

# The evolving immunisation landscape

## New vaccines and schedule changes

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Recent advances in Australia's immunisation program have introduced important changes for primary care, including new vaccines, updated schedules and expanded eligibility across multiple vaccine-preventable diseases. For GPs, staying informed about these changes is integral to providing comprehensive patient care and promoting vaccine uptake.

Vaccination remains a cornerstone in preventing serious illness and reducing healthcare burden across all age groups. Australia's National Immunisation Program (NIP) continues to adapt in response to changing epidemiology, emerging preventive strategies and advances in vaccine science. Over the past two years, substantial updates have been introduced across several disease areas, with implications for vaccine scheduling, eligibility assessment and patient counselling in primary care.

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### KEY POINTS

- Respiratory syncytial virus prevention now includes National Immunisation Program (NIP)-funded maternal vaccination in every pregnancy, as well as state- or territory-funded infant monoclonal antibody administration and adjuvanted vaccination for eligible older adults.
- Influenza vaccines for 2026 are trivalent, and the intranasal live attenuated influenza vaccine is registered for children and adolescents aged 2 years to less than 18 years.
- NIP-funded infant pneumococcal vaccination now includes the 20-valent pneumococcal conjugate vaccine, with higher-valency conjugate vaccines also emerging. Adult pneumococcal vaccination recommendations will change to the 21-valent pneumococcal conjugate vaccine from 1 July 2026.
- The recombinant zoster vaccine is a NIP-funded, two-dose, nonlive vaccine that provides robust protection against herpes zoster for up to 10 years.
- In adults aged 65 years and older, coronavirus disease 2019 vaccination within the preceding three months substantially reduces mortality risk compared with being unvaccinated.
- Australian Immunisation Register reporting is mandatory for NIP-funded vaccines, as well as influenza, coronavirus disease 2019 and Japanese encephalitis virus vaccines, and this supports accurate vaccination histories and eligibility assessment.
- Immunisation recommendations change; clinicians should refer to the online *Australian Immunisation Handbook* for up-to-date guidance.

Recent developments include the rollout of respiratory syncytial virus (RSV) vaccines for older adults, maternal RSV vaccination and national expansion of nirsevimab for infants, marking a major shift in RSV prevention. The approval of Australia's first intranasal live-attenuated influenza vaccine (LAIV) for children and adolescents, and the transition to higher-valent pneumococcal vaccines, further demonstrate the evolving immunisation landscape. These updates also reflect a growing focus on protecting vulnerable groups, including young children, Aboriginal and Torres Strait Islander people and individuals with immunocompromise, who remain at increased risk of severe vaccine-preventable disease.

### 1. CONDITIONS ASSOCIATED WITH AN INCREASED RISK OF SEVERE RESPIRATORY SYNCYTIAL VIRUS DISEASE IN INFANTS AND YOUNG CHILDREN<sup>1\*</sup>

- Preterm birth: born before 32 weeks' gestation
- Cardiac disease: haemodynamically significant congenital heart disease
- Significant immunosuppression, such as:
  - malignancy
  - solid organ transplant
  - haematopoietic stem cell transplant
  - inborn errors of immunity associated with T-cell or combined immunodeficiencies, such as severe combined immunodeficiency
- Chronic respiratory disease
  - chronic lung disease requiring ongoing oxygen or respiratory support
  - cystic fibrosis with severe lung disease or weight-for-length less than the 10th percentile
- Neurological conditions that impair respiratory function, such as:
  - congenital, hereditary or degenerative central nervous system disorders
  - cerebral palsy
  - brain or spinal cord conditions affecting respiratory control or function
  - neuromuscular disorders
  - conditions with impaired swallowing or coughing, or with aspiration risk
- Chromosomal abnormality: trisomy 21 or another genetic condition that increases the risk of severe respiratory syncytial virus infection

\* Accurate at the time of printing. Please refer to the *Australian Immunisation Handbook* website for updates.

This article provides a concise overview of these updates to support GPs in navigating schedule changes, advising patients and optimising immunisation in primary care.

### Respiratory syncytial virus

RSV usually causes mild symptoms but can lead to severe illness and hospitalisation in infants and young children, especially those born prematurely or with comorbidities (Box 1), as well as in older adults and those with medical risk conditions (Box 2).<sup>1-6</sup>

### 2. CONDITIONS ASSOCIATED WITH INCREASED RISK OF SEVERE RESPIRATORY SYNCYTIAL VIRUS DISEASE IN ADULTS<sup>1\*</sup>

#### Cardiac disease

- Congenital heart disease
- Congestive heart failure
- Coronary artery disease
- Chronic respiratory conditions

#### Suppurative lung disease

- Bronchiectasis
- Cystic fibrosis
- Chronic obstructive pulmonary disease
- Chronic emphysema
- Severe asthma (requiring frequent medical consultations or the use of multiple medications)

#### Immunocompromising conditions

- HIV infection
- Malignancy
- Immunocompromise due to disease or treatment
- Asplenia or splenic dysfunction
- Solid organ transplant
- Haematopoietic stem cell transplant
- Chimeric antigen receptor T-cell therapy

#### Chronic metabolic disorders

- Type 1 or 2 diabetes
- Amino acid disorders
- Carbohydrate disorders

- Cholesterol biosynthesis disorders
- Fatty acid oxidation defects
- Lactic acidosis
- Mitochondrial disorders
- Organic acid disorders
- Urea cycle disorders
- Vitamin or cofactor disorders
- Porphyrrias

#### Chronic kidney disease

- Chronic renal impairment – estimated glomerular filtration rate <30 mL/min (stage 4 or 5)

#### Chronic neurological conditions

- Hereditary and degenerative central nervous system diseases
- Seizure disorders
- Spinal cord injuries
- Neuromuscular disorders
- Other conditions that increase the risk of severe outcomes of respiratory infection

#### Chronic liver disease

- Conditions with progressive deterioration of liver function for >6 months including cirrhosis and other advanced liver diseases

#### Obesity

- Body mass index  $\geq 30$  kg/m<sup>2</sup>

\* Accurate at the time of printing. Please refer to the *Australian Immunisation Handbook* website for updates.

Children aged younger than 5 years account for most RSV-related hospitalisations, with the highest rates in infants aged 0 to 2 months (about one in 36). Preterm infants face a markedly higher risk, up to eight times greater for those born before 28 weeks.<sup>3,7</sup> Aboriginal and Torres Strait Islander children experience about twice the hospitalisation rates compared with non-Indigenous children.<sup>8-10</sup> In older adults, RSV-associated hospitalisations increase steadily from 50 years of age, with a 20-fold rise in those aged 65 years and older compared with younger adults.<sup>11</sup> A modelling study estimated that adults aged 75 years and older have a hospitalisation rate of 256 per 100,000.<sup>12</sup>

RSV relies on its fusion (F) protein to enter lung cells and cause infection. RSV vaccines and monoclonal antibodies are specifically designed to target the F protein in its prefusion conformation. This form

exposes critical neutralising epitopes that are hidden or altered after fusion, enabling high-affinity antibody binding and stronger virus neutralisation. Stabilising the F protein in this state maximises immunogenicity and provides robust, long-lasting protection while reducing the risk of vaccine-enhanced disease.<sup>13,14</sup> Vaccine-enhanced disease was a particular issue to overcome in the early vaccination trials of the 1960s with vaccine recipients developing more severe illness after exposure to RSV. Attention then turned to passive immunisation for high-risk infants in the 1990s.<sup>15</sup>

