AMT Vaccination Fact Sheet





KEY POINTS

- Massage therapists cannot provide advice or opinions about vaccinations to their clients
- Pfizer, Astra Zeneca (Vaxzevria), Moderna and Novavax are the four vaccines included in the current Australian vaccination rollout strategy
- Ongoing non-pharmaceutical measures, such as masks, ventilation, air purification, respiratory and hand hygiene, will still be needed
- Massage therapists who do not undergo vaccination will need to review their risk assessments and carefully consider their capacity to treat clients in vulnerable categories

TYPES OF VACCINES

The Australian Government has signed contracts for the supply of four COVID vaccines – Pfizer, Moderna, Novavax and Astra Zeneca. These vaccines belong to three different classes.



1. mRNA wrapped in a greasy sheath

mRNA vaccines are a new style of vaccine technology which is being used by Pfizer/ BioNTech and Moderna. They contain a single strand of genetic material - the mRNA (messenger RNA) - encapsulated in a protective envelope. The message carried by the mRNA is a blueprint for our cells to construct copies of the SARS-CoV-2 spike protein, which we then use to train our immune system to recognise and respond if it is exposed to the real SARS-CoV-2 virus.¹



2. Growing spike protein antigens

This is the most conventional style of vaccine. These vaccines stimulate an immune response by directly delivering inactivated pieces of the virus they are designed to protect us against. Like most of the vaccines we receive in childhood, the Novavax vaccine falls under this umbrella.²



3. Genes housed in a virus

These are inactivated cold or flu viruses (adenoviruses) that contain the genetic blueprint for the SARS-CoV-2 spike protein. Unlike mRNA vaccines, where the instructions are in the form of a long, fragile, single-stranded RNA molecule, this vaccine uses double-stranded DNA. DNA is not as fragile as RNA, and the adenovirus's tough protein coat helps protect the genetic material inside. That is why this style of vaccine is more rugged than the mRNA vaccines from Pfizer and Moderna, and can be stored at normal fridge temperatures (~4°C).

The Astra Zeneca vaccine uses this technology; its developers used a modified version of a chimpanzee adenovirus, known as ChAdOx1, which can enter cells but can't replicate inside them.³

EFFICACY AND SAFETY

COVID-19 vaccines are designed to prevent severe illness and death from COVID disease. Real-world evidence on prevention of infection and transmission is still evolving, particularly in relation to more transmissible variants of concern such as Delta.

Vaccine efficacy is determined in randomised controlled trials by dividing the cumulative incidence of disease in the vaccination group by the cumulative incidence in the placebo group to establish a risk ratio. This figure is then subtracted from 1. For example, the efficacy of the Pfizer vaccine was calculated by dividing 8 (the number of cases of COVID in the vaccination arm of the trial) by 162, the number of vaccinations in the placebo group. This produces a risk ratio of .05 or 5%. When subtracted from 1, the efficacy is .95 or 95%. There were 43,548 participants enrolled in this trial.⁴

Watch this excellent <u>brief explainer</u> on vaccine efficacy and safety.

Clinical trial and real world data thus far have shown that the vaccines being rolled out within Australia are safe.⁵⁶⁷

A rare and unusual condition involving blood clotting and low blood platelet count may occur from the AstraZeneca vaccine.

The Australian government currently has the incidence of this rare side effect at 4 to 6 people per million vaccinations.⁸

However, data from other countries has shown an incidence of closer to 1 in 100,000. The risk estimates are being updated on an ongoing basis, as part of global and national vaccine safety monitoring.

It is comparatively early days for Novavax, with stage 3 clinical trials having commenced in February 2021. In the U.S., the <u>Vaccine Adverse Event Register</u> (VAERs) has captured reports on COVID-19 since the country's vaccination rollout commenced on 14 December 2020.

