare Online account through myGov and via the Express Plus Medicare mobile app. Providers may also be asked to print an immunisation history statement. You may also advise your patients to call the AIR and request their immunisation history statement be sent to them. More information can be found on the *Services Australia website*.

Vaccine recipients can use their immunisation history statement as proof of vaccination against COVID-19, should they require it for any reason. They can also access a COVID-19 Digital Certificate which records all valid COVID-19 vaccine doses. The AIR will be updated to recognise vaccines that are considered valid in Australia. Refer to *Clinical advice on the use of a different COVID-19 vaccine as the second dose* for guidance on which vaccines will be considered valid.

19. Who will have access to recipients' vaccine information?

The Department of Health will collect, use and disclose personal information of vaccine recipients as authorised by the Australian Immunisation Register Act 2015 (Cth) and in accordance with the Privacy Act 1988 (Cth).

More information on how personal details are collected, stored and used, is available at: *www.health.gov.au/using-our-websites/privacy/privacy-notice-for-covid-19-vaccinations.*

Following their vaccination, individuals will be able to access their Immunisation History Statement (IHS) through their Medicare Online account through myGov, the Medicare Express Plus app, or their My Health Record.

AIR data is restricted to the individuals it relates to, vaccination providers (including state and territory health departments) and Commonwealth Officers who work on the AIR program from Services Australia and the Department of Health.

Immunisation statistics, such as immunisation coverage rates, are publicly available and published on the department's website.

Discussion checklist for providers obtaining consent

- ☐ Benefits of vaccination.
- ☐ Possible risk of contracting/transmitting COVID-19 despite vaccination.
- ☐ Requirement for 2 doses.
- ☐ Need to continue other public health measures (e.g. physical distancing, hand washing, wearing face mask, COVID-19 testing and quarantine/isolation as required).
- ☐ Safety of COVID-19 vaccines, including current safety investigation into very rare clotting condition.
- ☐ Management of side effects and seeking medical attention for side effects.
- ☐ Adverse events monitoring.
- ☐ Reporting of all vaccinations to the Australian Immunisation Register (AIR).

Pre-vaccination checklist (prior to each dose)

- ☐ Provide vaccine recipient with pre-vaccination information sheet and the information sheet on the specific vaccine that the recipient will receive, ie. Pfizer, Moderna or AstraZeneca.
- ☐ Obtain informed consent from recipient, using the discussion points above as appropriate.
- ☐ Document that informed consent was obtained (as per usual procedures).
- ☐ Check whether recipient has any contraindications or precautions for COVID-19 vaccinations.
- ☐ Check whether recipient has received another COVID-19 vaccine previously, and if yes, which brand and the date of receipt (verify records in AIR). The same brand should be used for the second dose, except in special circumstances. Further advice is available in the *ATAGI clinical advice on use of a different COVID-19 vaccine as the second dose in special circumstances*.
- ☐ Check whether recipient has received any vaccine within the past 7 days. A 7-day interval between a COVID-19 vaccine and any other vaccines is preferred.

Contraindications

Contraindications to AstraZeneca are:

- anaphylaxis after a previous dose
- anaphylaxis to any component of the vaccine, including polysorbate 80
- history of capillary leak syndrome
- thrombosis with thrombocytopenia occurring after a previous dose
- any other serious adverse event attributed to a previous dose of AstraZeneca (and without another cause identified) that has been reported to state adverse event reporting programs and/or the TGA, and has been determined following review by, and/or on the opinion of, an experienced immunisation provider or medical specialist taking into account whether repeat vaccine doses would be associated with a risk of recurrence of the serious adverse event.*

Contraindications to Pfizer or Moderna are:

- anaphylaxis to a previous dose of an mRNA COVID-19 vaccine (Pfizer of Moderna) is a contraindication to further doses of either vaccine
- anaphylaxis to any component of the vaccine, including polyethylene glycol (PEG)
- myocarditis and/or pericarditis attributed to a previous dose of either Pfizer or Moderna
- any other serious adverse event attributed to a previous dose of Pfizer or Moderna (and without another cause identified) that has been reported to state adverse event reporting programs and/or the TGA, and has been determined following review by, and/or on the opinion of, an experienced immunisation provider or medical specialist taking into account whether repeat vaccine doses would be associated with a risk of recurrence of the serious adverse event.*

* Assessment of adverse events following immunisation requires detailed information on the event, a determination of the likelihood of a causal link with vaccination, as well as the severity of the condition.

Serious adverse events are generally defined as those reactions which require hospitalisation (e.g., thrombosis with thrombocytopenia following the first dose of AstraZeneca), are medically significant (e.g., immune thrombocytopenia purpura, myocarditis), are potentially life threatening (e.g., anaphylaxis) and/or result in persistent or significant disability (e.g., Guillain-Barre Syndrome). These reactions do not typically include expected local or systemic reactions known to occur within the first few days after vaccination. Attributing a serious adverse event to a previous dose of a COVID-19 vaccine may require discussion with the individual's GP, local immunisation service or relevant medical specialist.

Precautions

General:

- Acute illness, e.g. fever ≥38.5℃
- Bleeding disorder or receipt of anticoagulant therapy
- Suspected immediate generalised allergic reaction to a previous dose or ingredient of the COVID-19 vaccine to be administered
- Confirmed mastocytosis with recurrent anaphylaxis requiring treatment.

Precautionary conditions for AstraZeneca:

- a history of cerebral venous sinus thrombosis (CVST)
- a history of heparin-induced thrombocytopenia (HIT)
- a history of idiopathic splanchnic (mesenteric, portal, splenic) thrombosis
- a history of antiphospholipid syndrome with thrombosis.

Precautionary conditions for Pfizer and Moderna:

- Recent (i.e. within the past 6 months) or current inflammatory cardiac illness e.g., myocarditis, pericarditis, endocarditis
- Acute rheumatic fever (i.e., active myocardial inflammation) or acute rheumatic heart disease
- Acute decompensated heart failure

Special circumstances warranting discussion before vaccination

- Immunocompromise
- Past history of COVID-19 or ongoing illness from COVID-19.

Post-vaccination checklist

- ☐ Monitor recipient for 15 minutes post-vaccination. Longer observation may be required for people with precautions to vaccination.
- ☐ Inform recipient of the brand of COVID-19 vaccine they have received.
- ☐ Inform recipient when the next dose is due (if dose 1 received), or that they have completed the primary vaccination course (if dose 2 received).
- ☐ Provide vaccine recipient with post-vaccination information sheet on the specific vaccine that the recipient received (Pfizer, Moderna or AstraZeneca).
- ☐ Document administration of COVID-19 vaccines (including correct brand) in AIR and in local clinical record.

References

1. World Health Organization. Background document to the WHO Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing 14 January 2021. *https://www.who.int/publications/i/item/background-document-on-mrna-vaccine-bnt162b2-(pfizer-biontech)-against-covid-19* [21/01/21]

2. World Health Organization. Interim recommendations for use of the AZD1222 (ChAdOx1-S (recombinant)) vaccine against COVID-19 developed by Oxford University and AstraZeneca. February 2021. Available at: *https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccinesSAGE_recommendation-AZD1222-2021.1.* [Accessed 16/02/2021]