Information Sheet on SARS-CoV-2 Immunisation
March 2021

Fact File
The Royal College of Pathologists of Australasia

RCPA

Information sheet on SARS-CoV-2 immunisation

There are many reasons to get vaccinated. COVID-19 can have serious, life-threatening complications, and there is no way to know how it may affect you.

Nearly 100 million cases of COVID-19 and over 2 million deaths have been reported globally during the pandemic. While the mortality rate is higher in older age groups and those with pre-existing illnesses, significant long-term morbidity is being seen in all age groups.

To date (1 March 2021), the Australian government has entered into four agreements for the supply of vaccines to protect the community against SARS-CoV-2, the virus which causes COVID-19. All vaccines are thoroughly tested for safety before they are approved for use in Australia and will have been subjected to extensive trials overseas to ensure efficacy and safety, including careful analysis of clinical trial data, ingredients, chemistry, manufacturing and other factors. The vaccines will also be further assessed by Australia's Therapeutic Goods Administration (TGA) before they are rolled out. The New Zealand (NZ) government has agreements for a similar range of vaccines and has comparable regulatory safeguards in place.

The rollout of COVID-19 vaccines in Australia and NZ are expected to commence in mid-late February 2021 beginning with the Pfizer/BioNTech messenger RNA (mRNA) vaccine. High-priority groups[1] for immunisation include:

- Quarantine and border workers,
- Frontline healthcare workers,
- Staff and residents in aged-care facilities.
- Certain laboratory personnel and essential staff involved in SARS-CoV-2 testing.

Efficiency and effectiveness have different meanings in the context of vaccinations. Efficacy is measured in controlled clinical trials, whereas effectiveness can only be measured once the approved vaccine is used in the general population.[2]

Pfizer/BioNTech mRNA vaccine (AU & NZ)

mRNA vaccines do not use the live virus that causes COVID-19, instead they are made of genetic material – mRNA. This vaccine gives instructions for our cells to make a harmless piece of protein which will trigger an immune response. When the vaccine is injected into the muscle of the upper arm, it is taken up by muscle or immune cells, which then produce the specific 'spike' protein. The immune system recognises that this protein doesn't belong in the body and begins building an immune response.

[1] As advised by the Australian Technical Advisory Group on Immunisation (ATAGI)
[2] The immunisation advisory centre, 2017

Required doses: 2

Efficacy:

One dose: 52%[3]
Two doses: 95%[4]

Potential side effects: The most common reported reactions are pain and redness at the injection site, fever, headache and muscle ache; particularly after the second dose.

Safety data: Nearly 1.9 million first doses of the Pfizer/BioNTech mRNA vaccine had been given in the United States as of 23 December 2020 with only 0.2% reports of adverse events.

Oxford/AstraZeneca adenovirus vector vaccine (AU & NZ)
This viral vector vaccine uses a harmless virus to deliver genetic code from SARS-CoV-2 into cells. This allows the body to develop a specific immune response against a pathogen without the need to have an infection. The Australian Government has an agreement for this vaccine to be manufactured locally by CSL in Melbourne.

Required doses: 2

70.4% overall efficacy[5]

During trials, a sub-group inadvertently received a lower initial dose, followed by a normal second dose, which gave an overall efficacy of 90.0%. This is currently being investigated further in the multi-national evaluation of the Oxford/AstraZeneca vaccine.

Safety data: Adverse events occurred similarly in both Oxford/AstraZeneca vaccine recipients and placebo recipients.

Janssen adenovirus vector vaccine (NZ)

Required doses: 1

Efficacy: 85%[6]

This vaccine was effective in countries with “variants of concern” and was well tolerated.

Novavax recombinant protein vaccine (AU & NZ)
Novavax uses a lab-made version of the SARS-CoV-2 spike protein which is inserted with an adjuvant (a substance to boost the immune response). This adjuvant is derived from the Molina tree (*Quillaja saponaria* Molina), not aluminium. Once the recombinant vaccine plus adjuvant is injected, the body’s immune system starts producing antibody and also induce T-cell immune responses.

Required doses: 2

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[3] 12 days after first dose

[4] 7 days after two doses given 21 days apart

[5] Based on interim efficacy results with 11,636 participants randomised to receive two doses of the Oxford/AstraZeneca vaccine or a placebo, with approximately four-months follow-up.

[6] Based on interim analysis from phase 3 trial data which showed 85% efficacy for preventing severe disease 28 days after vaccination in adults > 18yo.

Efficacy: 89.3%[7]

Safety data: If this vaccine is proven to be safe and effective and is approved for use by the TGA, it will be available in Australia as early as the first half of 2021.

No evidence of vaccine-induced immunopathology
The vaccine trials have reassuringly shown no evidence to suggest that vaccinated individuals infected by SARS-CoV-2 might develop more severe disease. There were ten cases of severe CoVID-19 disease that occurred after the first dose in the Pfizer/BioNTech mRNA vaccine study, however nine occurred in placebo recipients and only one in a vaccine recipient. In the Oxford/AstraZeneca study, ten participants were hospitalised for CoVID-19 infection more than three weeks after the first dose; two had severe disease, of whom one died; all were in the placebo group. In the Novavax UK study, 56 and six cases of CoVID-19 disease occurred ≥7 days after the second dose in the placebo and vaccine groups, respectively; the only severe case was in the placebo group.

