

ATAGI 2022 annual statement on **immunisation**

December 2022

ATAGI's priority actions for 2022

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About ATAGI

The Australian Technical Advisory Group on Immunisation (ATAGI) advises the Minister for Health on the National Immunisation Program (NIP) and other immunisation issues.

ATAGI's vision is to protect the Australian population from vaccinepreventable diseases (VPDs). This is shown in ATAGI's strategic intent.

ATAGI's purpose is to provide evidence-based advice to the Minister for Health and other key policymakers on:

- · immunisation policies
- immunisation programs
- future research priorities.

This includes identifying and prioritising gaps in the immunisation landscape to improve:

- the impact of immunisation programs
- · confidence in immunisation programs, as well as the vaccines used in the programs
- equity in access to, and outcomes of, immunisation programs.

ATAGI also develops and publishes the Australian Immunisation Handbook.

The ATAGI 2022 Annual Statement on Immunisation is the second publication in this series. It highlights the key successes, trends and challenges in the use of vaccines and control of VPDs in Australia in 2021. It also signals ATAGI's priority actions for addressing key issues for 2022 and beyond.

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Summary

In 2021, immunisation issues in Australia were dominated by the COVID-19 vaccine roll-out. COVID-19 control measures continued to contribute to lower rates of many vaccine-preventable diseases (VPDs) in Australia.



Key successes in immunisation in 2021

- Australia's COVID-19 immunisation program started in February 2021. Multiple safe and effective vaccines for adults and adolescents were delivered by a range of immunisation providers in different settings. More than 42.7 million doses of COVID-19 vaccine were administered across Australia in 2021.
- ATAGI and other groups responded rapidly to emerging evidence on COVID-19 vaccine safety and effectiveness. Recommendations were revised in line with the latest local and international evidence to ensure the ongoing safe and effective use of these vaccines in Australia.
- First Nations communities responded quickly and effectively to the COVID-19 pandemic. First Nations health leaders and community controlled health organisations worked in partnership with government and nongovernment organisations to implement culturally appropriate measures on disease prevention, health promotion and health risk communication. This helped First Nations communities avoid severe illness and death from COVID-19.
- The rates of many VPDs were much lower than in pre-COVID-19 pandemic years. This included influenza, measles, meningococcal disease and pertussis. Control measures for COVID-19 (such as border closures, physical distancing and hand hygiene) have likely contributed to this.
- COVID-19 did not have a major impact on the National Immunisation Program (NIP). Immunisation uptake in young children remained high, even during COVID-19 restrictions.
- Australia's vaccination data systems were strengthened. Mandatory reporting to the Australian Immunisation Register (AIR) was introduced in 2021 for all NIP vaccines, influenza vaccines and COVID-19 vaccines.



Key challenges and priorities for immunisation in Australia in 2022 and beyond

For COVID-19

- Maintaining community confidence in the national COVID-19 immunisation program, including among First Nations communities.
- · Monitoring safety and effectiveness of COVID-19 vaccines, including booster doses, use in children and effectiveness against new variants of concern.
- Evaluating the COVID-19 immunisation program.

For other vaccine-preventable diseases

- Maintaining community confidence in the NIP and maintaining high coverage of routine vaccinations to protect against VPDs - including influenza - both during and after the COVID-19 pandemic.
- Maintaining successful control or elimination of some VPDs, especially as international travel restrictions are lifted.
- Ensuring the safe use of all vaccines, especially live vaccines such as Zostavax (shingles vaccine).
- Ensuring equitable access to NIP-funded vaccines for First Nations communities and people at increased risk of disease.

Immunisation issues in Australia in 2021



COVID-19 vaccination

During 2021, ATAGI developed:

- clinical guidance for COVID-19 vaccine providers
- · resources for immunisation providers
- resources for consumers.

These resources were frequently updated as more vaccines were registered in more age groups, and as new evidence on vaccine handling, efficacy, effectiveness and safety became available.