The Australian immunisation strategy has been to target and protect those at high risk: young infants and older adults. In 2024, the first modern RSV immunisation products became available in Australia. Five products have been registered in the last three years with the TGA: the recombinant RSV prefusion F protein (RSVPreF)

**TABLE 1. TGA-APPROVED PRODUCTS FOR RSV PREVENTION<sup>5</sup>**

Category	Type	Year TGA approved	TGA-approved indication	Funded
Vaccines	Recombinant RSV prefusion F protein	2024	<ul style="list-style-type: none"> <li>Adults aged ≥60 years</li> <li>Maternal vaccination in pregnancy</li> </ul>	Yes, via NIP: maternal vaccination from 28 weeks' gestation in every pregnancy
	Recombinant RSV prefusion F protein OA (AS01E adjuvanted)	2024	<ul style="list-style-type: none"> <li>Adults aged ≥60 years</li> <li>Adults aged 50–59 years who are at increased risk for RSV disease</li> </ul>	Yes, via NIP: one dose at age ≥75 years OR Aboriginal and Torres Strait Islander adults aged ≥60 years
	RSV F protein mRNA (nucleoside modified)	2025	<ul style="list-style-type: none"> <li>Adults aged ≥60 years</li> </ul>	No
Monoclonal antibodies	Nirsevimab; long-acting	2023	<ul style="list-style-type: none"> <li>Infants aged &lt;24 months</li> </ul>	Yes, via state- and territory-funded programs targeting infants
	Clesrovimab; long-acting	2025	<ul style="list-style-type: none"> <li>Infants born during or entering their first RSV season</li> </ul>	No
	Palivizumab; short-acting	2015	<ul style="list-style-type: none"> <li>High-risk infants born during or entering their first RSV season</li> </ul>	No

Abbreviations: NIP = National Immunisation Program; RSV = respiratory syncytial virus.

vaccine, the RSVPreF3 OA (AS01E adjuvanted) vaccine, nirsevimab, the RSV F protein mRNA (nucleoside modified) vaccine and clesrovimab. These are in addition to palivizumab, a short-acting monoclonal antibody registered since 2015, and now largely superseded by newer agents. These products have differing indications, age approvals and funding criteria (Table 1).<sup>5,16,17</sup>

For infant protection, the RSVPreF vaccine is recommended as maternal immunisation from 28 weeks' gestation in every pregnancy to provide passive protection for up to six months. In a clinical trial, the RSVPreF vaccine demonstrated 57% efficacy against RSV-associated hospitalisation and 70% efficacy against severe RSV infection in infants during the first six months of life.<sup>10,18</sup> The RSVPreF vaccine became available for free under the NIP in February 2025.<sup>10</sup>

Common adverse events following maternal RSVPreF vaccination are predominantly mild injection-site reactions, with systemic and serious adverse event rates similar to placebo.<sup>18,19</sup> Postmarketing surveillance, including AusVaxSafety data (n = 968, as of 31 March 2026), confirms mostly mild, short-lived reactions, with fewer than 2% of patients seeking medical care.<sup>20</sup> Clinical trial results suggested a

possible tendency towards increased pre-term birth, but this has not been observed in early postmarketing surveillance, with US data showing rates within expected ranges and no increased risk identified among women vaccinated between 32 and 36 weeks' gestation.<sup>18,21</sup>

In addition, since April 2025, nirsevimab has been available as a long-acting monoclonal antibody offering up to six months of protection after a single dose. Clinical trials and postmarketing surveillance show nirsevimab is highly effective and well tolerated.<sup>14,22</sup> Most reported adverse events, such as injection-site reactions and fever, were mild and short-lived. Serious adverse events were rare (<1%) and unrelated to the drug, with no cases of antibody-dependent enhancement or severe hypersensitivity reported. Postmarketing surveillance in Spain, Western Australia and Italy confirmed these findings, showing consistent tolerability and no safety concerns.<sup>14,22–24</sup> Overall, nirsevimab remains well tolerated across different settings, supporting its use for RSV prevention in infants.

Nirsevimab is provided free through state and territory initiatives to protect infants and young children at increased risk of severe RSV infection. It is available in all

Australian jurisdictions, with some offering year-round administration (Australian Capital Territory, New South Wales, Queensland, Northern Territory) and others running seasonal programs aligned with RSV peak periods (South Australia, Tasmania, Victoria, Western Australia).<sup>25</sup>

The *Australian Immunisation Handbook* recommends nirsevimab for the following groups (funded eligibility varies by state and territory):<sup>26</sup>

- infants younger than eight months of age who have not received adequate maternal RSV protection, including those whose mothers were unvaccinated or vaccinated less than two weeks before birth
- children younger than 24 months of age with certain high-risk conditions, regardless of maternal vaccination status (Box 1).<sup>1</sup>

To maintain protection, high-risk children aged 8 to younger than 24 months should receive an additional dose before their second or third RSV season, with a minimum six-month interval between doses and administration ideally timed just before the RSV season.

Since rollout, RSV prevention programs have reduced infant hospitalisations by

57% in Western Australia and 48% in Queensland, preventing over 1000 admissions among infants aged younger than 6 months. In 2024, the effectiveness of nirsevimab against RSV hospitalisation in these jurisdictions was estimated at 83.1% (95% confidence interval [CI], 67.4–91.3).<sup>24,27,28</sup>

By 2025, all jurisdictions had access to NIP-funded maternal vaccination and state- or territory-funded nirsevimab. A sentinel hospital analysis of infants admitted with acute respiratory infection between 1 April 2024 and 30 November 2025 estimated an overall immunisation effectiveness against RSV hospitalisation of 82.0% (95% CI, 70.0–89.2), with effectiveness of 80.8% (95% CI, 67.8–88.6) for maternal vaccination and 89.5% (95% CI, 73.4–95.8) for nirsevimab.<sup>29</sup> Program impact was associated with reductions in hospitalisations of 43.8% among infants aged 0 to younger than 3 months, 20.1% among those aged 3 to younger than 6 months, and 8.5% among those aged 6 to 12 months.<sup>29</sup> These data highlight the substantial impact of Australia's RSV prevention strategy in reducing severe RSV disease and hospitalisations among vulnerable populations.

A single dose of an RSV vaccine – RSVPreF or RSVPreF3 OA (AS01E adjuvanted) – is recommended for adults aged 75 years and older, adults aged 60 years and older with medical comorbidities, and Aboriginal and Torres Strait Islander adults aged 60 years and older.<sup>30</sup> From 15 May 2026, the RSVPreF3 OA (AS01E adjuvanted) vaccine is NIP-funded for adults aged 75 years and older, and Aboriginal and Torres Strait Islander adults aged 60 years and older. Adults aged 50 to 59 years with medical conditions can also consider vaccination with the RSVPreF3 OA (AS01E adjuvanted) vaccine after discussion with their GP.

Given the recent introduction of RSV vaccines globally, longitudinal data on the duration of protection are currently limited to three years. In adults aged 60 years and older who received a single pre-season dose of the RSVPreF3 OA (AS01E adjuvanted) vaccine, the efficacy against RSV-related

lower respiratory tract disease was 82.6% (95% CI, 57.9–94.1) in season one, declining to 56.1% (95% CI, 28.2–74.4) in season two and 48.0% (95% CI, 8.7–72.0) in season three. In a subgroup that received a booster before season two, the efficacy in season three was higher at 68.4% (95% CI, 24.6–89.1), although not statistically significant. These data suggest that protection from one dose appears to persist for at least two to three years; the need for further doses remains uncertain.<sup>31</sup>

Postmarketing surveillance of more than 2000 RSVPreF3 OA (AS01E adjuvanted) vaccine recipients in Australia showed that over 63% reported no side effects in the first three days after vaccination, whereas the remaining 37% experienced mostly mild reactions (predominantly local injection-site reactions).