Information still to come
On the first anniversary of the CoVID-19 pandemic, several SARS-CoV-2 vaccines are in phase 3 trials with interim results reported and national vaccination programs in progress in many northern-hemisphere countries under emergency use authorisations. This is an incredible scientific achievement. However, there are some questions which remain unanswered. For example, it is not yet certain which vaccine candidate will prove the best, how long protection from the virus lasts, whether or not booster doses will be required (and how often), and whether variants of the virus will be affected by the vaccine. It is important to note that none of the current studies are head-to-head comparisons of the different vaccines. There are key differences in both study design and patient populations included, therefore caution should be observed in not mis-interpreting the data.

It is possible that future SARS-CoV-2 vaccines may require regular “updates” like the yearly influenza vaccinations. Reassuringly the Novavax recombinant vaccine has demonstrated protection against the “variants of concern” in the UK and South Africa.

Children, the elderly and the immunocompromised have been under-represented in the vaccine trials to date. Similarly, pregnant women have been excluded from the initial vaccine trials. Based on experience with other inactivated vaccines, there is no reason to expect that the SARS-CoV-2 vaccines will have a deleterious effect on pregnancy. Further studies are in progress and the results are due soon. Pregnant women will then be enrolled in ongoing SARS-CoV-2 vaccine trials as well as post-authorisation observational studies. Vaccination may be deferred until after the first trimester to avoid any potential risk of fever or other vaccine reactions during this critical time.

[7] Based on interim results from phase 3 trials in the United Kingdom with over 15,000 participants aged between 18-84.

SARS-COV-2 IMMUNISATION

COVID-19 Vaccination Fact Sheet

There are many reasons to be vaccinated

COVID-19 can have serious, life-threatening complications and there is no way to know how it may affect you.

Nearly 100 million cases of COVID-19 and +2 million deaths have been reported globally

While the mortality rate is higher in older age groups and those with pre-existing illnesses, significant long-term morbidity is being seen in all age groups.

In Australia and New Zealand

Our governments have entered into multiple agreements to supply vaccines to protect the community.

All vaccines must undergo rigorous testing for safety before they are approved for use in Australia and New Zealand.

Vaccine approval

The COVID-19 vaccines have been subjected to extensive overseas trials to ensure efficacy and safety. Clinical trial data is carefully analysed, as well as ingredients, chemistry and manufacturing processes.

Efficacy vs effectiveness

Efficacy is measured in controlled clinical trials, whereas effectiveness is measured once the vaccine is approved for use in the general population.

High-priority groups

The vaccine schedule ensures those who need the vaccine the most are prioritised:

- Quarantine and border workers
- Frontline healthcare workers
- Residents and staff in aged-care facilities
- Certain laboratory personnel and essential staff involved in SARS-CoV-2 testing

Vaccine types

The Pfizer/BioNTech vaccine is currently being administered in Australia and New Zealand, with the Oxford/AstraZeneca vaccine to follow shortly. Other vaccines are expected to be approved for rollout in due course.

Possible side effects

Not everyone will experience side effects.

Most common reported reactions are pain and redness at injection site, fever, headache, muscle ache.

Pfizer/BioNTech

mRNA vaccine

- Does not use the live virus that causes COVID-19
- Manufactured in USA and Belgium
- Made of genetic material (mRNA)
- Gives instructions for our cells to make a harmless piece of protein which then triggers an immune response
- Required doses: 2
- Efficacy 52% (one dose) 95% (two doses)

Oxford/AstraZeneca

viral vector vaccine

- Uses genetic code taken from SARS-CoV-2
- Manufactured in Australia, Europe, America and Asia
- Teaches the immune system how to fight the virus should it need to
- Required doses: 2
- Efficacy: 70.4% overall*

*During trials, a sub-group inadvertently received a lower initial dose, followed by a normal second dose, which had an overall efficacy of 90.0%. This is currently being investigated further in the multi-national evaluation of the Oxford/AstraZeneca vaccine.

SARS-CoV-2: the virus that causes COVID-19 infection

On the first anniversary of the COVID-19 pandemic, several SARS-CoV-2 vaccines are in phase 3 trials with interim results reported. National vaccination programs are in progress across the globe.

This is an incredible scientific achievement.

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Further reading

- Department of Health, Australian Government. CoVID-19 vaccines. Available at: https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines
- New Zealand Department of Health. COVID-19: Types of vaccines. Available at: https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-types-vaccines
- Tregonning JS, *et al*. Vaccines for CoVID-19. *Clin Exp Immunol* 2020; 202: 162-192.
- Polack FP, *et al*. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med* 2020; 383: 2603-2615.
- CDC COVID-19 Response Team; Food and Drug Administration. Allergic reactions including anaphylaxis after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine - United States, December 14-23, 2020. *MMWR Morb Mortal Wkly Rep* 2021;70: 46-51
- Voysey M, *et al*. 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; 397: 99-111.
- Johnson & Johnson press release. https://www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-endpoints-in-interim-analysis-of-its-phase-3-ensemble-trial
- Novavax press release. https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3
- Rasmussen SA, *et al.* Coronavirus disease 2019 (COVID-19) vaccines and pregnancy: what obstetricians need to know. *Obstet Gynecol* 2020 Dec 23; publish ahead of print.
- Efficacy and effectiveness. (2017). Retrieved 25 February 2021, from https://www.immune.org.nz/vaccines/efficiency-effectiveness