Australian Technical Advisory Group on Immunisation (ATAGI)

ATAGI immunisation provider guide to obtaining informed consent for COVID-19 vaccine.

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

Aims

This information will assist immunisation providers to gain consent for COVID-19 vaccination and answers some frequently asked clinical questions. It does not provide detailed information on vaccine handling and administration procedures. Providers should be familiar with the content of this, and the following, documents:

- *ATAGI Clinical guidance on use of COVID-19 vaccine in Australia in 2021 v2.0*
- *Consent form for COVID-19 vaccination*
- *Information on COVID-19 Pfizer (Comirnaty) vaccine*
- Information on COVID-19 Vaccine AstraZeneca
- *Preparing for COVID-19 vaccination*
- *After your COVID-19 vaccination with COVID-19 Pfizer (Comirnaty) vaccine*
- *After your COVID-19 vaccination* with COVID-19 Vaccine AstraZeneca

Method of consent

As with all other vaccines, informed consent is required before administering each COVID-19 vaccine dose. Verbal or written consent is acceptable. Written consent is not mandatory, although may be obtained in some settings as per local practices. Providers should always ensure that informed consent is obtained and documented as per standard practices. Before administering each of the two doses, providers should ensure that patients 1) agree to receive the vaccine, and 2) meet the criteria to receive the vaccine.

The Australian Government has prepared an optional written consent form for those providers who choose to use one.

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 vaccine efficacy of Comirnaty in the phase II/III clinical trial was approximately 95% against symptomatic COVID-19 and was consistent across age groups. The vaccine efficacy of COVID-19 Vaccine AstraZeneca against symptomatic COVID-19 in phase II/III clinical trials was in the range of 62-70%, and efficacy was greater with a longer interval between doses. Following introduction of both vaccines in England and Scotland, the short term effectiveness of both Comirnaty and COVID-19 Vaccine AstraZeneca after one dose were similar, with two dose effectiveness data awaited.
- **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:**
  It is currently unclear to what extent COVID-19 vaccines prevent asymptomatic infection or transmission of SARS-CoV-2 from a vaccinated person to others and in the population. This may also vary between different vaccines. Data on this will be gathered over time from additional clinical studies and as populations are vaccinated.

- **The need for a second dose of the same brand:**
  Comirnaty and COVID-19 Vaccine AstraZeneca both require two doses. The recommended interval between doses varies by brand (at least 21 days for Comirnaty; 12 weeks for COVID-19 Vaccine AstraZeneca). While the first dose will provide some protection, it may only be partial and may only last for the short-term. The second dose is needed to ensure optimal protection. The same vaccine brand should be used to complete the vaccination course. Vaccine recipients should be advised to make a booking for their second dose.
- **Continuation of 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**:
  Comirnaty and COVID-19 Vaccine AstraZeneca have been studied in tens of thousands of people, and are very safe. As of March 2021, more than 245 million 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 and fatigue, are very common within the first 48 hours. Very rarely, anaphylaxis has been reported after Comirnaty, occurring in the USA at a rate of about 5 cases per 1 million doses (as of January 2021). The rate of anaphylaxis reported after COVID-19 Vaccine AstraZeneca is approximately 1 case per million, which is consistent with the rate of anaphylaxis for other vaccines. The potential for other rare or unanticipated side effects to emerge over time is very low, but is being closely monitored, as for any vaccine or medicine.
- **Management of 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. However, a key differentiating factor is that respiratory symptoms (e.g. cough, runny nose etc.) are not known to be associated with Comirnaty or COVID-19 Vaccine 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. 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 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.
- **Personal details collection**:
  Please notify patients on 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

Vaccine covered in this list of common questions: Comirnaty (Pfizer), COVID-19 Vaccine AstraZeneca

Questions about COVID-19 vaccines

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

   No, it is not mandatory to get a COVID-19 vaccine. While the Australian Government strongly recommends COVID-19 vaccination, individuals can choose not to be vaccinated.

   It is possible that in the future, vaccination against COVID-19 might become a requirement for travel to certain destinations or for people working in or visiting certain high-risk workplaces or facilities, such as aged care facilities. If this becomes the case, there will be exemptions in place for people who are unable to be vaccinated.

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

   People residing in the Australian community, including visa holders, will be eligible for the COVID-19 vaccine national rollout according to priority groups. The COVID-19 vaccine will be voluntary, universal and free. The Government aims to have as many Australians as possible choose to be vaccinated for COVID-19. 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 12 days after the first dose of Comirnaty, and 22 days after the first dose of COVID-19 Vaccine 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 will receive additional training on the use of MDVs and must follow guidance on how to safely handle and administer vaccines supplied in MDVs. Refer to *Training materials for immunisation providers* for 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 contraindications and precautions to COVID-19 vaccination?**

   The only absolute contraindications to receipt of COVID-19 vaccines are:

   - Anaphylaxis after a previous dose.
   - Anaphylaxis to any component of the vaccine, including to polyethylene glycol (PEG) for Comirnaty, or to polysorbate 80 for COVID-19 vaccine AstraZeneca.