Culturally appropriate resources for the national COVID-19 vaccination program were also developed for:

- · First Nations communities
- · culturally and linguistically diverse communities.

New COVID-19 vaccines in 2021

The Therapeutic Goods Administration (TGA) provisionally registered these COVID-19 vaccines for use in Australia in 2021.

Vaccine brand name	Description	For use in ages	Date of registration
Comirnaty (Pfizer)	mRNA-based vaccine	≥16 years	25 January 2021
		≥12 years	22 July 2021
	mRNA-based vaccine booster dose	≥18 years	26 October 2021
	mRNA-based vaccine paediatric formulation	≥5 to ≤11 years	3 December 2021
Vaxzevria (AstraZeneca)	Viral vector vaccine	≥18 years	15 February 2021
Spikevax (Moderna)	mRNA-based vaccine	≥18 years	9 August 2021
		≥12 years	3 September 2021
	mRNA-based vaccine booster dose	≥18 years	7 December 2021

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Table continued

Vaccine brand name	Description	For use in ages	Date of registration
Janssen COVID-19 Vaccine	Viral vector vaccine	≥18 years	25 June 2021 (registered but not used in Australia)

These vaccines were rigorously evaluated for safety and effectiveness before they were provisionally registered and provided to Australians for free through the NIP. This process was different to the usual process for listing vaccines on the NIP.

Other countries may use other COVID-19 vaccines. Some of these vaccines are recognised by the TGA for the purpose of travel to Australia. However, from 6 July 2022, travellers no longer need to provide proof of COVID-19 vaccination to travel to and from Australia.

COVID-19 vaccine safety

The TGA has overall responsibility for the safety of vaccines on the Australian Register of Therapeutic Goods (ARTG), including COVID-19 vaccines. ATAGI also closely monitors COVID-19 vaccine safety issues, and carefully assesses the benefits against the potential risks, from a program perspective.

Before the roll-out of COVID-19 vaccines in Australia, the TGA made enhancements to Australia's well-established vaccine safety monitoring process. These are described in the TGA's COVID-19 vaccine safety monitoring plan.

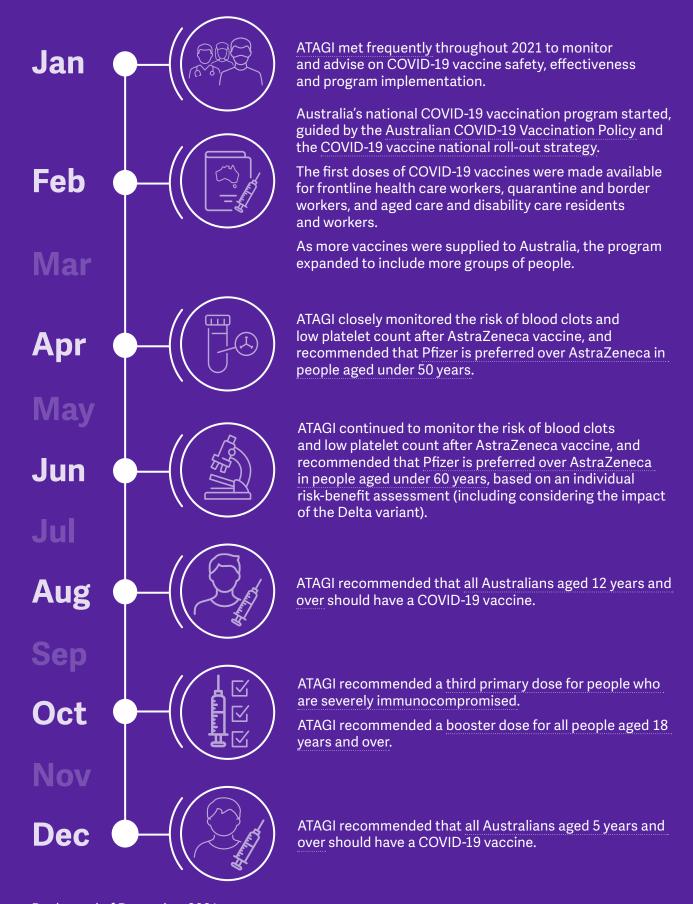
The TGA published updates on its safety monitoring process throughout 2021 in COVID-19 vaccine weekly safety reports. The TGA also met with state and territory vaccine safety teams weekly throughout 2021, as well as chairing the International Coalition of Medicines Regulatory Authorities (ICMRA) COVID-19 Vaccine Pharmacovigilance Network every fortnight, to ensure close national and international collaboration on emerging vaccine safety issues.

