

Vaccination Administration – Consent, Monitoring & Documentation

COVID-19 VACCINATION HUB



The Western Health COVID-19 Vaccination Hub will administer COVID-19 vaccine to eligible healthcare workers and members of the public. This QRG outlines the consent, administration and monitoring following vaccine documentation processes for both groups, and should be read in conjunction with [Victorian COVID-19 Vaccination Hub Guidelines](#) , [COVID-19 vaccination – ATAGI immunisation provider guide to obtaining informed consent for COVID-19 vaccine](#) and [OP-GC5 Immunisations for Health Care Workers](#)

Identifying Vaccine Recipients

Eligible vaccine recipients will receive an invitation to make a booking via Timify – a business continuity plan platform. When operational, bookings will be made via the COVID-19 Vaccination Management System (CVMS) - a Victorian-wide secure system developed by the Department of Health.

Invitations are being sent out in priority order based on the [Commonwealth’s priority rollout plan](#).

For healthcare workers this invitation will be sent to their work email address. At that time the healthcare worker can register on the system and book their vaccination appointment.

The wider public are not yet able to make a booking to receive the vaccine. Processes on how the public can make a booking will be published when this is able to occur.

Pre-vaccination screening

As part of the booking process on Timify and prior to vaccination the vaccine recipient will be taken through pre-vaccination screening questions which will assist in identifying any potential risks associated with receiving the vaccine or whether any special requirements need to be put in place. Pre vaccination screening ensures compliance with the [COVID-19 vaccination – ATAGI immunisation provider guide to obtaining informed consent for COVID-19 vaccine](#) guideline.

Specific advice related to the administration of the Astra Zeneca vaccine is provided as detailed in the [Patient information sheet on AstraZeneca COVID-19 vaccine](#).

Vaccine information

Prior to your vaccination appointment, click on the following links to read up on:

- [COVID-19 vaccination – Information on COVID-19 Pfizer \(COMIRNATY\) vaccine](#)
- [COVID-19 vaccination – Information on COVID-19 AstraZeneca vaccine](#)

Confirming receipt of any previous doses

At check in, the COVID-19 Vaccination Management System will be reviewed to confirm dates and times of any previous doses (if applicable), including the brand of vaccine previously administered.

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Obtaining Consent

Common law requires that valid consent is given prior to a medical procedure, including administering a vaccine. Verbal or implied consent is acceptable and written consent is not required (although may be obtained in some settings as per local practices).

For consent to be considered legally valid, the [Australian Immunisation Handbook](#) describes the following elements as necessary:

- It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of receiving a vaccine.
- It must be given voluntarily in the absence of undue pressure, coercion or manipulation.
- It must cover the specific procedure that is to be performed.
- It can only be given after the potential risks and benefits of the relevant vaccine, the risks of not having it, and any alternative options have been explained to the person.
- The person must have the opportunity to seek more details or explanations about the vaccine or its administration.
- The information must be provided in a language or by other means that the person can understand. Where appropriate, involve an interpreter or cultural support person.
- Consent must be obtained before vaccination, after establishing that there are no medical condition(s) that contraindicate vaccination.

Recording Consent

Vaccine recipients consent to receive the COVID-19 vaccine will be recorded via the COVID-19 Vaccine Management System. Vaccine recipients are required to review the [Consent form for COVID-19 vaccination](#) prior to providing consent.

Recording Vaccine Administration

Detailed records of each vaccination, including any side effects or adverse events are recorded in the COVID-19 Vaccination Management System.

Additionally, as of 1 March 2021, it will be mandatory for immunisation providers to provide details of all vaccinations given to infants, children and adults to the national database Australian Immunisation Register (AIR).

The COVID-19 Vaccination Management System will direct upload the details of the COVID-19 vaccination for each individual into AIR.

For Western Health staff, this information will also be recorded in the Western Health healthcare worker database when available. Reports will be sent to other health services on vaccine recipients to allow for local databases to be updated when CVMS has reporting capability operational.

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Adverse Event following Vaccine Administration

An adverse event following immunisation (AEFI) is an unwanted or unexpected event following the administration of a vaccine(s).