   Precautions should be considered if the vaccine recipient:

   - **Is acutely unwell, e.g. febrile ≥38.5℃.** Vaccination should be temporarily deferred until the recipient has recovered.
   - **Has a bleeding disorder or is receiving anticoagulant therapy**. Refer to the Australian Immunisation Handbook for guidance on *vaccinating people with bleeding disorders.*
   - **Has any of the following histories** and may therefore require vaccination in a facility with medical staff in attendance, observation for at least 30 minutes post-vaccination, and/or consultation with an immunologist or specialist immunisation clinic prior to vaccination:
     - Immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (e.g. urticarial/hives) to a previous dose of a COVID-19 vaccine.
     - Generalised allergic reaction (without anaphylaxis) to any component of the COVID-19 vaccine to be administered.
     - Anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral), where ingredients such as PEG or polysorbate 80 may conceivably be the cause.
     - Known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment.

   Special circumstances that may warrant discussion during the consenting process include if the recipient:

   - Is pregnant.

- Is immunocompromised (e.g. as a result of congenital or acquired immunodeficiency, or if they are taking immunosuppressive medication).
- Has a past history of COVID-19 or ongoing illness from COVID-19.

For further information on counselling and vaccinating these groups refer to the ***ATAGI Clinical Guidance on use of COVID-19 Vaccine in Australia in 2021 v2.0***.

8. What are the side effects of Comirnaty?

The side effects from Comirnaty are generally mild and short-lived, with onset mostly within 1 day after vaccination and 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.

9. What are the side effects of COVID-19 Vaccine AstraZeneca?

In clinical trials, adverse events following COVID-19 Vaccine 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 COVID-19 Vaccine 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 Comirnaty?

The only known vaccine-related serious risk from Comirnaty is anaphylaxis. Anaphylaxis (a severe allergic reaction) is known to occur rarely after any type of vaccine.

No cases of anaphylaxis were seen in the phase II/III study of Comirnaty. However, anaphylaxis has been very rarely reported in US recipients of Comirnaty 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 Comirnaty 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 Comirnaty.

In the phase II/III clinical trial of Comirnaty 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 COVID-19 Vaccine AstraZeneca?

The risk of serious adverse events after COVID-19 Vaccine AstraZeneca is very low.

In clinical trials, one participant had a new diagnosis of multiple sclerosis 10 days after receiving COVID-19 vaccine AstraZeneca, 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 rate of anaphylaxis following COVID-19 Vaccine AstraZeneca in the UK was reported to be around 1 in 1,000,000, similar to the known rate of anaphylaxis for all other vaccines.

12. 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.
- They are concerned about a potential side effect or have new or unexpected symptoms.
- They have an expected vaccine side effect which has not resolved after a few days.

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

13. 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.

14. 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 15 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.

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.

15. 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 NSW, Western Australia, Queensland, Northern Territory or ACT 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 which 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.

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

Comirnaty is not a live vaccine, and it is not possible to get COVID-19 from the vaccine.

COVID-19 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)

17. 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?

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 a whole of life, national immunisation register which records vaccines given to all people in Australia.

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 this statement as proof of vaccination against COVID-19, should they require it for any reason.

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

The Department of Health will collect, use and disclose your personal information 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: *https://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
- ☐ 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, which is either the COVID-19 Pfizer (Comirnaty) vaccine or the COVID-19 Vaccine 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 if anaphylaxis occurred after the first dose.
- ☐ Check whether recipient has received any vaccine within the past 14 days. A 14-day interval between a COVID-19 vaccine and any other vaccines is preferred.

Contraindications

- Anaphylaxis to a previous dose of the vaccine being given
- Anaphylaxis to a component of the vaccine being given

Precautions

- Acute illness, e.g. fever ≥38.5℃
- Bleeding disorder or receipt of anticoagulant therapy
- Suspected immediate generalised allergic reaction to a previous dose of COVID-19 vaccine
- Generalised allergic reaction to any component of the COVID-19 vaccine to be administered
- Prior anaphylaxis to other vaccines or to medications (injectable or oral) where polyethylene glycol or polysorbate 80 could conceivably be the cause
- Known systemic mast cell disorder with raised mast cell tryptase that requires treatment

Special circumstances warranting discussion before vaccination

- Pregnancy
- 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, which is either the COVID-19 Pfizer (Comirnaty) vaccine or the COVID-19 Vaccine 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