A special subgroup of the ATAGI COVID-19 Working Group met regularly throughout 2021 to discuss vaccine safety issues. From May 2021, ATAGI met every week to monitor vaccine safety and provide advice in response to new information.

Overall adverse events

In 2021, almost 5 million people participated in the AusVaxSafety vaccine safety survey after their COVID-19 vaccinations. Of these people:

- 55.8% reported no adverse events
- 44.2% reported at least one adverse event
- 1.0% reported visiting a doctor or emergency department.



By the end of December 2021:

- more than 42.7 million doses of COVID-19 vaccines had been administered across Australia
- more than 19 million people had received at least one dose (94.4% of people over the age of 16 years)
- more than 18 million people had received 2 doses (91.4% of people over the age of 16 years).

Specific adverse events

Thrombosis with thrombocytopenia syndrome (TTS) is a very rare but serious adverse event following the AstraZeneca vaccine. In 2021, ATAGI developed and updated recommendations on vaccine brand preferences for different age groups as more evidence on TTS became available. ATAGI worked with the Thrombosis and Haemostasis Society of Australia and New Zealand to develop strategies to minimise risks from TTS.

Myocarditis and pericarditis are adverse events of special interest initially noted following mRNA COVID-19 vaccines (Pfizer or Moderna). ATAGI developed clinical guidance in collaboration with subject matter experts, and continues to monitor the rates of these adverse events.



Prevention and control of other vaccinepreventable diseases

Rates of a number of VPDs were lower in 2021 compared with pre-COVID-19 pandemic years. Measures for preventing the spread of COVID-19 (such as border closures, physical distancing and hand hygiene) have likely contributed to this. Disruption to usual health care systems and practices may have also contributed to lower VPD identification and notifications.



Influenza

- Influenza was extremely uncommon in 2021. Notification rates were 97% lower than the same period in 2020, and 99% lower than the 5-year mean for the same period. There was no notable increase in cases during the usual peak winter season.
- Low notifications made it difficult to assess the effectiveness of influenza vaccines. This will be closely monitored as international borders open.
- More details are in the national 2021 influenza season summary.



Measles

- No cases of measles have been notified since March 2020.
- Measles has been eliminated in Australia. This means that cases of measles in Australia have been either acquired overseas or linked to overseas travel, and there is no ongoing transmission. Elimination is the result of high vaccination coverage leading to high levels of immunity in the community, as well as our well-performing surveillance and response
- The decrease in cases is the result of international border restrictions from March 2020. As international borders open, there is potential for measles cases to be brought in to Australia.



Meningococcal disease

- 76 notifications of invasive meningococcal disease were reported in 2021 – this was 16% lower than the same period in 2020, and 69% lower than the 5-year mean.
- Of the 61 cases where serogroup information was available, the most common serogroup in 2021 was serogroup B (35 cases), followed by serogroup W (14 cases) and serogroup Y (12 cases). Serogroup B and serogroups A, C, W and Y are preventable by different vaccines.



Pertussis

 Pertussis notifications were 84% lower in 2021 compared with the same period in 2020, and 95% lower than the 5-year mean.