## Influenza

Influenza is a highly contagious RNA virus of the *Orthomyxoviridae* family that causes an acute respiratory illness and is a major contributor to hospitalisation and mortality.<sup>32</sup> Children younger than 5 years of age, and adults aged 65 years and older experience the highest rates of influenza-related hospitalisation.<sup>33</sup>

In 2025, Australia recorded one of the highest numbers of laboratory-confirmed influenza cases since influenza became nationally notifiable in 2001, with more than 480,000 cases reported.<sup>34</sup> Influenza notifications were the highest among children aged 5 to 9 years, followed by those aged 0 to 4 years. Contributing factors include suboptimal influenza vaccination coverage and an extension of influenza activity to November 2025, associated with the late emergence of a rapidly spreading H3N2 subclade (subclade K).<sup>35,36</sup>

The Australian influenza vaccination program recommends vaccination for all individuals aged 6 months and older and uses the Southern Hemisphere influenza vaccine formulation. Annual influenza vaccine effectiveness varies depending on how well circulating strains match those included in the vaccine and can range between 40

and 60%, with higher effectiveness against intensive care unit admissions.<sup>37,38</sup> Vaccinated people have a lower estimated incidence of influenza (0.9%) compared with unvaccinated people (2.3%).<sup>39</sup> Moreover, over eight seasons, between 2010 to 2017, influenza vaccination was associated with a 31% (95% CI, 3–51%) reduction in influenza-related mortality.<sup>40</sup>

Despite a well-established vaccination program, influenza vaccine uptake in Australia has been suboptimal and remained so in 2025. Data on age-specific coverage between 1 March and 31 August are shown in Table 2.<sup>41</sup>

Influenza vaccination campaigns in temperate regions of Australia commence in autumn (usually March to April). In tropical areas of Australia, where influenza circulation is less seasonal, vaccination can be administered year-round. Protection following immunisation generally persists for about four to six months.<sup>32</sup> Influenza vaccination is funded under the NIP for children aged 6 months to 5 years, pregnant women, all Aboriginal and Torres Strait Islander people aged 6 months and older, and individuals aged 6 months and older with underlying medical conditions that increase their risk of severe influenza.

Two doses of influenza vaccine, given four weeks apart, are recommended for:<sup>42</sup>

- children aged 6 months to younger than 2 years receiving the influenza vaccine for the first time
- individuals of any age receiving their first influenza vaccine following haematopoietic stem cell transplant, solid organ transplant or chimeric antigen receptor T-cell therapy
- children aged 6 months to younger than 9 years with a medical risk condition receiving the influenza vaccine for the first time.

Influenza vaccination is recommended in every pregnancy, at any gestational age, using an inactivated influenza vaccine. If vaccination occurred before pregnancy or earlier in the same year, revaccination during pregnancy is recommended, including with the subsequent annual vaccine if

**TABLE 2. SNAPSHOT OF THE LATEST 2025 INFLUENZA VACCINE COVERAGE DATA IN AUSTRALIA<sup>41\*\*†</sup>**

Age group	Australian Capital Territory (%)	New South Wales (%)	Victoria (%)	Queensland (%)	South Australia (%)	Western Australia (%)	Tasmania (%)	Northern Territory (%)	Australia-wide (%)
6 months to <5 years	48.4	24.4	30.4	20.1	27.6	23.0	29.6	35.4	25.7
5 to <15 years	24.3	13.3	16.0	13.2	15.3	15.3	14.8	12.8	14.5
15 to <50 years	32.7	19.5	23.7	18.3	23.6	18.8	23.4	21.5	20.8
50 to <65 years	44.3	30.1	34.2	31.4	36.2	30.9	39.4	25.4	32.3
≥65 years	66.0	58.2	61.8	60.4	66.6	59.8	67.9	34.9	60.5

\* Year-to-date coverage calculated using vaccinations given 1 March to 31 August 2025 (inclusive). Australian Immunisation Register as of 7 September 2025.

† Coverage data in this table may differ slightly from estimates published elsewhere because of differences in calculation methodologies and/or the Australian Immunisation Register being used in the calculation having been downloaded on different dates.

available while pregnant, to optimise maternal and infant protection.<sup>42</sup> Travellers are advised to receive a repeat influenza vaccine before overseas travel if more than six months have elapsed since receiving their previous dose.<sup>32</sup> Until recently, all influenza vaccines in Australia were inactivated quadrivalent, containing two strains of influenza A and two strains of influenza B. In 2026, Australia transitioned to trivalent influenza vaccines, containing two A strains and one B lineage, because of the lack of circulation of the B/Yamagata lineage virus since 2020.<sup>42</sup> The currently available influenza vaccines include injectable (inactivated) and intranasal (live attenuated) vaccines, which have comparable effectiveness.<sup>43</sup>

The trivalent inactivated influenza vaccine (surface antigen, inactivated, prepared in cell cultures) is the first cell-based vaccine to be added to the NIP and has been available since 2024 for eligible high-risk groups aged 5 to 64 years. Cell-based influenza vaccines provide an alternative to traditional egg-based formulations and may reduce the risk of egg-adapted mutations during production.<sup>44</sup> They also allow for faster, egg-independent manufacturing and rollout in response to significant genetic shifts.<sup>45</sup>

Individuals with egg allergy can safely be vaccinated with egg-based vaccines as the amount of residual egg protein is less

than 1 microgram.<sup>43</sup> The absolute contraindication to influenza vaccination is anaphylaxis to a previous influenza vaccine or any of its components. Anyone who has experienced a severe reaction after a prior dose should consult their immunisation provider to discuss the risks and benefits of vaccination.

#### Newly approved live-attenuated vaccine in Australia

The intranasal LAIV was approved by the TGA in November 2025 for children and adolescents aged 2 to less than 18 years, offering a needle-free option.<sup>46</sup> Several states – including New South Wales, Queensland, South Australia and Western Australia – fund the intranasal LAIV for children aged 2 to 4 years (Queensland includes children aged 5 years [inclusive] and Western Australia extends coverage to 11 years of age [inclusive]). Children younger than 18 years of age outside these programs can access it privately.<sup>47-50</sup> The vaccine is administered intranasally, with 0.1 mL given per nostril. Its needle-free delivery aims to support improved uptake among paediatric populations in Australia.