VAERs is a comprehensive database of all adverse events reported after a vaccine is administered, regardless of whether a causal link between the vaccine and the event is established. (In other words, the adverse event may be completely coincidental to the vaccination.) Vaccine providers are encouraged to report any clinically significant health problem following vaccination, whether they believe the vaccine was the cause or not. Also, reports may include incomplete, inaccurate, and unverified information.

As at 10 September 2021, 377 million doses of COVID-19 vaccine had been administered in the U.S.⁹ Over the same period, 6296 deaths were reported to VAERS. These deaths represent 0.000016% of total doses administered, or 16 deaths per million doses. Of these reported deaths, 69% occurred in the 65+ age group and 84% occurred in the 50+ age group.¹⁰ (If you are interested in searching the VAERS data register, watch this <u>video explainer</u> first.) It's important to note that there may not be a causal link between the deaths and the vaccination. Many of the reports available within VAERS attribute death to other causes, such as road traffic accidents.

U.S. data have established the rate of anaphylactic allergic reactions to the Pfizer vaccine at 4.7 cases per million doses. No deaths have resulted from these cases.¹¹

BREAKTHROUGH INFECTION AND WANING IMMUNITY

Real-world evidence about breakthrough infection after vaccination and waning immunity is rapidly evolving.

There is already quite a lot of evidence that all the COVID-19 vaccines are much better at reducing the risk of severe disease than they are at reducing the risk of infection. This is because the current generation of vaccines are not yet capable of inducing sterilising immunity, which means that the immune system is able to stop a pathogen from replicating within the body and therefore stop infection.

However, the main value of COVID-19 immunisation is in reducing the risk of severe disease and death, and the real-world evidence clearly shows that the vaccines remain incredibly effective at preventing serious illness, hospitalisation and death.

Viral breakthrough infections occur when vaccinated individuals become infected with the pathogen against which vaccines were developed. There is now a number of large pre-print studies reporting on breakthrough infection and waning immunity after vaccination.

A <u>study of Israel's vaccination program</u> shows that the two-dose regimen of the Pfizer vaccine is highly effective in reducing viral loads of Delta breakthrough infections during the initial two months after the second dose.¹² However, the protection against viral load started reducing two months after the second vaccine dose, followed by a complete diminution at 6 months post second dose. The analysis revealed only a small difference in viral load between vaccinated and unvaccinated individuals. The study authors state that this waning efficacy could be regained by a third vaccine dose administered at least five months after the second dose but evidence around the efficacy of this approach is still emerging.

A study of an outbreak at a large public gathering in Massachusetts reports that vaccinated people infected with the Delta variant of COVID can carry detectable viral loads similar to those of people who are unvaccinated, although the viral load diminishes more rapidly in the vaccinated. Another small US study¹³ compared the viral load in vaccinated and unvaccinated individuals who have been infected with the Delta variant of COVID. There was no significant difference in viral load between fully vaccinated and unvaccinated individuals, underscoring the potential for a significant proportion of vaccinated individuals with breakthrough infections to transmit infection to others.

A large British public health study¹⁴ found that protection from Pfizer and Astra Zeneca against the Delta variant weakens within three months. It also found that those who get infected after receiving two shots of either the Pfizer or AstraZeneca vaccine may be of greater risk to others than with previous variants and that they tend to have a viral load similar to the unvaccinated.

Based on more than three million nose and throat swabs taken across Britain, the study found that, 90 days after a second shot of Pfizer or Astra Zeneca vaccines, efficacy in preventing infection dropped to 75% and 61% respectively. Two doses of Pfizer have greater initial effectiveness against new COVID-19 infections but this declines faster compared with two doses of Astra Zeneca. Results suggest that after four to five months the effectiveness of these two vaccines would be similar.

The results also clearly show that having two vaccine doses remains the most effective way to ensure protection against severe illness, hospitalisation and death.