Pneumococcal disease

- Notifications of invasive pneumococcal disease were 21% higher than the same period in 2020, but 25% lower than the 5-year mean.
- Most cases were in children under 5 years of age and adults aged 65 years and older.
- Serotype information was available for 80% of notified cases. The 2 most frequently reported serotypes were serotype 3 (10.3%) and serotype 19F (7.4%). These serotypes are covered by the available pneumococcal vaccines. Some of these cases were vaccine failures, and this issue will continue to be monitored.



National immunisation policy and practice

Human papillomavirus vaccination program

Australia has been a world leader in research and evaluation of the human papillomavirus (HPV) vaccine. This vaccine is given to adolescents through the NIP to prevent cervical cancer and some other cancers.

An evaluation of the impact of the national HPV vaccination program in 2021 found that:

- vaccination coverage is high
- adverse events are mainly mild and transient (temporary)
- the burden of HPV-related disease has substantially reduced since the vaccine was introduced in Australia in 2007.

For First Nations adolescents, the 2021 Cervical Cancer Elimination Progress Report found that 84% of adolescents had their first dose of HPV vaccine, but only 68.5% had completed the 2 dose course. To help improve the completion rate, culturally appropriate resources were developed in partnership with First Nations communities. Projects such as Yarning about HPV Vaccination and cross-cultural responses to the HPV vaccine continue to inform a culturally appropriate approach. New relationships with cultural leadership in First Nations communities will help to ensure ongoing engagement, access and follow-up for HPV vaccination.

Meningococcal B vaccination program

A study on the use of meningococcal B vaccine in adolescents was published in 2021. A state-funded vaccination program in South Australia commenced in infants and young children in 2018, and was extended to adolescents in 2019.

The South Australian program contributed to informing the introduction of meningococcal B vaccination for people at increased risk of invasive meningococcal disease and First Nations infants under the NIP in 2020.

Changes to the National Immunisation Program

There were no changes to the NIP in 2021.

The shingles vaccination catch-up program was extended for a further 2 years. People aged 71–79 years can receive the Zostavax vaccine under the NIP until 31 October 2023.

Immunisation coverage

Influenza vaccines

The number of influenza vaccine doses received in 2021 was notably lower than in 2020. In children aged 6 months to under 5 years, vaccination coverage decreased in all states and territories by up to 20%, including in First Nations children. All children in this age group can receive free influenza vaccines under the NIP.

Uptake of influenza vaccines in 2021 was also lower in several other age groups compared with 2020. This included First Nations people aged 5-14 years (17% lower) and 15–49 years (10% lower) – all of whom can receive funded influenza vaccines under the NIP - as well as other children aged 5-14 years (13% lower).

As international borders open, influenza may start to spread in Australia. Children under 5 years of age are especially vulnerable because they may never have been exposed to influenza and may not have received a vaccine. Immunisation services may see increased demand for influenza vaccines, particularly in young children. This is because children aged 6 months to under 5 years are strongly recommended to receive the fully funded NIP annual influenza vaccine, and children aged under 9 years continue to require 2 doses in their first influenza vaccination season.

Childhood vaccines

COVID-19 response measures (such as physical distancing and travel restrictions) did not have a significant impact on vaccine uptake in young children in 2021:

- 92.3% of children received their second dose of diphtheria-tetanusacellular pertussis (DTPa) vaccine within 2 months of reaching 4 months of age in 2021, compared with 93.6% in 2020 and 93.7% in 2019.
- 87.6% of children received their first dose of measles-mumps-rubella (MMR) vaccine within 2 months of reaching 12 months of age in 2021, compared with 88.1% in 2020 and 88.7% in 2019.

Maintaining high uptake of childhood vaccination is important because there is likely to be an increase in VPDs such as measles with the easing of international border restrictions.