There are systems in place to record AEFI both at the vaccination hub and also if the event occurs outside the place of vaccination.

Reporting an immediate AEFI (at place of vaccination) occurs with notification to SAEFVIC.

All AEFI's are recorded in CVMS as an adverse event report – a report will automatically be forwarded to SAEFVIC & followed up if required.

AEFI can also be reported through SAEFVIC online reporting by the attending practitioner.

Reporting a delayed AEFI (outside place of vaccination)

Vaccine recipients are advised to seek medical attention from their local general practitioner or emergency department should a delayed AEFI occur. Following medical attention, clinicians should report an AEFI to SAEFVIC either online www.saefvic.org.au or by phone call 1300 882 924.

Vaccine recipients may also choose to report directly via the Victorian Coronavirus Hotline on 1800 675 398 or the National Coronavirus Hotline on 1800 020 080 or to SAEFVIC.

Vaccine recipients may also seek advice from the Western Health [COVID-19 Vaccination Hub Hotline](#)

COVID Vaccination Hotline: 8345 0661 (0800 – 1630 – 7 days a week)
or email: covidvaccination@wh.org.au

Safety Surveillance following Vaccine Administration

AusVaxSafety

AusVaxSafety was established in 2014 to monitor adverse events following immunisation with influenza vaccines in children. It is led by the National Centre for Immunisation Research and Surveillance (NCIRS) and is funded by the Commonwealth Government.

AusVaxSafety is conducting national COVID-19 vaccine safety surveillance in Australia. This is to ensure ongoing safety of COVID-19 vaccines used in Australia.

More information is available from the following link: <https://www.ausvaxsafety.org.au/our-work/covid-19-vaccine-safety-surveillance>

Vaccine recipients will receive a nationally standardised campaign of SMS messages sent on day 3 and day 8 following each dose, with a final message on day 42 following the last dose, where they will be able to report any adverse reactions and whether they were medically attended.

Further information regarding the safety surveillance can be found here:

- Participant information sheet: [How will AusVaxSafety monitor vaccine safety?](#)
- Publicly facing COVID-19 vaccine safety results: [AusVaxSafety website](#)

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COVID-19 Victorian Specialist Immunisation Service (VicSIS)

The Victorian Specialist immunisation Services (VicSIS) network oversees and provides specialist services for those identified as *at-risk* for adverse events following immunisation (AEFI) or those who experience AEFIs in the context of a COVID-19 vaccine.

VicSIS is comprised of nine COVID-19 Specialist Immunisation Clinics which can provide comprehensive consultation pre- and post-vaccination.

Pre-vaccination consultations are for persons at-risk of an AEFI (e.g. previous anaphylaxis to a vaccine or polysorbate 80) or may have vaccine related concerns to an underlying special risk or medical condition (e.g. immunocompromised).

Post-vaccination consultations are for persons who experienced an AEFI following a dose of a COVID-19 vaccine and who require clinical review prior to the consideration of further doses, or ongoing follow up of their AEFI.

All COVID-19 vaccines approved in Australia are safe and most people should be able to be vaccinated without needing a referral to a specialist immunisation service, regardless of underlying comorbidities. However, if you are concerned about the safety implications of vaccination then a referral to VicSIS can also be made. To help guide decision making around referrals, a list of FAQs can be found at <https://mvec.mcri.edu.au/references/covid-19-vaccines-frequently-asked-questions>. VicSIS will provide individual immunisation recommendations, allergy testing and vaccination under supervision as required.

Refer to a Specialist Immunisation Service

Referrals to the Sunshine **Specialist Immunisation Clinic** must be sent via email COVIDvaccinationSIS@wh.org.au using the [VicSIS referral form](#).

Referral to a VicSIS **Allergy Clinic** (Monash Medical Centre / Austin Hospital) is required if a person has a history of:

- Immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (e.g. urticaria/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 (e.g. PEG in the Pfizer/BioNTech vaccine, or polysorbate 80 in the COVID-19 vaccine AstraZeneca)
- A prior history of 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
- A known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment