

# Pneumococcal vaccines

## PNEUMOCOCCAL VACCINES FOR AUSTRALIANS: INFORMATION FOR IMMUNISATION PROVIDERS

This fact sheet provides information for immunisation providers on pneumococcal disease and the use of pneumococcal vaccines in Australia.

### Disease and epidemiology

- Pneumococcal disease refers to a range of clinical diseases caused by bacterium *Streptococcus pneumoniae* (also called pneumococcus).
- Diseases where pneumococci are isolated from body sites that are normally sterile are grouped together as 'invasive pneumococcal disease' (IPD). IPD would present clinically as pneumonia, bacteraemia and meningitis.
- The risk of IPD is greatest in very young infants and people aged >60 years.
- Aboriginal and Torres Strait Islander people, particularly young adults, have a substantially higher prevalence of risk factors associated with, and incidence of, IPD compared to non-Indigenous people.
- Certain underlying medical conditions, including those causing immunocompromise, as well as some behavioural factors, like tobacco smoking and excessive alcohol consumption, are associated with an increased risk of IPD.

### Who should be vaccinated?

- Recommendations for the use of pneumococcal vaccines are based on the different characteristics of the available vaccines and the different risks of IPD depending on age, Indigenous status, the state/territory of residence, the presence and nature of individual risk factors, and previous doses of pneumococcal vaccine received.
- Routine pneumococcal vaccination is recommended and funded for all Australian children. Key changes to the vaccination schedule for children using 13vPCV come in to effect on 1 July 2018.
- Pneumococcal vaccines are also available for Aboriginal and Torres Strait Islander adults aged ≥50 years, non-Indigenous adults aged ≥65 years and individuals with condition(s) associated with increased risk of IPD.

### Vaccines

- There are two major types of pneumococcal vaccines – pneumococcal conjugate vaccine (PCV) and pneumococcal polysaccharide vaccine (PPV). Vaccine formulations vary in their 'valency', i.e. the number of pneumococcal serotypes included in the vaccine.
- The vaccines currently used in the National Immunisation Program (NIP) are 13-valent pneumococcal conjugate vaccine (13vPCV) and 23-valent pneumococcal polysaccharide vaccine (23vPPV). 13vPCV is highly effective (over 80–90%) against IPD due to 13vPCV serotypes in children. 23vPPV is around 80% effective against IPD due to 23vPPV serotypes in adults.
- Common adverse events reported after 13vPCV are mild and transient injection site reactions. Injection site reactions are common in adults after 23vPPV but are mostly non-serious and self-limiting.

## The disease

Pneumococcal disease refers to a range of clinical diseases caused by the bacterium *Streptococcus pneumoniae* (pneumococcus).

### Causative agent

There are over 95 serotypes of pneumococci, each with immunologically distinct polysaccharide capsules.<sup>1-3</sup> The natural reservoir of pneumococci is the mucosal surface of the human upper respiratory tract. Pneumococci colonise the nasopharyngeal mucosa of many individuals, especially children, without causing any symptoms or disease (known as asymptomatic nasopharyngeal carriage or colonisation). Different pneumococcal serotypes vary in their propensity to cause nasopharyngeal colonisation or disease.<sup>4,5</sup> Worldwide, only a limited number of serotypes are responsible for most cases of pneumococcal disease, although the distribution varies between countries and regions.<sup>6</sup> Pneumococcal vaccines are designed to cover the serotypes most frequently associated with severe pneumococcal disease.<sup>7</sup>

### Clinical features

Pneumococci cause a range of diseases that affect various sites in the body. Pneumococcal pneumonia, meningitis and febrile bacteraemia are associated with a high risk of morbidity and mortality. Pneumococcal otitis media, sinusitis and bronchitis are more common but have less serious manifestations. Pneumococcal disease where pneumococci are isolated from body sites that are normally sterile, such as the bloodstream or cerebrospinal, synovial or pleural fluid, are grouped together as invasive pneumococcal disease (IPD).<sup>8</sup>

### Transmission

*S. pneumoniae* carriage is critical to the spread of the bacteria between hosts<sup>9</sup> and person-to-person transmission occurs primarily from direct contact with the secretions of a carrier, particularly respiratory droplets. In most cases, after acquisition, the pneumococci are carried typically for weeks to months in the nasopharynx before being cleared by the immune system.<sup>9,10</sup>

### Diagnosis

A diagnosis of IPD is based on the isolation of the organism from these normally sterile sites by culture or a nucleic acid test such as PCR.<sup>8</sup> In the absence of a laboratory-confirmed sterile site isolate, a diagnosis of pneumococcal disease is presumptive; this may be based on testing for *S. pneumoniae* antigen in urine, isolation of *S. pneumoniae* from a non-sterile site and/or characteristic clinical or radiological features.<sup>11</sup>

### Treatment

Typical treatment for pneumococcal disease is administration of appropriate antibiotics. However, some serotypes have developed resistance to commonly used antibiotics.

### Epidemiology

Very young infants are at the greatest risk of IPD due to their immature immune systems. The risk of IPD also increases with age, particularly after the age of 60 years.<sup>5</sup> Certain other host factors are also associated with an increased risk of IPD.<sup>12</sup> These include tobacco smoking, and certain chronic medical conditions (refer to [List 1](#)). Some conditions, such as haematological malignancies and HIV/AIDS, increase the risk of IPD in adults by over 30 fold.<sup>13</sup> Aboriginal and Torres Strait Islander people have a substantially higher prevalence of risk factors for, and incidence of, IPD compared to non-Indigenous Australians, particularly among young adults.<sup>14</sup>

The incidence rate of IPD among all Australians was 6.7 per 100,000 in 2014 (1,564 cases reported). Higher rates were reported among children, especially those aged <1 year (20.8 per 100,000), and older adults, especially those aged ≥85 years (30 per 100,000).<sup>15</sup> In adults, it is estimated that pneumococci account for over one third of all community-acquired pneumonia and about half of hospitalised pneumonia (bacteraemic and non-bacteraemic).<sup>16-18</sup> In young children, bacteraemia without focus is the commonest form of IPD (approximately 70%), followed by bacteraemic pneumonia and meningitis.<sup>18</sup>

The introduction of universal pneumococcal vaccination for infants and young children in Australia in 2005 (using 7-valent pneumococcal conjugate vaccine, 7vPCV) led to a dramatic reduction in the overall incidence of IPD. The greatest decline was seen in the primary target group for vaccination of children <5 years of age.<sup>19</sup> There was also a substantial herd protection benefit from the 7vPCV childhood program, particularly a reduction in vaccine-type IPD among those not targeted for vaccination. The rate of IPD due to serotypes covered in the 7vPCV declined by 95% between 2002 and 2008 in children aged <5 years.<sup>20</sup> During the same period, the rate of 7vPCV-type IPD in adults aged ≥65 years decreased by 74%. Non-Indigenous children in Australia, in whom there was a higher proportion of IPD due to 7vPCV types in the pre-vaccine era, experienced a greater impact from 7vPCV than Aboriginal and Torres Strait Islander children.<sup>14</sup> There is also evidence that use of 7vPCV led to a reduction in hospitalisations due to pneumonia and otitis media in Australia.<sup>21,22</sup>

In Australia, gains from the 7vPCV program against IPD were partially offset by serotype replacement disease. This was predominantly due to the emergence of serotype 19A, as in some other countries.<sup>23,24</sup> With the use of 13vPCV in the NIP for children since July 2011, the incidence of IPD due to the extra six serotypes covered in the 13vPCV has declined. In particular, there has been a significant reduction in IPD due to serotype 19A across all age groups.<sup>25,26</sup>

***The rationale for the change in pneumococcal vaccination schedule for children:*** The changes to the pneumococcal vaccination schedule are being introduced to further improve disease control. In spite of the large reductions in overall pneumococcal disease in the Australian population seen following the changeover to 13vPCV, there have been cases of IPD due to vaccine serotypes reported in toddlers >12 months despite receiving the recommended three doses of 13vPCV using previously recommended 3+0 schedule (breakthrough cases). The rate of breakthrough cases has been substantially less in other countries that used schedules with a booster dose at 12 months of age in their 13vPCV programs. Additionally, the reduction in pneumococcal disease in older age groups mediated through reduction in asymptomatic carriage of pneumococcus in children was less in Australia compared to that in countries that used 13vPCV schedules with a booster.

Moving the 3rd 13vPCV dose (previously recommended at 6 months) to a booster dose at 12 months will prolong the protection of vaccinated children beyond 12 months of age. Research also shows that a 12-month booster dose leads to a greater reduction in carriage, which, in turn, results in better herd protection. Moving an existing dose

within the schedule means that children do not require an extra dose of 13vPCV.

For older adults, 23vPPV was funded nationally from 2005.<sup>27,28</sup> In the following 7 years there was a 35% decline in total IPD rates in people aged  $\geq 65$  years.<sup>29</sup> This decline is likely to be largely due to the herd impact from the 7vPCV program in children that commenced at the same time.<sup>29</sup>

## Who should be vaccinated

Recommendations regarding the use of pneumococcal vaccines are based on the different characteristics of the available vaccines and the different risks of IPD based on:

- age
- Indigenous status
- state/territory of residence
- the presence and nature of individual risk factors, including both immunocompromising and non-immunocompromising conditions
- previous dose(s) of pneumococcal vaccine(s) received

[List 1](#) provides the risk factors/ conditions associated with an increased risk of IPD. This is to help immunisation providers plan an appropriate vaccine schedule.

In Australia, for people aged **>5 years only**, recommendations for pneumococcal vaccination for those at risk of IPD differ depending on whether a person has a condition in [List 1](#) classified as Category A: Conditions associated with the *highest increased risk* of IPD or Category B: Conditions associated with an *increased risk* of IPD.

**List 1: Conditions associated with an increased risk of invasive pneumococcal disease (IPD) in children and adults, by severity of risk\*†**

<b>Category A: Conditions associated with the <i>highest increased risk of IPD</i></b>
<ul style="list-style-type: none"> <li>• functional or anatomical asplenia, including:               <ul style="list-style-type: none"> <li>• sickle cell disease or other haemoglobinopathies</li> <li>• congenital or acquired asplenia (e.g. splenectomy), splenic dysfunction</li> </ul> </li> <li>• immunocompromising conditions, including:               <ul style="list-style-type: none"> <li>• congenital or acquired immune deficiency, including symptomatic IgG subclass or isolated IgA deficiency (<i>Note: children who require monthly immunoglobulin infusion are unlikely to benefit from vaccination</i>)</li> <li>• immunosuppressive therapy (including corticosteroid therapy <math>\geq 2</math> mg/kg per day of prednisolone or equivalent for more than 1 week) or radiation therapy, where there is sufficient immune reconstitution for vaccine response to be expected</li> <li>• haematological and other malignancies</li> <li>• solid organ transplant</li> <li>• haemopoietic stem cell transplant (HSCT)</li> <li>• HIV infection (including AIDS)</li> <li>• chronic renal failure, or relapsing or persistent nephrotic syndrome</li> </ul> </li> <li>• proven or presumptive cerebrospinal fluid (CSF) leak</li> <li>• cochlear implants</li> <li>• intracranial shunts</li> </ul>
<b>Category B: Conditions associated with an <i>increased risk of IPD</i></b>
<ul style="list-style-type: none"> <li>• chronic cardiac disease               <ul style="list-style-type: none"> <li>• particularly cyanotic heart disease or cardiac failure in children</li> <li>• excluding hypertension only (in adults)</li> </ul> </li> <li>• chronic lung disease, including:               <ul style="list-style-type: none"> <li>• chronic lung disease in preterm infants</li> <li>• cystic fibrosis</li> <li>• severe asthma in adults (requiring frequent hospital visits and use of multiple medications)</li> </ul> </li> <li>• diabetes mellitus</li> <li>• Down syndrome</li> <li>• alcoholism</li> <li>• chronic liver disease</li> <li>• preterm birth at &lt;28 weeks gestation</li> <li>• tobacco smoking¶</li> </ul>

\* List adapted from [The Australian Immunisation Handbook](#).

† For individuals aged >5 years (but not for those aged ≤5 years), recommendations for pneumococcal vaccination differ between categories in this table, i.e. depending on whether the person has a condition in Category A: Conditions associated with the highest increased risk of IPD or Category B: Conditions associated with an increased risk of IPD.

¶ Tobacco smoking is not a medical condition, but is associated with an increased risk of IPD.

## Vaccination schedule for children under National Immunisation Program from 1 July 2018

### Healthy infants and young children (up to 5 years of age) – refer to [Table 1](#)

All healthy infants (i.e. children without any of the risk conditions in List 1) are recommended to receive a primary course with 2 doses of 13vPCV at 2 and 4 months of age followed by a booster dose at 12 months of age.

This schedule of 2 primary doses with a booster dose replaces the schedule with 3 primary doses with no booster recommended to these children prior to 1 July 2018 (see [Epidemiology](#) for the rationale for this change).

Aboriginal and Torres Strait Islander children in four jurisdictions where the incidence of IPD is higher than in

other jurisdictions are recommended to receive a primary course with 3 doses of 13vPCV at 2, 4 and 6 months of age, followed by a booster dose at 12 months of age (prior to 1 July 2018 the booster dose was recommended at 12–18 months of age).

### Infants and young children (up to 5 years of age) with condition(s) associated with an increased risk of IPD – refer to [Table 1](#)

Children aged ≤5 years with condition(s) associated with an increased risk of IPD, included in [List 1](#) (regardless of category), are recommended to receive a primary course with 3 doses of 13vPCV at 2, 4 and 6 months of age, followed by a 13vPCV booster dose at 12 months of age, and a 23vPPV dose at 4–5 years of age.

**Table 1: Recommendations for pneumococcal vaccinations in Australian children up to 5 years of age (modified from [The Australian Immunisation Handbook](#))**

Risk status	Vaccine for use	Jurisdiction and Indigenous status	Age of child			
			2 and 4 months*	6 months	12 months	4–5 years
Children without any risk conditions in List 1	13vPCV, as is currently used in the NIP	ACT, NSW, TAS or VIC	13vPCV	–	13vPCV	–
		NT, QLD, SA or WA NT, QLD, SA or WA: Aboriginal and Torres Strait Islander healthy children <sup>†</sup>	13vPCV	13vPCV	13vPCV	–
All children with a risk condition in List 1 <sup>‡</sup>	13vPCV	Regardless	13vPCV	13vPCV	13vPCV	23vPPV

\* The 1st dose can be given as early as 6 weeks of age; the next scheduled doses should still be given at 4 and 6 months of age.

† Healthy children refers to children without any of the risk conditions included in List 1.

‡ Regardless of risk category A or B

**Children aged >5 years to <18 years with condition(s) associated with an increased risk of IPD – refer to [Table 2](#)**

Additional dose(s) of pneumococcal vaccine(s) are recommended for children aged >5 years to <18 years with condition(s) associated with increased risk of IPD included in [List 1](#).

**Table 2: Recommendations for pneumococcal vaccination for Australian children aged >5 to <18 years\* with condition(s) associated with an increased risk of IPD (based on [The Australian Immunisation Handbook](#))**

IPD risk category	Previous 13vPCV received	Previous 23vPPV received	Recommended dose(s) of pneumococcal vaccine(s) <sup>†</sup>
With existing <b>Category A</b> conditions – Highest increased risk	Yes	Yes (at age 4–5 years)	A dose of 23vPPV 5 years after the 1st 23vPPV (at around 10 years of age) Next dose of 23vPPV 10 years later (at 18–20 years of age)
	No	Yes (at age 4–5 years)	1 dose of 13vPCV <sup>‡</sup> A dose of 23vPPV 5 years after the 1st 23vPPV (at around 10 years of age) Next dose of 23vPPV 10 years later (at 18–20 years of age)
	No	No	1 dose of 13v PCV 1st dose of 23vPPV 2 months later Next dose of 23vPPV 5 years after the 1st 23vPPV dose (at around 10 years of age for those presenting at age ~5 years) Subsequent dose of 23vPPV 10 years later (at 18–20years of age)
Newly identified <b>Category A</b> conditions – Highest increased risk	Yes	No	1st dose of 23vPPV at diagnosis Next dose of 23vPPV 5 years after the 1st 23vPPV dose Subsequent dose of 23vPPV 10 years later
	No	No	1 dose of 13v PCV at diagnosis 1st dose of 23vPPV 2 months later Next dose of 23vPPV 5 years after the 1st 23vPPV Subsequent dose of 23vPPV 10 years later
With existing <b>Category B</b> conditions – Increased risk	Regardless	Yes (at age 4–5 years)	A dose of 23vPPV 10 years after the 1st 23vPPV dose (at age of 15–18 years) (counted as 1st adult 23vPPV dose)
Newly identified <b>Category B</b> conditions – Increased risk	Regardless	Yes	A dose of 23vPPV 5 years after the 1st 23vPPV Next dose of 23vPPV 5–10 years later (counted as 1st adult 23vPPV dose)
		No	1st dose of 23vPPV at diagnosis Next dose of 23vPPV 5–10 years later (counted as 1st adult 23vPPV dose)

\* See also *Vaccination of people who are immunocompromised* in [The Australian Immunisation Handbook](#) for more recommendations for immunocompromised people, including more specific revaccination recommendations for haematopoietic stem cell transplant (HSCT) recipients.

† HSCT recipients require 3 doses of 13vPCV post transplantation, followed by 23vPPV, irrespective of previous vaccine doses received.

‡ The minimum interval between a previous 23vPPV dose and the single 13vPCV dose, if required, is 12 months.

**Adults with condition(s) associated with an increased risk of IPD– refer to [Table 3](#)**

All adults (Aboriginal and Torres Strait Islander and non-Indigenous) aged  $\geq 18$  years who have specified at-risk conditions for IPD are recommended to receive up to 3 lifetime doses of 23vPPV. The 2nd 23vPPV dose is recommended at approximately 5–10 years (minimum 5 years) after the first 23vPPV dose. For Aboriginal and Torres Strait Islander adults, a 3rd dose of 23vPPV is

recommended at age 50 years or at least 5 years after the 2nd dose (whichever is later). For non-Indigenous adults, the 3rd dose of 23vPPV is recommended at age 65 years or at least 5 years after the 2nd dose (whichever is later). For patients with a Category A condition, which renders them at the highest risk of IPD, a single dose of 13vPCV is recommended if they have never received any dose of 13vPCV previously (refer to [Table 3](#), including footnotes).

**Table 3: Recommendations for pneumococcal vaccination in Australian adults (based on [The Australian Immunisation Handbook](#))**

Risk category	Indigenous status	Age	Recommended dose(s) of 13vPCV	Recommended dose(s) of 23vPPV*
Without any risk conditions	Non-Indigenous	$\geq 65$ years	–	Single dose
	Indigenous	$\geq 50$ years	–	Initial dose, then one repeat (2nd) dose 5 years later
Category A conditions <sup>†</sup>	Non-Indigenous	18–64 years	Single dose <sup>‡</sup>	Initial dose, then one repeat (2nd) dose 5–10 years later, then one more repeat dose at age 65 years <sup>§</sup>
		$\geq 65$ years	Single dose <sup>‡</sup>	Initial dose, then one repeat (2nd) dose 5 years later, then one more repeat dose 5 years after the 2nd dose
	Indigenous	18–49 years	Single dose <sup>‡</sup>	Initial dose, then one repeat (2nd) dose 5–10 years later, then one more repeat dose at age 50 years <sup>§</sup>
		$\geq 50$ years	Single dose <sup>‡</sup>	Initial dose, then one repeat (2nd) dose 5 years later, then one more repeat dose at age 65 years <sup>§</sup>
Category B conditions	Non-Indigenous	18–64 years	–	Initial dose, then one repeat (2nd) dose 5–10 years later, then one more repeat dose at age 65 years <sup>§</sup>
		$\geq 65$ years	–	Initial dose, then one repeat (2nd) dose 5 years later <sup>¶</sup>
	Indigenous	18–49 years	–	Initial dose, then one repeat (2nd) dose 5–10 years later, then one more repeat dose at age 50 years <sup>§</sup>
		$\geq 50$ years	–	Initial dose, then one repeat (2nd) dose 5 years later

\* The minimum interval between any 2 doses of 23vPPV should be 5 years, and no more than 3 lifetime adult doses of 23vPPV are recommended. For adults, prior childhood doses of 23vPPV that may have been given at either 18–24 months and/or 4–5 years of age should not be counted.

† HSCT recipients require 3 doses of 13vPCV post transplantation, followed by 23vPPV, irrespective of previous vaccine doses received (refer also *Vaccination of people who are immunocompromised* in [The Australian Immunisation Handbook](#) for more recommendations for immunocompromised people, including more specific revaccination recommendations for haematopoietic stem cell transplant (HSCT) recipients.

‡ For patients with a Category A condition, a single dose of 13vPCV is recommended if they have never received any 13vPCV dose previously. This dose should precede the 1st dose of the recommended 23vPPV vaccine by 2 months. For those who have had prior 23vPPV dose, this 13vPCV dose should be given at least 12 months after the most recent dose of 23vPPV.

§ This 3rd dose should be given at the specified age or 5 years after the 2nd dose, whichever is later.

¶ Those whose Category B condition is diagnosed after receiving their recommended dose of 23vPPV at age 65 years should receive one single revaccination (2nd) dose at diagnosis or 5 years after the previous dose, whichever is later.

### **Older adults without condition(s) associated with an increased risk of IPD– refer to [Table 4](#)**

For non-Indigenous adults aged 65 years who do not have any condition(s) associated with an increased risk of IPD, a single dose of 23vPPV is recommended. A 2nd or subsequent 23vPPV dose is no longer recommended (since December 2011) for non-Indigenous adults other than for individuals who have specified conditions predisposing them to an increased risk of IPD (refer above). For Aboriginal and Torres Strait Islander adults aged 50 years, a dose of 23vPPV is recommended, followed by a 2nd dose 5 years after the 1st dose.

### **Catch-up**

Regardless of whether 7vPCV, 10vPCV or 13vPCV was used for the primary course, 13vPCV is the pneumococcal conjugate vaccine formulation used for further catch-up doses if required. The schedules for catch-up doses of 13vPCV in children have also been updated to align with the changes that come into effect on 1 July 2018. Catch-up schedules for pneumococcal vaccinations, which may also include 23vPPV, are complex and depend on a person's age at presentation; demographic and medical risk factors; and vaccination history. Further advice regarding catch-up schedules is available in [The Australian Immunisation Handbook](#).

### **Vaccines**

There are two major types of pneumococcal vaccines – pneumococcal conjugate vaccine (PCV) and pneumococcal polysaccharide vaccine (PPV). Among the pneumococcal conjugate vaccines, formulations vary in their 'valency', that is, the number of pneumococcal serotypes included (refer to [Table 4](#)) and the conjugating proteins used. Serotypes covered in 7vPCV are common to the newer-generation conjugate vaccines with extended valency (e.g. 10vPCV, 13vPCV), and also to the 23vPPV.

Pneumococcal conjugate vaccines are immunogenic in young infants and can induce an immune memory response. In contrast, 23vPPV is poorly immunogenic in children aged <2 years for most serotypes and does not induce immune memory.

The two pneumococcal vaccines available in Australia and currently used on the NIP are:

- Pneumovax 23<sup>®</sup> (Seqirus/Merck) – 23-valent pneumococcal polysaccharide vaccine (23vPPV)
- Prevenar 13<sup>®</sup> (Pfizer) – 13-valent pneumococcal conjugate vaccine (13vPCV)

### **Contraindications**

The only absolute contraindications to pneumococcal vaccines are:

- anaphylaxis following a previous dose of any pneumococcal vaccine
- anaphylaxis following any vaccine component.

### **Precautions**

#### **Pregnancy and breastfeeding**

Pneumococcal vaccine is not routinely recommended for pregnant or breastfeeding women. Women of child-bearing age who have conditions associated with increased risks of IPD should be vaccinated before a planned pregnancy, or as soon as practicable after delivery.

#### **Concurrent administration with other vaccines**

A study in the United States suggested a slightly higher risk of febrile seizure associated with concurrent administration of 13vPCV and inactivated trivalent influenza vaccine than after receipt of either of the vaccines alone on separate days.<sup>30</sup> Because the increase in risk is relatively low, and a more recent study did not demonstrate the same association between febrile seizures and the concurrent administration of these two vaccines,<sup>31</sup> 13vPCV and inactivated influenza vaccine may be given concurrently to children aged 12–23 months. However, immunisation service providers should advise parents regarding the risk and provide the option of administering these two vaccines on separate days (with an interval of not less than 3 days). In adults, Zostavax<sup>®</sup>, the vaccine to prevent herpes zoster, can be given at the same time as 23vPPV, using separate injection sites and syringes (refer also to the NCIRS fact sheet on [Zoster vaccine for Australian adults](#)<sup>d</sup>).