Adolescent vaccines (mainly delivered through school immunisation programs)

School-based immunisation programs were disrupted in 2021 due to COVID-19. As a result, vaccination uptake was lower in 2021 than in previous years:

- HPV vaccine 58% of adolescents completed the 2 dose course within the same year in 2021, compared with 73% in 2020 and 85% in 2019. For those who had their first dose in 2020 but not their second dose, 64% went on to complete the course in 2021 through catch-up vaccination, resulting in an overall completion rate of 90% for the 2020 cohort over 2 years. This shows the success of catch-up vaccination in 2021, despite disruptions to school programs. It is expected that a similar or higher proportion of adolescents who received their first dose in 2021 will finish their course in 2022.
- dTpa vaccine 273,054 booster doses were administered to adolescents in 2021, which was 4% lower than in 2020 and 15% lower than in 2019.
- Meningococcal ACWY vaccine 226,862 doses were administered to adolescents during 2021, which was 7% lower than in 2020 and 9% lower than in 2019.

Zoster (herpes zoster) vaccine

Older Australians are eligible to receive the Zostavax vaccine on the NIP at 70 years of age. In 2021, 30.5% of adults had the vaccine before their 71st birthday, which was similar to previous years (30.9% in 2020 and 31.6% in 2019).

Mandatory reporting to the AIR for all NIP vaccines started on 1 July 2021. Zoster vaccine coverage may be affected by under-reporting before that time. The impact of mandatory reporting to the AIR on zoster vaccine coverage will continue to be monitored.

Important changes to the Australian Immunisation Handbook

A second zoster vaccine (Shingrix) became available in Australia in June 2021. Shingrix has different characteristics to the live attenuated zoster vaccine (Zostavax) available on the NIP. ATAGI developed a Statement on the clinical use of zoster vaccines in older adults in Australia to provide clinical guidance while the Handbook is being updated.

The Rabies and other lyssaviruses chapter was updated with new recommendations for pre-exposure and post-exposure prophylaxis.

Mandatory reporting to the Australian Immunisation Register

In February 2021, the Australian Immunisation Register Amendment (Reporting) Act 2021 came into force. This Act makes it mandatory for all immunisation providers to report all administered doses of vaccines to the AIR.

Mandatory reporting helps to ensure that everyone has a complete record of the vaccines they have received throughout their life. This is important to inform individual vaccination decisions, as well as to enable national monitoring of vaccination coverage, administration and vaccine safety that is based on a complete and reliable dataset.



New vaccines

One new vaccine (other than COVID-19 vaccines) was registered with the TGA in 2021.

Vaccine brand name	Description	Protects against	For use in ages
Flublok Quadrivalent	Quadrivalent recombinant influenza vaccine	Influenza	≥18 years

ATAGI monitors new vaccines for their potential to be included on the NIP. Vaccines recommended for the NIP need to show benefits for the Australian population or high-risk groups. They also need to be cost-effective.



Vaccine safety

The TGA has overall responsibility for vaccine safety surveillance in Australia. Vaccine safety surveillance is conducted in 2 ways by states and territories in collaboration with the TGA:

- Spontaneous (passive) surveillance is where people who have been vaccinated and/or their carers can report any vaccine side effects they have experienced. Reports are usually made to the jurisdictional vaccine safety services, but can also be made directly to the TGA or through a health care provider.
- Active surveillance is where people who have been vaccinated and/or their carers are contacted directly and asked if they have experienced any vaccine side effects. The current active vaccine safety surveillance is known as the AusVaxSafety system.

Active and passive vaccine safety surveillance activities are now integrated in most states and territories. All reports of serious adverse events following immunisation are forwarded to the TGA.

ATAGI continues to work closely with the TGA to advise on and promote the safe use of all vaccines, including COVID-19 vaccines.

Safe use of Zostavax

Zostavax is a vaccine that protects older Australians from shingles (herpes zoster) and its complications. Zostavax has been associated with serious adverse events, leading to several TGA safety advisories, a safety alert from the Chief Medical Officer and updates to the Handbook.

In June 2021, the TGA required new safety measures for Zostavax to address the very rare but serious risk of fatal infection caused by this live vaccine (called disseminated vaccine strain varicella-zoster virus infection) in people with weakened immune systems (immunocompromise). ATAGI continued to assess options to ensure the safe use of this vaccine throughout 2021.

