FactSheet

Pneumococcal vaccines

NATIONAL CENTRE FOR IMMUNISATION RESEARCH & SURVEILLANCE

FREQUENTLY ASKED QUESTIONS

This fact sheet provides responses to common questions about pneumococcal vaccines. More detailed information about pneumococcal disease and the available pneumococcal vaccines can be found in the NCIRS fact sheet Pneumococcal vaccines for Australians: information for immunisation providers.

Questions about pneumococcal vaccines and vaccine schedules

Questions about pneumococcal disease

Questions about pneumococcal vaccines and vaccine schedules

Q1. What changes have been introduced to pneumococcal vaccination schedule from 1 July 2018?

From 1 July 2018, the three doses of the pneumococcal vaccine (Prevenar 13®, 13-valent pneumococcal conjugate [13vPCV]), used in the National Immunisation Program (NIP) for children, are given at the ages of 2, 4 and 12 months

instead of at ages 2, 4 and 6 months. This means the 13vPCV dose given at 6 months of age is to be given at 12 months of age. As a result, the previous schedule that consisted of three primary doses only (3+0 schedule) is replaced by a schedule with two primary doses and one booster dose (2+1 schedule). The total number of doses given to these children remains unchanged. Refer to Q2 below regarding identifying children eligible for the new 2+1 schedule.

Children with increased risk of pneumococcal disease who were previously given four doses of 13vPCV continue to receive a 4-dose schedule: 3 primary doses at ages 2, 4 and 6 months and a booster (fourth) dose at age 12 months (3+1 schedule). This includes all children with specific underlying at-risk conditions described in the *Australian Immunisation Handbook* (refer to List 1) and all Aboriginal and Torres Strait Islander children living in the Northern Territory, Queensland, South Australia and Western Australia. The booster dose of 13vPCV in the 3+1 schedule is to be given at 12 months of age for these children, instead of between 12 and 18 months of age. Table 1 summarises the 13vPCV vaccination schedule from 1 July 2018. Also see Table 1 in the NCIRS fact sheet on pneumococcal vaccines.

Table 1: Comparison of the current (following the 1 July 2018 changes) and previous recommendations for the childhood pneumococcal vaccination schedule using 13vPCV

Target group		Previous recommendation	Current recommendation (from 1 July 2018)	Schedule change
Children without underlying medical conditions associated with increased risk of IPD	All children in ACT, NSW, TAS or VIC	3+0 (2, 4 and 6 months)	2+1 (2, 4 and 12 months)	3rd primary dose moved to 12 months to become a booster dose
	Non-Indigenous children in NT, QLD, SA or WA			
	Aboriginal and Torres Strait Islander children in NT, QLD, SA or WA	3+1 (2, 4, 6 and 12–18 months)	3+1 (2, 4, 6 and 12 months)	Booster dose to be given at 12 months instead of 12-18 months
All children with underlying medical conditions associated with increased risk of IPD*		3+1 (2, 4, 6 and 12 months)	3+1 (2, 4, 6 and 12 months)	No change

* Refer to List 1 in NCIRS fact sheet on pneumococcal vaccines for these conditions.

These changes to the pneumococcal vaccination schedule coincide with a number of other changes to the childhood immunisation schedule from 1 July 2018 under the NIP. For additional information regarding all changes to the NIP and all childhood and adult NIP immunisations, refer to *Immunise Australia* or NCIRS provider resources.

Q2. How do you identify the children to whom the pneumococcal vaccine schedule changes apply?

For all non-Indigenous and Aboriginal and Torres Strait Islander children living in the Australian Capital Territory, New South Wales, Tasmania and Victoria who do not have conditions that increase their risk of pneumococcal disease, the new schedule from 1 July 2018 is determined by their birth date.

