Government of Western Australia
Department of Health

COVID-19 VACCINATION

COVID-19 vaccine safety surveillance information for healthcare providers

Safety of COVID-19 vaccines

In clinical trials of tens of thousands of patients, the vaccines appear to be safe. Tens of millions of people globally have received a COVID-19 vaccine. 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. There are no known serious adverse events attributable to vaccination, with the exception of anaphylaxis, which for Pfizer/BioNTech was observed in the USA in late December 2020 to occur at a rate of approximately 1 in 100,000 doses given, and which is treatable. The potential for rare or unanticipated side effects to emerge over time is low, but is being closely monitored, as for any vaccine or medicine.

Likely side effects from COVID-19 vaccines

As with all vaccines, some minor side effects can be expected, these are usually mild and temporary. Clinical trials of COVID-19 vaccines have reported temporary side effects typical of vaccines, such as pain at the injection site, fever or muscle aches.

Management of side effects

Most side effects start within 24 hours of vaccination and will resolve in 1–2 days on their own. To reduce discomfort, paracetamol or ibuprofen can be taken. Some of the expected vaccine side effects are similar to the symptoms of COVID-19; however, a key differentiating factor is that respiratory symptoms (e.g. cough, runny nose etc) are not caused by the vaccine. People with typical vaccine side effects (injection site pain, mild 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. People with respiratory symptoms should be tested for COVID-19.

Will there be any ongoing monitoring of vaccine safety?

Monitoring of vaccines will continue after a vaccine has been received. Vaccine recipients may be contacted within the week after vaccination via SMS with a brief survey to collect data on any Adverse Events Following Immunisation (AEFI). This is part of a national adverse events surveillance system called AusVaxSafety. Vaccine recipients can also report any AEFI at www.safevac.org.au.

Healthcare providers are required to report AEFI. Vaccine recipients may be referred to a specialist immunology clinic for review or supervision for future vaccination. If you require clinical advice specific to a COVID-19 vaccine AEFI:

- Call the WAVSS team at **08 6456 0208** (Mon-Fri, 9am-5pm)
- Call the on-call adult immunologist at **08 9224 2244** (outside office hours only)

For more information

Adverse events following immunisation (AEFI) - https://ww2.health.wa.gov.au/Articles/A_E/Adverse-event-following-immunisation-AEFI
COVID-19 vaccines - health.gov.au/initiatives-and-programs/covid-19-vaccines

Australian Technical Advisory Group on Immunisation (ATAGI) - https://www.health.gov.au/news/preliminary-advice-from-atagi-on-general-principles-for-the-covid-19-vaccination-program

Reporting adverse events following immunisation

Information for healthcare providers

With heightened community awareness of vaccines, your patients may express greater concern around vaccine safety. It is important you are prepared to respond to potential adverse events following immunisations in your patients.

What is an Adverse Events following immunisation (AEFI)?

An AEFI is an unwanted or unexpected event occurring after the administration of a vaccine. An AEFI may occur several hours or days after vaccination. An AEFI may be due to a person's response to the vaccine, coincidence (that is, it would have occurred regardless of vaccination) or incorrect handling or administration of a vaccine

Do I need to report all AEFIs?

Healthcare providers who become aware of an AEFI have a statutory responsibility to notify the Western Australian Department of Health within 72 hours of diagnosis. You should report:

- Any significant event following immunisation
- Any vaccine reaction which requires assessment by a doctor or nurse
- Any reaction which has affected a family's confidence in future immunisation

Common expected reactions following immunisation, such as mild fever, redness or swelling at the injection site, do not need to be reported.

How do I report an AEFI?

Report the adverse event online at www.safevac.org.au. You will need to register if it is your first time reporting an AEFI. The Western Australian Vaccine Safety Surveillance (WAVSS) clinical team will assess all reported AEFIs. The WAVSS team may contact you or the patient directly if further details are required. The patient may be referred to a specialist clinic for review or supervision for future vaccination. All AEFIs will be reported to the Therapeutic Goods Administration (TGA) by WAVSS staff.

If you require clinical advice specific to a COVID-19 vaccine AEFI:

- Call the WAVSS team at 08 6456 0208 (Mon-Fri, 9am-5pm)
- Call the on-call adult immunologist at 08 9224 2244 (outside office hours only)

For clinical advice for all other AEFIs call the WAVSS team at 08 6456 0208 (Mon-Fri, 9am-5pm)

For more information

Adverse Events Following Immunisation (AEFI) - health.wa.gov.au/Articles/A_E/Adverse-event-following-immunisation-AEFI
Western Australian Vaccine Safety Surveillance (WAVSS) system - health.wa.gov.au/Articles/U_Z/Western-Australian-Vaccine-Safety-Surveillance-WAVSS

This document can be made available in alternative formats on request for a person with disability.