The intranasal LAIV delivers live, attenuated influenza viruses to the nasal passages, where they replicate locally without causing illness, inducing mucosal immunoglobulin A and T-cell-mediated immune responses in

the respiratory tract.<sup>26,51</sup> By targeting the primary site of viral entry, this mucosal immune response limits viral replication and more closely mimics the protection induced by natural influenza infection compared with intramuscular vaccines.<sup>51</sup>

The intranasal LAIV has been widely used in the Northern Hemisphere since 2003, with international data showing comparable effectiveness to injectable vaccines in children. A recent European systematic review found no overall difference in efficacy between intranasal LAIVs and inactivated intramuscular vaccines, whereas subgroup analysis of large multicentre trials showed trivalent LAIVs were significantly more effective than trivalent inactivated intramuscular vaccines (odds ratio [OR], 0.50; 95% CI, 0.28–0.88).<sup>52</sup> Safety data were reassuring, with only 23 serious vaccine-related adverse events reported among 17,833 participants and no significant difference between vaccine types.<sup>52</sup>

International experience demonstrates that high influenza vaccine uptake in children can confer broader community benefits. In England, a pilot program delivering LAIVs to primary school children through a targeted school-based strategy achieved uptake of 56.8%.<sup>53</sup> Compared with nonpilot areas, this was associated with a 94% reduction in GP consultations for influenza-like illness and a 74% reduction in emergency

### 3. KEY POINTS ON THE INTRANASAL LIVE ATTENUATED INFLUENZA VACCINE

#### What is it?

- Intranasal live attenuated influenza vaccine

#### Formulation

- 10,000,000 fluorescent focus units per strain (total 0.2 mL), intranasal spray applicator

#### Registered population

- Children and adolescents aged ≥24 months to <18 years

#### Dose

- Total dose 0.2 mL intranasally (0.1 mL per nostril)
- 2 doses ≥4 weeks apart if influenza-naïve and <9 years of age
- 1 dose if ≥9 years of age or previously vaccinated

#### State-funded target groups (as of January 2026)

- New South Wales: 2 to <5 years of age
- Queensland: 2 to 5 years of age (inclusive)
- South Australia: 2 to <5 years of age
- Western Australia: 2 to 11 years of age (inclusive)

#### Common adverse events

- Mild, transient nasal congestion
- Runny nose
- Headache
- Fatigue

#### Storage requirements

- Store at 2–8°C
- Do not freeze

department respiratory presentations. Notably, indirect effects were also observed in adults aged 17 years and older, with a 59% reduction in GP consultations for influenza-like illness in pilot compared with nonpilot areas. Studies from Ireland and Spain have also demonstrated significant increases in influenza vaccine uptake with school-based delivery models and provide valuable insights for similar programs in the future in Australia.<sup>54,55</sup>

Expected side effects are generally mild and transient, including nasal congestion, runny nose, headache and fatigue, whereas serious adverse events are extremely rare. The intranasal LAIV has been added to the Australian Immunisation Register and should be reported, as with all other influenza vaccines. Key points regarding

the intranasal LAIV are summarised in Box 3.

#### Influenza vaccination for older people

Influenza-related mortality is the highest in adults aged 65 years and older, and vaccination in this group significantly reduces hospitalisations from influenza and pneumonia, as well as all-cause mortality.<sup>32,56</sup>

High-dose or adjuvanted vaccines help overcome age-related immunosenescence and offer enhanced protection over standard influenza vaccines. Postlicensure studies among adults aged 65 years and older have shown that adjuvanted influenza vaccines are 4.7 to 33% more effective than standard-dose vaccines in preventing hospitalisation because of influenza or pneumonia.<sup>57–59</sup>

Recommended vaccines include the trivalent influenza vaccine (surface antigen, inactivated, adjuvanted), which is registered for use in adults aged 50 years and older and NIP funded for adults aged 65 years and older, and the high-dose trivalent inactivated influenza vaccine (split virion) available via private prescription for adults aged 60 years and older.<sup>16</sup> Both are preferred over standard influenza vaccines in these age groups, with no preference between them. Aged care settings are particularly vulnerable to respiratory viral outbreaks, with high rates of severe disease and mortality. Accordingly, influenza vaccination is strongly recommended for both residents and staff.<sup>60</sup>

#### Herpes zoster

Reactivation of varicella zoster virus causes herpes zoster, also known as shingles, an inflammation of the dorsal root ganglion resulting in neuropathic pain and a vesicular rash with a dermatomal distribution.<sup>61</sup>

About 20 to 30% of people will have herpes zoster in their lifetime, even in the absence of a reported or recalled history of chickenpox.<sup>62</sup> The risk of herpes zoster is greater in older adults because of waning immunity and in people with immunocompromise. Complications of herpes zoster include postherpetic neuralgia, which can

cause debilitating pain more than 90 days after rash onset, and herpes zoster ophthalmicus, an ophthalmic emergency involving the trigeminal nerve and orbital structures.<sup>63,64</sup> In the most severe cases, herpes zoster can cause disseminated infection with multiorgan involvement.<sup>64</sup>

The nonlive recombinant herpes zoster vaccine replaced the live-attenuated herpes zoster vaccine on the NIP in November 2023.<sup>65</sup> The live-attenuated herpes zoster vaccine was subsequently withdrawn from use in Australia in December 2024.<sup>62</sup> The nonlive recombinant herpes zoster vaccine contains varicella-zoster virus glycoprotein E and the AS01B adjuvant, which enhances the vaccine-related immune response. A two-dose schedule is recommended, administered two to six months apart for people who are immunocompetent and one to two months apart for people with immunocompromise.

An international open-label phase 3b study demonstrated sustained efficacy of the recombinant herpes zoster vaccine against herpes zoster, with an effectiveness of 79.8% (95% CI, 73.7–84.6) in adults aged 50 years and older, and 73.2% (95% CI, 62.9–80.9) in those aged 70 years and older, as well as high protection against postherpetic neuralgia (87.5%; 95% CI, 64.8–96.8) and other zoster-related complications (91.7%; 95% CI, 43.7–99.8). Protection remained durable for up to 11 years after completion of the two-dose schedule, with efficacy sustained at 82.0% (95% CI, 63.0–92.2).<sup>66</sup>

An additional benefit of the recombinant herpes zoster vaccine may be a reduction in dementia risk. Promising research has demonstrated a statistically significant reduction in the risk of dementia among patients who receive two doses of recombinant zoster vaccine, especially in women.<sup>67</sup> This research was conducted in adults aged 65 years and older, but there may also be benefits to administering the recombinant herpes zoster vaccine to younger individuals.<sup>68</sup> More recently, a large retrospective cohort study reported a 21% reduction in cardiovascular events among vaccinated individuals.<sup>69</sup>

The nonlive recombinant herpes zoster vaccine is funded under the NIP for the following high-risk groups:<sup>70</sup>

- all people aged 65 years and older
- Aboriginal and Torres Strait Islander people aged 50 years and older
- immunocompromised patients aged 18 years and older who are considered at increased risk of herpes zoster because of an underlying condition, immunomodulatory treatments or immunosuppressive treatments (Box 4).

The nonlive recombinant herpes zoster vaccine is recommended but not funded for adults aged 50 years and older who are immunocompetent.<sup>70</sup>

Herpes zoster may result from reactivation of the wild-type virus or, extremely rarely, the vaccine strain.<sup>70</sup> If an individual received the varicella vaccine at the recommended age of 18 months and has no history of chickenpox, they may not require a herpes zoster vaccine. If their varicella infection or vaccination history is unknown, it is safe and recommended to administer a herpes zoster vaccine at the appropriate age, given the significant morbidity associated with herpes zoster episodes.<sup>70</sup> The nonlive recombinant herpes zoster vaccine is not interchangeable with varicella vaccines and is not indicated for the prevention of chickenpox.<sup>71</sup>

For optimal long-term immunity, the two-dose nonlive recombinant herpes zoster vaccine schedule should be completed even if an individual develops herpes zoster infection after the first dose, as this is not a contraindication. Following shingles infection, vaccination should be deferred for 12 months in immunocompetent individuals and for three months in people with immunocompromise, because of conferred natural immunity.<sup>70</sup>

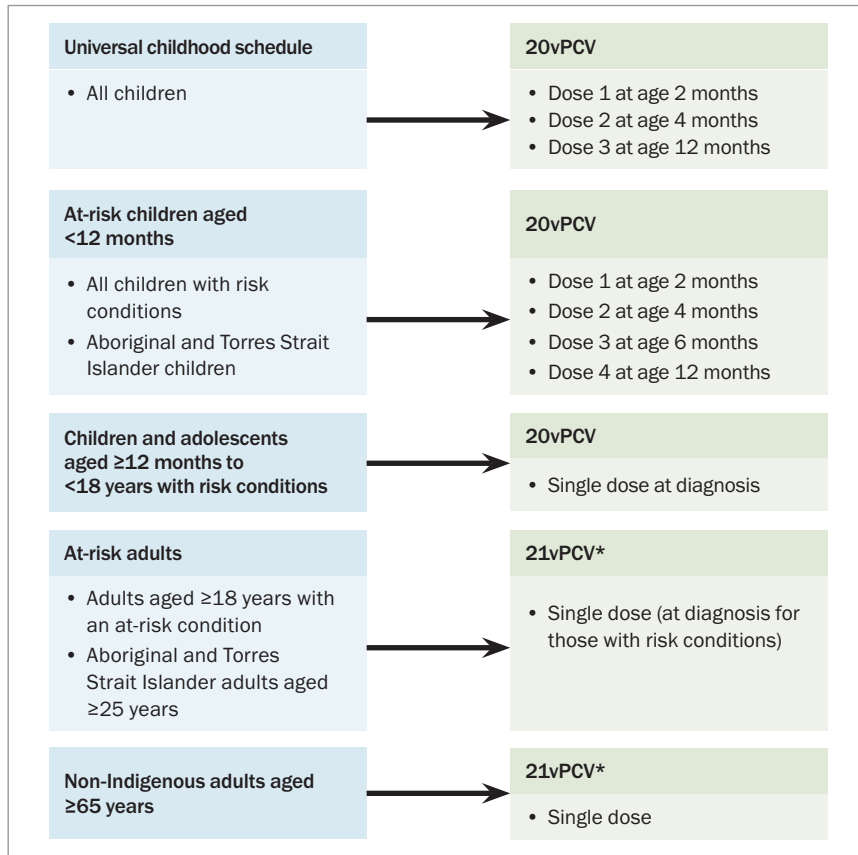
The nonlive recombinant herpes zoster vaccine is a highly reactogenic vaccine, with reactions more frequent after the second dose than the first. It frequently causes mild, short-lived injection-site reactions such as pain, swelling and redness, as well as systemic symptoms such as fatigue, myalgia, fever and gastrointestinal upset, which

4. RISK GROUPS ELIGIBLE FOR NIP-FUNDED RECOMBINANT HERPES ZOSTER VACCINE <sup>70*</sup>	
<p><b>Acute haematological malignancies, for example:</b></p> <ul style="list-style-type: none"> <li>• Acute leukaemia</li> <li>• Aggressive lymphomas</li> </ul>	<p><b>Chronic kidney disease, for example:</b></p> <ul style="list-style-type: none"> <li>• Stage 5 chronic kidney disease or dialysis</li> </ul>
<p><b>B- and T-cell targeted monoclonal antibody therapies, for example:<sup>†</sup></b></p> <ul style="list-style-type: none"> <li>• Anti-CD20 monoclonal antibodies</li> <li>• Anti-B-cell activating factor antibodies</li> <li>• Anti-CD52 monoclonal antibodies</li> <li>• Anti-thymocyte globulin</li> </ul>	<p><b>Conventional immunosuppressive agents, for example:<sup>†</sup></b></p> <ul style="list-style-type: none"> <li>• Methotrexate ≥20 mg/week</li> <li>• Azathioprine ≥3 mg/kg/day</li> <li>• 6-mercaptopurine ≥1.5 mg/kg/day</li> <li>• Mycophenolate ≥1 g/day</li> <li>• Cyclophosphamide</li> <li>• Systemic calcineurin inhibitors</li> <li>• Mechanistic target of rapamycin inhibitors</li> <li>• Purine analogues</li> </ul>
<p><b>Biological therapies, for example:<sup>†</sup></b></p> <ul style="list-style-type: none"> <li>• Tumour necrosis factor inhibitors</li> <li>• Soluble tumour necrosis factor receptors</li> <li>• T-cell co-stimulation modulators</li> <li>• Type I interferon receptor inhibitors</li> <li>• Proteasome inhibitors</li> </ul>	<p><b>Human immunodeficiency virus infection:</b></p> <ul style="list-style-type: none"> <li>• CD4 cell count &lt;200 cells/microL</li> </ul>
<p><b>Cancer therapies, for example:<sup>†</sup></b></p> <ul style="list-style-type: none"> <li>• Chemotherapy for haematological malignancy</li> <li>• Chemotherapy for solid organ tumours</li> </ul>	<p><b>Immunomodulatory drugs, for example:<sup>†</sup></b></p> <ul style="list-style-type: none"> <li>• Sphingosine-1-phosphate receptor modulators</li> </ul>
<p><b>Cellular therapies and stem cell transplantation, for example:</b></p> <ul style="list-style-type: none"> <li>• Autologous haematopoietic stem cell transplant (≤24 months)</li> <li>• Chimeric antigen receptor T-cell therapy</li> <li>• Allogeneic haematopoietic stem cell transplant</li> <li>• Allogeneic transplant with ongoing graft-versus-host disease requiring immunosuppressive therapy</li> </ul>	<p><b>Immunosuppressive therapy, for example:<sup>†</sup></b></p> <ul style="list-style-type: none"> <li>• Solid organ transplant recipients receiving immunosuppressive therapy</li> </ul>
<p><b>Chronic haematological malignancies, for example:</b></p> <ul style="list-style-type: none"> <li>• Myelodysplastic syndromes</li> <li>• Chronic myeloproliferative disorders</li> <li>• Lymphoproliferative malignancies and plasma cell dyscrasias (including myeloproliferative neoplasms)</li> <li>• Chronic lymphocytic leukaemia</li> <li>• Indolent non-Hodgkin lymphoma</li> <li>• Multiple myeloma</li> </ul>	<p><b>Inborn errors of immunity with ongoing functional deficits, for example:</b></p> <ul style="list-style-type: none"> <li>• Humoral immunodeficiencies (e.g. X-linked agammaglobulinaemia)</li> <li>• Combined immunodeficiencies (e.g. severe combined immunodeficiency)</li> <li>• Phagocytic disorders (e.g. chronic granulomatous disease)</li> <li>• Other inborn errors of immunity</li> </ul>
	<p><b>IL inhibitors, for example:<sup>†</sup></b></p> <ul style="list-style-type: none"> <li>• Anti-IL-1, IL-4/13, IL-5 and IL-6 antibodies</li> </ul>
	<p><b>Oral small-molecule targeted therapies, for example:<sup>†</sup></b></p> <ul style="list-style-type: none"> <li>• Bruton's tyrosine kinase inhibitors</li> <li>• Janus kinase inhibitors</li> <li>• Breakpoint cluster region-Abelson inhibitors</li> </ul>
<p>Abbreviations: CD = cluster of differentiation; IL = interleukin; NIP = National Immunisation Program.</p> <p>* Accurate at the time of printing. Please refer to the <i>Australian Immunisation Handbook</i> website for updates.</p> <p><sup>†</sup> Funding applies only if immunosuppressive therapy is current or was received within the previous 6 months.</p>	

typically resolve within a few days.<sup>70</sup> A transient increase in herpes zoster incidence has been observed shortly after the first dose in adults aged 65 years and older; however, these episodes are typically mild, with good vaccine effectiveness after completion of the two-dose schedule.<sup>72</sup> Educating patients about the expected reactogenicity can help support adherence to the second dose.<sup>73,74</sup>