Influenza vaccines

AusVaxSafety data show that 2021 seasonal influenza vaccines were very safe. The safety survey in 2021 had 230,577 participants, with 93.4% reporting no adverse events.

Challenges and priorities for immunisation in Australia in 2022 and beyond



Key challenges for prevention and control of vaccine-preventable diseases through immunisation

For COVID-19

- Maintaining confidence in the national COVID-19 immunisation program through effective communication strategies.
- Monitoring safety, effectiveness and the optimal schedule of COVID-19 vaccines (particularly those used in Australia), including booster doses, use in children and effectiveness against new variants of concern.
- · Monitoring epidemiology and providing advice to prevent a surge of COVID-19 in Australia and our region as international travel increases.
- Evaluating the COVID-19 immunisation program.

For other vaccine-preventable diseases

- Maintaining a strong NIP in Australia in the face of changing epidemiology of VPDs and reopening of our borders to international travel.
- Monitoring the changing epidemiology of measles, polio, diphtheria and other VPDs in the Western Pacific region due to disrupted immunisation programs.
- Increasing uptake of vaccines for population groups with a higher risk of certain VPDs, and ensuring a reliable data system that captures this.
- · Maintaining community confidence in Australia's NIP through effective communication strategies.



ATAGI's priority actions for 2022

Ongoing priorities

- · Advise on immunisation policies that enable equitable access to NIPfunded vaccines for population groups with increased risks of VPDs, as well as reliable systems to capture uptake in these groups. Priorities for consideration include:
 - hepatitis B vaccination for non-immune adults of First Nations communities
 - pneumococcal vaccination for younger adults of First Nations communities (aged <50 years)
 - expansion of eligible medical risk conditions for receiving NIP-funded influenza vaccines
 - catch-up measles vaccination for non-immune people born since 1966.
- Strengthen the evaluation of evidence and continue publishing evidencebased immunisation recommendations through the Handbook. This includes continuing to work closely with the National Health and Medical Research Council (NHMRC) to further facilitate the process of endorsing Handbook recommendations.
- Advise on and promote the safe and appropriate use of all vaccines, including live vaccines such as Zostavax, and promote support to immunisation providers.
- Advise on the need to evaluate existing national immunisation programs, such as for zoster, influenza and pneumococcal disease.
- Continue to work with international partners, including national immunisation technical advisory groups (NITAGs) of other countries.
- Support the development of evidence-based immunisation resources that are culturally sensitive and appropriate to unique First Nations communities.
- Scope vaccines on the horizon for potential NIP consideration. These may include newer influenza and pneumococcal vaccines, registered vaccines such as Shingrix that are not on the NIP, and vaccines in the pipeline such as respiratory syncytial virus and group A Streptococcus vaccines. NIP vaccines must show benefits to the Australian population or high-risk population groups, and be cost-effective.

Specific priorities for 2022

COVID-19 immunisation program

- · Continue to advise on strategies to implement a safe and effective national COVID-19 immunisation program that has public confidence and equitable access for priority populations.
- Continue to advise on the evaluation of the COVID-19 immunisation program, and any issues with data and information sources on disease, vaccination uptake and vaccine safety.

Routine vaccination in Australia and our region

- Advise on how to increase uptake of influenza vaccine, especially in young children, during and after the COVID-19 pandemic.
- Advise on how to prevent reintroduction or a surge in cases of a range of VPDs in Australia as international travel restrictions are lifted. COVID-19 has disrupted immunisation programs in many countries in our region and beyond, and there is a risk of reintroducing these VPDs into Australia.

Monitoring and evaluation

· Advise on the need to set up an end-to-end system that can track and record every dose of distributed and administered vaccines in national and jurisdictional immunisation programs. This will improve vaccine allocation, minimise wastage and help the assessment of vaccine effectiveness.