- Children born after 1 January 2018 (reaching the age of 6 months on or after 1 July 2018) will receive two primary doses of 13vPCV at 2 and 4 months of age followed by one booster dose at 12 months of age. (i.e. these children will receive the new 2+1 schedule).
- Children born between 1 July 2017 and 31 December 2017, who have already received a third dose of 13vPCV at 6 months of age (reaching 12 months of age on or after 1 July 2018) will get three primary doses plus the booster. If for some reason their third dose was delayed, their booster dose should be given at least 2 months after their third dose.
- Children older than 12 months on 1 July 2018 who have received three doses of 13vPCV do not require any further doses and cannot receive further doses of 13vPCV for free under the NIP.

All children with increased risk of pneumococcal disease will continue to receive three doses of 13vPCV at 2, 4 and 6 months followed by a booster at 12 months of age (see also Q1).

Schedules for catch-up doses of 13vPCV for children who have not received any pneumococcal conjugate vaccine (PCV) doses or who have only received incomplete courses of PCVs according to their age at presentation are covered

in relevant tables in the *Australian Immunisation Handbook*. These catch up schedules have been updated to align with the changes introduced on 1 July 2018.

Q3. Why has the childhood pneumococcal vaccination schedule changed?

Changes to the pneumococcal vaccination schedule have been introduced to further improve disease control. The 13vPCV vaccination program that commenced in 2011 has been highly effective in reducing overall pneumococcal disease in vaccinated children and others (through herd immunity). However, cases of invasive pneumococcal disease (IPD), caused by pneumococcal serotypes (i.e. subtypes) covered by the vaccine, have been reported in toddlers older than 12 months who have received three doses of 13vPCV using the previous 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 vaccination programs. Additionally, the reduction in pneumococcal disease in older age groups, mediated through reduction in asymptomatic carriage of pneumococcus in children, has been less in Australia compared to countries that used 13vPCV schedules with a booster. Moving the third 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 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.

Q4. What is the current pneumococcal vaccine schedule for adults?

The number and type of pneumococcal vaccines given to adults are based on age, Aboriginal and Torres Strait Islander status and the presence of conditions associated with increased risk of pneumococcal disease. Refer to Q6 for specific pneumococcal vaccination recommendations for people with underlying medical conditions.

A single dose of 23vPPV is recommended for all healthy non-Indigenous adults at 65 years of age. Non-Indigenous adults aged >65 years who did not receive a dose at 65 years of age are recommended to receive a single catch-up dose as soon as possible. Aboriginal and Torres Strait Islander people with no underlying medical conditions are recommeded to receive a dose of 23vPPV at the age of 50 years and a second dose 5 years later. These vaccines are available under the NIP. Non-Indigenous adults do not need repeat doses of 23vPPV unless they have underlying medical conditions (see Table 3 in NCIRS fact sheet on pneumococcal vaccines).

Q5. Are repeat doses of 23vPPV given to older adults?

One repeat dose of 23vPPV is recommended for older Aboriginal and Torres Strait Islander people aged ≥ 50 years and for all older adults with underlying Category B risk conditions (refer to List 1 in NCIRS fact sheet on pneumococcal vaccinations for these risk conditions). A further (third) dose of 23vPPV is recommended for older adults only if they have underlying Category A risk conditions (refer to Table 3 in NCIRS fact sheet on pneumococcal vaccines).

Q6. What are pneumococcal vaccination recommendations for people with underlying medical conditions?

Recommendations for vaccination of people with underlying medical conditions are based on their age, Aboriginal and Torres Strait Islander status and the level of risk of IPD. These conditions are grouped into two subsets according to the level of risk of IPD: Category A, which includes the conditions that have the highest risk, and Category B, which includes all other at-risk conditions (see List 1 in NCIRS fact sheet on pneumococcal vaccinations). Pneumococcal vaccination recommendations for people with these risk factors are complex. Refer to Tables 2 and 3 in the NCIRS fact sheet on pneumococcal vaccinations for schedules.

Q7. Are there specific pneumococcal vaccine recommendations for haematopoietic stem cell transplant recipients?

Yes, individuals who undergo haematopoietic stem cell transplantation are at particularly high risk of infectious diseases, including those caused by encapsulated bacteria such as pneumococcus. Their protective immunity against vaccine-preventable diseases is completely or partially lost following transplantation. Therefore, three doses of 13vPCV followed by one dose of 23vPPV are recommended post transplantation to these individuals regardless of previous vaccination history and age. The three 13vPCV doses should be given at 6, 8 and 12 months after transplantation. The dose of 23vPPV should be given 24 months after transplantation. This schedule should be followed regardless of

transplant type (allogeneic or autologous), donor source (peripheral blood, bone marrow or umbilical cord) or preparative chemotherapy (ablative or reduced intensity).

Q8. What is the recommended interval between 13vPCV and 23vPPV doses?

The recommended interval between doses of 13vPCV and 23vPPV varies depending on which of the two vaccines has been received first. When 23vPPV is given after 13vPCV, as in individuals with newly diagnosed Category A risk conditions, the recommended interval between the doses is 2 months. When 13vPCV is given after 23vPPV as would occur in individuals with pre-existing Category A risk conditions who have had previous doses of 23vPPV, the recommended interval is at least 12 months between the 13vPCV dose and the most recent 23vPPV dose. If a repeat dose of 23vPPV is to be given, it needs to be at least 2 months after the 13vPCV dose and 5 years after the previous 23vPPV dose.

Q9. Is 13vPCV available to adults under the NIP?

At present 13vPCV is not offered to adults under the NIP. However, it is registered for use in Australia for people aged ≥6 weeks. Australian Technical Advisory Group on Immunisation (ATAGI) recommends 13vPCV for adults with the highest risk of pneumococcal disease (i.e. those adults with conditions labeled Category A in the list of at-risk conditions, see List 1 in NCIRS factsheet on pneumococcal vaccinations). A large randomised placebo controlled trial (Community-Acquired Pneumonia Immunization Trial in Adults, CAPITA) that explored the efficacy of 13vPCV in adults aged ≥65 years in the Netherlands who had not received any other pneumococcal vaccine previously found that adults who received 13vPCV were protected against IPD as well as non-invasive pneumonia caused by serotypes covered in the vaccine.[1]

Q10. Is it safe to give 13vPCV and influenza vaccines at the same visit?

The current recommendation is that it is safe to give 13vPCV and inactivated influenza vaccine at the same visit when both vaccines are indicated. However, there is one study in the USA that reported a slightly higher risk of fever and febrile convulsions in children aged 6 months to 5 years who received the two vaccines concurrently compared to those who received the vaccines at separate visits.[2] This risk was about 18 more cases per 100,000 doses in children in that age group. The risk was highest in the 12–24-month age group and lowest for those aged around 5 years. Overall this risk is still small, and a more recent study did not show a similar increase of febrile convulsions when the two vaccines were given together.[3] It is recommended that immunisation providers advise parents of this possible risk and offer the option of giving the two vaccines on separate days (at least 3 days apart).

Q11. Can 23vPPV and Zostavax be given at the same visit?

Zostavax®, the vaccine to prevent herpes zoster (shingles) in adults, can be given at the same time as 23vPPV or 13vPCV using separate injection sites and syringes. A large observational study from the USA did not find evidence of any impact on the protective efficacy of Zostavax® against shingles when it was co-administered with 23vPPV.[4] Refer also to the NCIRS fact sheet on Zoster vaccine for Australian adults.

Q12. Are there any contraindications to pneumococcal vaccines?

Pneumococcal vaccines are only contraindicated for anyone who has previously had anaphylaxis to the respective vaccine or its components.

Pregnant women should not routinely receive pneumococcal vaccines. However, inadvertant administration during pregnancy is unlikely to result in serious adverse effects. Vaccination may also be considered for pregnant women who are at high risk of IPD who were not vaccinated before pregnancy.

Q13. Which pneumococcal vaccines are available in Australia and what are the key differences between them?

There are two pneumococcal vaccines available in Australia to provide protection against *Streptococcus pneumoniae* (*S. pneumoniae*) in humans:

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

These are two different types of vaccines – a sugar-based (polysaccharide) vaccine (23vPPV) and polysaccharide linked to a protein carrier (conjugate) vaccine (13vPCV).[5] 23vPPV generates protective antibodies against pneumococcal disease without involving T-cells that are required for long-term immune memory. Immunity triggered by 23vPPV is relatively short lived and the vaccine is less immunogenic in children less than 2 years of age. 13vPCV generates a higher-quality immune response resulting in adequate protection in young children and longer-term immune memory.

23vPPV and 13vPCV contain 12 serotypes in common.[6] Table 2 summarises details regarding these two vaccines.

Table 2: Serotypes contained in pneumococcal vaccines currently available in Australia, their registered age for use, and the population and age group covered by the NIP

Vaccine	Serotypes common to these vaccines	Additional serotypes	Age group registered for use	Population and age group covered by the NIP
Prevenar 13® (Pfizer) 13-valent PCV	1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F	6A	≥6 weeks	All infants
Pneumovax 23® (Seqirus/Merck) 23-valent PPV		2, 8, 9N, 10A, 11A, 12F, 15B, 17F, 20, 22F, 33F	≥2 years	• All non-Indigenous adults aged ≥65 years • All Aboriginal and Torres Strait Islander adults aged ≥50 years • Aboriginal and Torres Strait Islander adults aged 18–49 years with conditions associated with increased risk of IPD

Q14. Are pneumococcal vaccines safe?

Pneumococcal vaccines are safe and well tolerated. Mild reactions at the injection site may occur in young children. These include pain/tenderness and redness, occurring in around 50% of 13vPCV recipients, and induration or swelling in about 33%.[7,8]

The frequency of local and systemic reactions after a primary or repeat dose of 23vPPV varies among different populations.[9-11] Approximately 50% of 23vPPV adult recipients will experience some soreness and around 20% will experience swelling and redness after a primary dose.[11] Systematic reactions reported after 23vPPV in adults include mylagia, fatigue and chills. Fever ≥37.5°C can occur in up to 10% 23vPPV recipients, but high fever is rare.[11]

Questions about pneumococcal disease

Q15. What is pneumococcal disease? How serious is it?

Pneumococcal disease refers to a range of clinical diseases caused by the bacterium *S. pneumonia*. In most cases, acquisition of the bacterium will lead to stable asymptomatic colonisation (carriage) or clearance of the organism by the host's immune system; however, progression to disease may also result. Serious disease conditions arise when *S. pneumoniae* invades the bloodstream and spreads to other parts of the body that are normally sterile such as blood, cerebrospinal fluid and pleural fluid, causing IPD. Clinical presentations of IPD include severe and potentially fatal conditions such as meningitis, pneumonia and septicaemia.[12-14] Localised mucosal infections of *S. pneumoniae* in the body are generally less serious and include infections such as those of the middle ear (otitis media), sinuses (sinusitis) and bronchi (bronchitis).

Pneumococcal disease contributes to a substantial amount of global morbidity and mortality, and is of significant public health concern. The use of pneumococcal vaccines in the last few decades has led to marked reductions in pneumococcal disease in Australia. However, IPD continues to occur in Australia, mostly affecting young children, older adults and those with underlying medical conditions. In 2016 there were 1,655 cases of IPD reported. Around 15% of IPD notifications are in Aboriginal and Torres Strait Islander people. The rate of IPD is around 16 per 100,000 in children aged <2 years and 20 per 100,000 in adults aged ≥65 years.[15]

Q16. How is pneumococcal disease transmitted?

Typically, *S. pneumoniae* will colonise the upper respiratory tract, sinus or nasopharynx of humans. Nasopharyngeal colonisation is most common in infancy and most people will be colonised by *S. pneumoniae* at least once during their lifetime. Approximately 40–95% of infants and 1–10% of adults are colonised at any time.[16] Carriage of the bacterium occurs after colonisation until the host's immune system is able to clear the organism. Carriage represents the main reservoir for person-to-person transmission of *S. pneumonia*, as transmission of pneumococci occurs via the respiratory droplets of a carrier (e.g. due to coughing or sneezing).[13]

Additional resources for primary medical care/vaccination providers

- NCIRS pneumococcal vaccines for Australians fact sheet
- Immunise Australia website
- National Immunisation Program schedule

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