### Pneumococcal disease

*Streptococcus pneumoniae* can lead to invasive pneumococcal disease (IPD), a serious bacterial infection that includes meningitis, bacteraemic pneumonia and sepsis. Pneumococcal disease poses a significant health burden in Australia, contributing to severe illness and mortality among vulnerable groups. Children aged younger



**Figure.** Pneumococcal vaccines funded under the National Immunisation Program. See the *Australian Immunisation Handbook* for a list of specified risk conditions eligible to receive free pneumococcal vaccines.<sup>75†</sup>

Abbreviations: PCV = pneumococcal conjugate vaccine; v = valent.

\* As of 1 July 2026.

† Accurate at the time of printing. Please refer to the *Australian Immunisation Handbook* website for updates.

than 2 years, older adults, individuals with underlying medical conditions, and Aboriginal and Torres Strait Islander peoples are at increased risk of severe disease (Table 3).<sup>75,76</sup>

Australia's pneumococcal vaccination program has evolved to address changing disease patterns. More than 100 pneumococcal serotypes exist, and a subset causes invasive disease. Two principal vaccine platforms are available: pneumococcal conjugate vaccines (PCVs) and polysaccharide vaccines (PPVs), with PCVs eliciting a T-cell-dependent response with establishment of B-cell memory and longer-term immunity.<sup>77,78</sup> 7vPCV was NIP funded for all infants in 2005 and replaced by 13vPCV in 2011, leading to a substantial

reduction in IPD caused by vaccine serotypes.<sup>79</sup> However, this was accompanied by serotype replacement, with an increased incidence of disease because of an emergence of non-13vPCV serotypes.<sup>76,80</sup> In response, higher-valency PCVs have been developed, with the TGA having approved 15vPCV (adding serotypes 22F and 33F), 20vPCV (adding five more: 8, 10A, 11A, 12F and 15B) and 21vPCV (discussed in more detail below), which now account for a growing proportion of IPD cases.<sup>75,81</sup> From 1 September 2025, 20vPCV became the NIP-funded vaccine for all children aged younger than 18 years, replacing both 13vPCV and 23vPPV.<sup>82,83</sup>

The current pneumococcal vaccination schedule for all ages is shown in the Figure.

The infant pneumococcal schedule now has 20vPCV administered at 2 months (or from 6 weeks), 4 months and 12 months (2+1 schedule) of age, and a 6-month dose (3+1 schedule) for children at increased risk, including Aboriginal and Torres Strait Islander children and those with specified risk conditions (Table 3).<sup>75</sup> Children who commenced vaccination with 13vPCV or 15vPCV should complete the series with 20vPCV, whereas those who have completed an age-appropriate schedule do not require additional doses.

The 20vPCV includes seven of the 11 additional serotypes previously covered by 23vPPV, and the remaining four serotypes now account for a minimal IPD burden. Therefore, 23vPPV is no longer recommended in children, including those at increased risk. This transition simplifies the schedule while maintaining broad serotype coverage and protection against IPD.

For Aboriginal and Torres Strait Islander children and children with risk conditions who completed a primary series with 13vPCV or 15vPCV, a single dose of 20vPCV is recommended in place of 23vPPV at the age of 4 years or at least 12 months after the last PCV dose, whichever is later. If 23vPPV has already been administered, 20vPCV replaces the second 23vPPV dose and should be given at an interval of at least five years after the first dose.<sup>75</sup>

The 20vPCV has been shown in clinical trials to be safe for use in children, with a safety profile comparable with that of 13vPCV. The most common reaction is pain at the injection site. Systemic reactions may include irritability, drowsiness and mild fever, and are typically transient, with no evidence of increased serious adverse events compared with 13vPCV. The only absolute contraindication is anaphylaxis to the vaccine or its components.<sup>75,84</sup>

Other conjugate vaccines (15vPCV and 20vPCV) are registered for adult use but are not NIP funded and are available on private prescription.<sup>82</sup> Australia's adult pneumococcal vaccination program has been under review. 21vPCV has been

**TABLE 3. RISK CONDITIONS FOR PNEUMOCOCCAL VACCINATION AND ELIGIBILITY FOR NIP FUNDING<sup>75\*</sup>**

Risk category	Details or specific conditions	NIP funded
Previous episode of invasive pneumococcal disease	Any previous episode of invasive pneumococcal disease	Yes
Functional or anatomical asplenia	Sickle cell disease or other haemoglobinopathies	Yes
	Congenital or acquired asplenia (for example, splenectomy) or hypoplasia	
Immunocompromising conditions	Inborn errors of immunity, including primary immunodeficiency, such as symptomatic immunoglobulin G subclass or isolated immunoglobulin A deficiency	Yes
	Haematological malignancies	
	Solid organ transplant	
	Haematopoietic stem cell transplant	
	HIV infection	
	Immunosuppressive therapy, where sufficient immune reconstitution for vaccine response is expected; this includes those with underlying conditions requiring but not yet receiving immunosuppressive therapy	No
Nonhaematological malignancies receiving chemotherapy or radiotherapy (currently or anticipated)		
Proven or presumptive cerebrospinal fluid leak	Cochlear implants	Yes
	Intracranial shunts	
Chronic respiratory disease (individual conditions listed and those that are similar based on clinical judgement)	Suppurative lung disease, bronchiectasis and cystic fibrosis	Yes
	Chronic lung disease in preterm infants	
	Chronic obstructive pulmonary disease and chronic emphysema	No
	Severe asthma (defined as requiring frequent medical consultations or the use of multiple medications)	
	Interstitial and fibrotic lung disease	
Chronic renal disease	Relapsing or persistent nephrotic syndrome	Yes
	Chronic renal impairment – estimated glomerular filtration rate <30 mL/min (stage 4 or 5 disease)	Yes, if estimated glomerular filtration rate <15 mL/min only (including patients on dialysis), otherwise no
Infants born to mothers who received biological therapies during pregnancy	Infants exposed to anti-cluster of differentiation 20 therapies (such as rituximab) in utero	No
Cardiac disease (individual conditions listed and those that are similar based on clinical judgement)	Congenital heart disease	Yes, for children who are aged <5 years when they start their recommended schedule, otherwise no
	Coronary artery disease	
	Congestive heart failure	
Children born earlier than 28 weeks' gestation	Any person born earlier than 28 weeks' gestation	Yes, for children who are aged <5 years when they start their recommended schedule, otherwise no
Chromosomal abnormality	Trisomy 21 or another genetic condition that increases the risk of severe disease	Yes, for children who are aged <5 years when they start their recommended schedule, otherwise no
Chronic liver disease	Conditions with progressive deterioration of liver function for more than 6 months including cirrhosis and other advanced liver diseases	No
Diabetes mellitus	Any person with diabetes	No
Smoking	Current smoker or ex-smoker in the immediate past	No
Harmful use of alcohol	Consuming on average ≥60g of alcohol (6 Australian standard drinks) per day for men and ≥40g of alcohol (4 Australian standard drinks) per day for women	No

\* Accurate at the time of printing. Please refer to the *Australian Immunisation Handbook* website for updates.