#### **Vaccine efficacy and effectiveness**

A pivotal trial among children in the United States showed that the protective efficacy of 7vPCV against IPD caused by the serotypes contained in the vaccine was >95%.<sup>32</sup> Registration of 13vPCV was based on immunogenicity studies showing non-inferiority against 7vPCV for the common serotypes and comparable antibody response to the additional serotypes.<sup>33,34</sup> Among Australian infants, the effectiveness of both 7vPCV and 13vPCV was around 90%.<sup>35</sup> Effectiveness of 13vPCV was particularly high against IPD caused by serotype 19A.



A large study in the Netherlands showed that 13vPCV had a 46% efficacy against community-acquired pneumonia due to vaccine serotypes, in people aged  $\geq 65$  years who had not previously received any pneumococcal vaccine.<sup>36</sup> In the same study, the efficacy against IPD due to vaccine serotypes was 75%.

The efficacy of 23vPPV against IPD in adults was approximately 80% in randomised controlled trials (RCT).<sup>37-39</sup> Effectiveness of 23vPPV against IPD among non-Indigenous Australian adults was 61%.<sup>29</sup> The protective effect of 23vPPV against pneumonia in adults is less certain; efficacy estimates based on RCTs have been statistically non-significant. Some observational studies have reported the effectiveness of 23vPPV against pneumonia hospitalisations in adults to be about 20%.<sup>40,41</sup>

### Vaccine safety

In a pivotal head-to-head trial in young children, 13vPCV had an overall safety profile comparable to that of

7vPCV.<sup>33</sup> The common adverse events reported after 13vPCV were mild and transient injection site reactions, including tenderness (around 75%), swelling (around 30%) and redness (around 45%). The proportion of infants who had fever of  $>39^{\circ}\text{C}$  to  $\leq 40^{\circ}\text{C}$  was approximately 3% after the 1st dose and 8% after the 3rd dose. No incidents of high fever ( $>40^{\circ}\text{C}$ ) were reported. Irritability was the most commonly reported systemic event (approximately 90%).

The proportion of 23vPPV recipients reporting local and systemic reactions after a primary or repeat dose varies among different study populations. Among US adults aged 60–64 years, local injection site reactions were reported by 60–70% of participants after a 1st dose of 23vPPV.<sup>42,43</sup> Generally, injection site reactions were common after a repeat dose of 23vPPV in adults.<sup>44</sup> Overall, injection site reactions are mostly non-serious and self-limiting.

**Table 4: Serotypes contained in pneumococcal vaccines currently available in Australia, their registered age for use, and the population and age group covered by the National Immunisation Program (NIP)**

Vaccine	Serotypes common to these vaccines*	Additional serotypes	Age group registered for use	Population and age group covered by the NIP
Prevenar 13 <sup>®</sup> 13vPCV 13-valent conjugate vaccine (Pfizer)		1, 5, 7F, 3, 19A, 6A	$\geq 6$ weeks	All infants
Pneumovax 23 <sup>®</sup> 23vPPV 23-valent polysaccharide vaccine (Seqirus/Merck)	4, 6B, 9V, 14, 18C, 19F, 23F	1, 5, 7F, 3, 19A, 2, 8, 9N, 10A, 11A, 12F, 15B, 17F, 20, 22F, 33F	$\geq 2$ years	<ul style="list-style-type: none"> <li>All non-Indigenous adults aged <math>\geq 65</math> years</li> <li>All Indigenous adults aged <math>\geq 50</math> years</li> <li>Indigenous adults aged 18–49 years with conditions associated with increased risk of IPD</li> </ul>

### Additional resources for primary medical care/vaccination providers

- Immunise Australia website [www.immunise.health.gov.au](http://www.immunise.health.gov.au)
- National Immunisation Program schedule [www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/national-immunisation-program-schedule](http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/national-immunisation-program-schedule)
- [Clinical update: National Immunisation Program \(NIP\) Childhood Schedule Changes from 1 July 2018](#)

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