Although vaccination plays a significant role in reduction of severe COVID disease, the implication of viral loads in vaccinated individuals and onward transmission are yet to be quantified. As Australia shifts into a "living with COVID" phase of pandemic management, massage therapists need to employ risk mitigations that assume that every client who attends for treatment is infected, regardless of their vaccination status. This is particularly crucial given the evidence around waning immunity and uncertainties around the schedule for, and availability of, booster vaccinations.

COVID VARIANTS

The genetic material of SARS-CoV-2 is ribonucleic acid (RNA). To replicate and establish infection, SARS-CoV-2 RNA needs to hijack a host cell and use the cell's machinery to duplicate itself.¹⁵

During the process of duplicating the viral RNA, errors can occur which result in copies that are similar but not exact. These errors are called mutations, and viruses with these mutations are called variants. Variants could differ by just a single mutation or many mutations.

A variant is referred to as a strain when it shows distinct physical properties. Put simply, a strain is a variant that is built differently, and so behaves differently, to its parent virus. These behavioural differences can be subtle or obvious. The Alpha variant (B.1.1.7), the Beta variant (B.1.351) and the Delta variant are the most common SARS-CoV-2 variants. Each contains several different mutations.

The Delta variant is currently dominating throughout many countries, including Australia.

At this stage, trials of the different styles of vaccines are showing that they offer less protection against some of these variants. However, the real-world evidence is showing that the vaccines used in the Australian rollout offer high levels of protection against severe illness and hospitalisation.

HERD IMMUNITY

Herd immunity (also called 'herd protection') occurs when most of a population is immune to an infectious disease. It provides indirect protection to people in that population who are not immune to the disease.¹⁶

For example, if 80% of a population were to be immune to SARS-CoV-2 virus, four out of every five people who encounter someone with COVID-19 would not get sick (and would not spread the disease any further). In this way, the spread of COVID-19 could be kept under control. Depending how contagious an infection is, usually 50% to 90% of a population needs immunity to achieve herd immunity. Herd immunity for COVID-19 cannot be achieved through natural infection. In the pre-vaccine era, <u>no epidemic infection controlled itself through</u> <u>herd immunity</u>. This includes diseases such as smallpox and measles, which caused ongoing, uncontrolled epidemics until vaccines were used.

WILL VACCINATION BE MANDATORY?

The Australian Government's policy is that receiving a vaccination is voluntary, although it aims to have as many Australians vaccinated against COVID-19 as possible.

There are currently no laws or public health orders in Australia that specifically enable employers to require their employees to be vaccinated against COVID-19.

There may be limited circumstances where an employer may require their employees to be vaccinated. This will depend on:

- whether a specific law (such as a State or Territory public health law) requires an employee to be vaccinated; and
- whether an enterprise agreement, other registered agreement or employment contract includes a provision about requiring vaccinations.

If no law, agreement or employment contract applies that requires vaccination, whether or not it is lawful and reasonable for an employer to direct their employees to be vaccinated would be assessed on a case-by-case basis.

Additional considerations may include whether employees have a legitimate reason for not being vaccinated (for example, a medical reason), and how protections for employees under antidiscrimination laws may apply.¹⁷

The Human Rights Commission provides a <u>good</u> <u>explainer</u> on vaccines and discrimination.

Discussion about the implementation of vaccine passports is ongoing. The Human Rights Commission explainer <u>Human rights</u> <u>considerations for vaccine passports</u> also provides helpful guidance.

IMPLICATIONS FOR MASSAGE THERAPISTS

Vaccines work with your immune system by training your body to fight the virus if you are exposed. Ongoing non-pharmaceutical measures, such as masks, ventilation, respiratory and hand hygiene, will still be needed in massage therapy clinical practice to reduce the risks of virus transmission.

Typically, it takes a few weeks for the body to produce antibodies after vaccination. Therefore, it is possible that a person could be infected with the virus that causes COVID-19 just before or after vaccination and then get sick because the vaccine did not have enough time to provide protection - there are both clinical-trial data and real-world data showing that this can occur.