### 5. PRIMARY CORONAVIRUS DISEASE 2019 VACCINATION RECOMMENDATION BY AGE AND MEDICAL RISK<sup>87\*</sup>

- Adults ≥18 years of age (not severely immunocompromised): one primary dose
- Adults ≥18 years of age (severe immunocompromised): two primary doses, with a third dose considered based on individual risk–benefit assessment
- Infants and children 6 months to <5 years of age with medical risk factors: two primary doses may be considered
- Infants and children 6 months to <5 years of age with severe immunocompromise: two primary doses may be considered
- Children and adolescents 5 to <18 years of age with medical risk factors: one primary dose may be considered
- Children and adolescents 5 to <18 years of age with severe immunocompromise: one or two primary doses may be considered

\* Some individuals who have completed their primary coronavirus disease 2019 vaccination course are advised to receive additional booster doses every 6 or 12 months, depending on their risk of severe disease. Table 4 outlines the groups eligible for booster doses.

recommended by Australia's Pharmaceutical Benefits Advisory Committee for listing to prevent pneumococcal disease in individuals aged 18 years and older with an at-risk condition, Aboriginal and Torres Strait Islander adults aged 25 years and older, and non-Indigenous adults aged 65 years and older, and will be NIP funded for these groups from 1 July 2026.<sup>85</sup> 21vPCV targets a different set of serotypes (15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B) that tend to cause pneumococcal disease in older adults.<sup>86</sup> This vaccine will replace the previous recommendation of 13vPCV with or without 23vPCV in adults. It is important for vaccine providers to be abreast of the current vaccines available and the recommendations and schedules for different population groups in this evolving environment.

### Coronavirus disease 2019

Australia's national coronavirus disease 2019 (COVID-19) vaccination program

was launched in February 2021. Although the pandemic saw an initial mass vaccine uptake among eligible Australians, ongoing exposure to COVID-19 in the community since then has resulted in widespread hybrid immunity, and the COVID-19 vaccination strategy has shifted towards protecting vulnerable populations (namely, the elderly and people with medical comorbidities) from hospitalisation and severe disease.<sup>87,88</sup> Of the 110,000 hospitalisations involving a COVID-19 diagnosis in a 12-month period between 2023 and 2024, 45% were in people aged 65 to 84 years.<sup>89</sup> There were 25,500 hospitalisations of patients with one recorded comorbid chronic condition; 8.2% spent time in intensive care and 7.5% died in hospital.<sup>89</sup> Crucially, among patients aged 65 years and older, receiving a COVID-19 vaccine in the past three months reduced the risk of death from COVID-19 by as much as 74.9% compared with those who were unvaccinated. After six months, the risk was reduced by more than 50%.<sup>90</sup> Therefore, continuing to offer boosters to these groups significantly reduces mortality and hospitalisation.

Additional benefits of vaccination have been seen in relation to long COVID. Vaccination appears to prevent the prolongation of acute COVID-19 symptoms and may ameliorate symptoms such as fatigue and brain fog in some patients with long-term sequelae after infection.<sup>91</sup>

Two COVID-19 mRNA vaccine formulations are currently available in Australia, targeting the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) JN.1 and LP.8.1 subvariants. Both mRNA vaccines are designed to target more recent circulating SARS-CoV-2 variants and are expected to be more effective than older formulations. Original and bivalent COVID-19 vaccine formulations containing the ancestral SARS-CoV-2 strain are no longer available in Australia.<sup>92</sup>

COVID-19 vaccines are generally well tolerated. Common side effects of COVID-19 vaccination include injection-site pain, fatigue, headache, muscle aches, chills and joint pain.<sup>92</sup>

The recommended primary COVID-19 vaccination schedule varies according to age and medical risk (Box 5).<sup>87</sup> The groups recommended for booster doses are summarised in Table 4.<sup>87</sup>

### Vaccination in people with immunocompromise

All previously discussed vaccines include specific recommendations for people who are medically at risk and those who have immunocompromise. This reflects the increased susceptibility of these populations to severe vaccine-preventable diseases. Weakened immunity arises from inherited disorders or secondary causes such as underlying medical conditions (e.g. diabetes) or immunosuppressive therapy.<sup>93,94</sup> Vaccine responses are often attenuated in these populations, necessitating modified schedules, including additional or booster doses. Both susceptibility to infection and vaccine responsiveness vary according to the nature and severity of immunosuppression, concomitant therapies and age.<sup>95</sup> Vaccination should be individualised, considering history, type and duration of immunosuppressive therapy, and degree of immunocompromise. Further details on medical conditions, immunosuppressive therapies and associated levels of immunocompromise can be found in the *Australian Immunisation Handbook*.<sup>96</sup>

Live vaccines are contraindicated in moderate to severe immunosuppression because of infection risk, whereas nonlive vaccines are safe. Ideally, all vaccines should be completed before starting immunosuppressive therapy, with live vaccines given at least four weeks before treatment.<sup>96</sup> Infants exposed to immunosuppressive biological agents in utero should not receive live vaccines, including the Bacille Calmette–Guérin vaccine, until at least 6 months of age. The rotavirus vaccine is an exception and can be given safely to most infants, except those exposed to anti-cluster of differentiation 20 antibodies (e.g. rituximab).<sup>96,97</sup>

Advances in immunomodulatory therapies and complex treatment regimens make assessing immunosuppression

**TABLE 4. CORONAVIRUS DISEASE 2019 BOOSTER DOSE RECOMMENDATIONS<sup>87</sup>**

Patient group	Younger than 5 years of age	5 to 17 years of age	18 to 64 years of age	65 to 74 years of age	75 years of age and older
Without severe immunocompromise	Not recommended	Not recommended	Consider a dose every 12 months	Recommended every 12 months and can consider a dose every 6 months	Recommended every 6 months
With severe immunocompromise	Not recommended	Consider a dose every 12 months	Recommended every 12 months and can consider a dose every 6 months	Recommended every 12 months and can consider a dose every 6 months	Recommended every 6 months

challenging. If uncertainty exists regarding vaccine safety, timing or the appropriateness of serological testing, guidance should be sought from an immunisation or infectious diseases specialist.

### Role of serological testing

Serology is not routinely recommended but may guide decision-making in specific situations, such as vaccination planning before immunosuppression, confirming immunity after vaccination, determining booster needs or informing postexposure management (e.g. the need for immunoglobulin post-measles exposure). Serological testing should be considered only when:<sup>94</sup>

- a reliable assay is available
- a clear correlate of protection (a measurable immune marker indicating immunity) is established
- results will inform clinical decisions such as revaccination or prophylaxis.

Evidence supports serology for certain vaccines, such as hepatitis B, measles, rubella, rabies and varicella.<sup>94</sup> Even with these pathogens, unnecessary testing should be avoided because of difficulty in interpretation, which can lead to inappropriate decisions and delays in immunisation. Serology guidance within the *Australian Immunisation Handbook* is likely to evolve as new assays become available, and when in doubt, guidance should be sought from an immunisation or infectious diseases specialist.

### Australian Immunisation Register

The Australian Immunisation Register is a national, whole-of-life register that records

vaccines administered to individuals in Australia. It evolved from the Australian Childhood Immunisation Register, which was expanded to include all age groups in 2016.<sup>98,99</sup> It is mandatory for vaccine providers to record NIP-funded, COVID-19, influenza and Japanese encephalitis virus vaccines (including route of administration) and it is recommended that all vaccines, including those administered overseas, are reported. From 1 March 2025, it also became mandatory to report whether an individual was pregnant at the time of vaccination.<sup>100</sup>

The Australian Immunisation Register has become a valuable central resource for both individuals and vaccinators, including clinicians, immunisation nurses and pharmacists, supporting the review of vaccination histories and informing eligibility and timing of subsequent vaccines, particularly as new vaccines are incorporated into the NIP.<sup>100</sup>

### Adverse events following immunisation

Vaccines are generally safe, although adverse reactions may occasionally occur. An adverse event following immunisation (AEFI) refers to any undesirable or unexpected event that occurs after a vaccine is administered.<sup>101</sup>

AEFIs may arise from an individual's response to a vaccine component, the vaccination procedure itself, coincidental events unrelated to vaccination or issues with vaccine handling or administration. Most serious AEFIs develop within the first 10 minutes after vaccination, making close observation during this period

essential for timely recognition and management of acute reactions.<sup>101</sup>

Of the vaccines discussed, most have mild acute AEFIs, including fever, myalgia and local reactions, although the nonlive recombinant herpes zoster vaccine is particularly reactogenic. Data on current, up-to-date Australian experience can be found at <https://www.ausvaxsafety.org.au/>. Notable adverse events of special interest include Guillain–Barré syndrome (GBS), myocarditis and thrombosis with thrombocytopenia syndrome.

GBS is a rare, immune-mediated neuropathy. Although most cases follow gastrointestinal or respiratory infections, it has been infrequently associated with certain vaccines. GBS occurs in the general population at a rate of one to two cases per 100,000 people per year. Seasonal influenza vaccines are linked to an estimated one additional case per 1,000,000 doses. The risk of developing GBS is several times higher after influenza infection than after influenza vaccination.<sup>102</sup>

There is also a rare risk of GBS after the nonlive recombinant herpes zoster vaccine.<sup>81,103</sup> Postmarketing data for this vaccine in adults aged 65 years and older show a rare risk of about six cases per 1,000,000 doses after the first dose, with no increased risk after the second dose. Vaccination is recommended unless the patient experienced GBS within six weeks of a vaccine without a trigger. An increased risk of GBS following RSVPreF or RSVPreF3 OA (AS01E adjuvanted) vaccines has been reported. A US analysis presented in October 2024 estimated an excess of nine cases

## 6. ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI) REPORTING – WHAT IMMUNISATION PROVIDERS NEED TO KNOW

### Who can report

- Immunisation providers
- Individuals or parents

### When to report

- If a reaction:
  - does not fit the common reaction for that vaccine
  - is serious (e.g. anaphylaxis), uncommon or rare

### How to report

- State or territory AEFI reporting systems (jurisdiction-specific):
  - information can be found on the Australian Government Department of Health, Disability and Ageing website: [www.health.gov.au/topics/immunisation/immunisation-information-for-health-professionals/reporting-and-managing-adverse-vaccination-events#how-to-report-an-aeafi](http://www.health.gov.au/topics/immunisation/immunisation-information-for-health-professionals/reporting-and-managing-adverse-vaccination-events#how-to-report-an-aeafi)
- Reports can be submitted directly to the TGA: [www.tga.gov.au/safety/report-problem/report-adverse-event-or-safety-problem/reporting-adverse-events-health-professionals](http://www.tga.gov.au/safety/report-problem/report-adverse-event-or-safety-problem/reporting-adverse-events-health-professionals)

### AEFI clinics

- All jurisdictions provide AEFI assessment services – most clinics review children and some also assess adults. Information can be found on the National Centre for Immunisation Research and Surveillance website (<https://ncirs.org.au/health-professionals/specialist-immunisation-services>)

### Surveillance

- AusVaxSafety collects real-time self-reported postvaccination data to support the rapid detection of any emerging safety issues

of GBS per 1,000,000 doses of the RSVPreF vaccine and seven per million doses of the RSVPreF3 OA (AS01E adjuvanted) vaccine in adults aged 65 years and older.<sup>10</sup> A large national study from England identified a small but measurable increase in GBS following RSV vaccination, with a relative incidence of 3.34 and an attributable risk of about 23 cases per 1,000,000 doses with the RSVPreF vaccine.<sup>104</sup>

For patients with a previous history of GBS, irrespective of what the trigger may have been, the risk of recurrence of GBS following vaccination is thought to be low. Overall, GBS remains a rare event following immunisation, and the absolute risks are far exceeded by the protective benefits of vaccination.

Myocarditis and pericarditis following COVID-19 vaccination are very rare, with the highest incidence reported in adolescent males after a second dose of an mRNA vaccine. Of note, no cases of myocarditis have been reported in children aged 6 months to 11 years. Although uncommon, COVID-19 vaccine recipients should be informed of this risk.<sup>105,106</sup>

Individuals with recent myocarditis or pericarditis within the past three months, acute rheumatic fever or acute rheumatic heart disease with myocardial inflammation, or acute decompensated heart failure should seek advice from their GP, immunisation specialist and cardiologist before vaccination to determine appropriate timing.<sup>87</sup>

Emerging evidence supports a favourable long-term prognosis for vaccine-associated myocarditis. A recent prospective follow-up study of 256 people with confirmed or probable myocarditis after mRNA COVID-19 vaccination conducted between April 2021 and July 2022 found that 60% reported ongoing symptoms at three to six months, decreasing to 35% at 12 to 18 months. Overall, clinical severity remained mild among the individuals, with low hospitalisation rates and improved quality of life over time.<sup>107</sup>

Thrombosis with thrombocytopenia syndrome has not been associated with any of the current COVID-19 vaccines used in Australia. The syndrome was previously observed only after the first dose of the COVID-19 ChAdOx1-S vaccine at about two to three cases per 100,000 doses, and this vaccine was discontinued nationally in March 2023.<sup>108</sup>

Australia has robust surveillance systems that support early identification of potential vaccine safety issues.<sup>101</sup> AEFIs should be reported to the local public health

unit and the TGA. This helps identify and understand safety concerns with newly introduced vaccines, monitor AEFI rates across Australia and detect problems related to vaccine manufacture, storage, delivery or administration.

Immunisation providers should be familiar with the appropriate pathways for reporting adverse events following immunisation, as highlighted in Box 6.

## Conclusion

Overall, immunisation has evolved into a truly life-course intervention, with an expanding repertoire of vaccines providing protection against an increasing number of infectious diseases across all age groups. Although this progress reflects remarkable scientific and public health achievement – ‘for every generation, vaccines work’ – the growing complexity of schedules and risk-based recommendations can present challenges for providers. In this context, the Australian Immunisation Register serves as a crucial tool, enabling accurate, real-time access to individual vaccination histories and supporting informed clinical decision-making. Clinicians, particularly GPs, play a central role in using this resource to optimise vaccine delivery, while also empowering patients and families to engage with and understand their own immunisation status. In a setting with robust infrastructure and access, there is both an opportunity and a responsibility to maximise the benefits of immunisation across the lifespan through clear communication, system integration and equitable implementation. **MT**

## References

A list of references is included in the online version of this article ([www.medicinetoday.com.au](http://www.medicinetoday.com.au)).

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# The evolving immunisation landscape

## New vaccines and schedule changes

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