Side effects from vaccination such as headache, pain, chills and fever, usually occur within two or three days. Therapists should advise their clients that massage therapy is not indicated for at least three days post vaccination.

The symptoms of the rare clotting condition associated with the Astra Zeneca vaccine mostly start between 4 and 20 days after vaccination. Massage therapists should screen clients for the following symptoms:

- severe, persistent headaches that do not settle with paracetamol or other painkillers
- blurred vision
- weakness of face or limbs
- confusion or seizure
- shortness of breath that is not usual
- chest pain
- persistent abdominal pain
- leg swelling
- pin-prick rash or bruising not at the injection site that cannot be explained.

Other than screening for the above unusual symptoms, massage therapists should continue to treat vaccinated clients as usual, outside the initial 48 -72 hour window immediately post-vaccination.

Massage therapists cannot refuse treatment to clients based on their vaccination status. If a client volunteers their vaccination status, it is sensible practice to record this in their file.

It is outside massage therapists' scope of practice to provide advice or opinions to clients about vaccination.

FOOTNOTES



- ¹ <u>https://www.abc.net.au/news/science/2021-02-04/covid-19-vaccines-production-pfizer-moderna-astrazeneca-novavax/13109264</u>, accessed 4 February 2021
- ² <u>https://www.nytimes.com/interactive/2020/health/novavax-covid-19-vaccine.html</u>, accessed 22 February 2021
- ³ https://www.nytimes.com/interactive/2020/health/oxford-astrazeneca-covid-19-vaccine.html, accessed 22 February 2021
- ⁴ Polack FP. et al; C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 Dec
- 31;383(27):2603-2615. doi: 10.1056/NEJMoa2034577. Epub 2020 Dec 10. PMID: 33301246; PMCID: PMC7745181
- 5 Ibid
- ⁶ Voysey, M. et al; Oxford COVID Vaccine Trial Group. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. Lancet. 2021 Jan 9;397(10269):99-111. doi: 10.1016/S0140-6736(20)32661-1. Epub 2020 Dec 8. Erratum in: Lancet. 2021 Jan 9;397(10269):98. PMID: 33306989; PMCID: PMC7723445.
- ⁷ Keech, C. et al. Phase 1-2 Trial of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine. N Engl J Med. 2020 Dec 10;383(24):2320-2332. doi: 10.1056/NEJMoa2026920. Epub 2020 Sep 2. PMID: 32877576; PMCID: PMC7494251.
- ⁸ <u>https://www.health.gov.au/sites/default/files/documents/2021/04/covid-19-vaccination-after-your-astrazeneca-vaccine-covid-19-vaccination-after-your-astrazeneca-vaccine.pdf</u>, accessed 26 April 2021
- ⁹ https://covid.cdc.gov/covid-data-tracker/#vaccinations, accessed 10 September 2021
- ¹⁰ https://wonder.cdc.gov/vaers.html, accessed 20 February 2021
- ¹¹ Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021. JAMA. Published online February 12, 2021. doi:10.1001/jama.2021.1967
- ¹² Levine-Tiefenbrun, M. et al; Viral loads of Delta-variant SARS-CoV2 breakthrough infections following vaccination and booster with the BNT162b2 vaccine. *medRxiv*. 2021
- ¹³ Riemersma KK. et al; Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant, *medRxiv* 2021
- ¹⁴ Pouwels ,KB. et al; Impact of delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. 2021
- ¹⁵ https://www1.racgp.org.au/newsgp/clinical/what-s-the-difference-between-mutations-variants-a, accessed 13 February 2021
- ¹⁶ https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html, accessed 23 February 2021
- ¹⁷ <u>https://coronavirus.fairwork.gov.au/coronavirus-and-australian-workplace-laws/health-and-safety-in-the-workplace-during-coronavirus/</u> <u>covid-19-vaccinations-and-the-workplace</u>, accessed 20 February 2021