

**Australian Technical Advisory Group on Immunisation**

**Public consultation on changes to the recommended use of pneumococcal vaccines**

The Australian Technical Advisory Group on Immunisation (ATAGI) is consulting with stakeholders on proposed changes to the pneumococcal vaccination recommendations for inclusion in *The Australian Immunisation Handbook*, with an intention to submit the recommendations to the National Health and Medical Research Council (NHMRC) for its approval under section 14A of the *National Health and Medical Research Council Act 1992.*

This draft includes new recommendations and the rationale for the proposed changes. You are invited to make a submission on the draft recommendations by 1 March 2020. In particular, ATAGI is seeking comments on the following:

* Are there additional potential benefits, harms or unintended consequences which could arise from the proposed changes to the use of pneumococcal vaccines, not already outlined, and how likely are they to occur?
* Are there additional clinical or implementation considerations which need to be outlined?

Should you require additional information please contact ATAGI Secretariat on atagi.secretariat@health.gov.au.

Changes to the recommended use of pneumococcal vaccines

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# Plain-language summary

Pneumococcal disease is a very serious bacterial infection. It can cause:

infection of the lungs (pneumonia)

infection of the middle ear (otitis media)

swelling and infection of the brain (meningitis)

infection of the blood (septicaemia)

coma

death

Invasive pneumococcal disease (IPD) is when the bacteria are found in the blood, spinal fluid or another part of the body that would normally be sterile. IPD mainly affects:

young children

older people

Aboriginal and Torres Strait Islander people

people with certain long-term diseases

people with weakened immune systems

Vaccination is the best protection against pneumococcal disease. There are 2 types of pneumococcal vaccine, called 13vPCV and 23vPPV.

The recommendations for pneumococcal vaccines are changing. This will make pneumococcal vaccines more readily available and give extra protection to people who are most at risk of disease. The changes will also make it easier to understand:

who should get pneumococcal vaccines

which vaccine they should get

when they should get it

There are no changes to the routine infant schedule. All children are recommended to receive 3 doses of 13vPCV at ages 2, 4 and 12 months.

Broadly, the new recommendations are:

* Anyone with an increased risk of pneumococcal disease is recommended to receive 1 extra dose of 13vPCV and 2 doses of 23vPPV. This includes:
* people with certain risk conditions at any age

Aboriginal and Torres Strait Islander people aged ≥50 years.

Aboriginal and Torres Strait Islander children in certain states and territories are already recommended to receive an extra dose of 13vPCV. They should also receive 2 doses of 23vPPV.

* Otherwise healthy people of all ages with no risk factors for pneumococcal disease are no longer recommended to receive 23vPPV. Infants should receive 3 doses of 13vPCV in the routine schedule, and older Australians a single dose of 13vPCV at age ≥70 years.

# Summary of revised recommendations

People with medical risk factors

* Children diagnosed with certain risk conditions at ≤12 months of age are recommended to receive 4 doses of 13vPCV and 2 doses of 23vPPV
* Children and adolescents aged >12 months to <18 years with newly identified risk conditions are recommended to receive 1 dose of 13vPCV and 2 doses of 23vPPV
* Adults of any age ≥18 years with newly identified risk conditions are recommended to receive 1 dose of 13vPCV and 2 doses of 23vPPV

Aboriginal and Torres Strait Islander people

* Aboriginal and Torres Strait Islander children aged ≤5 years living in certain states and territories are recommended to receive 4 doses of 13vPCV and 2 doses of 23vPPV
* Aboriginal and Torres Strait Islander adults aged ≥50 years without conditions associated with an increased risk of pneumococcal disease are recommended to receive 1 dose of 13vPCV and 2 doses of 23vPPV

Healthy non-Indigenous adults

* Non-Indigenous adults aged ≥70 years without conditions associated with an increased risk of pneumococcal disease are recommended to receive 1 dose of 13vPCV

Figure 1 also shows a summary of the revised recommendations.

Figure 1 Summary of revised recommendations for pneumococcal vaccination



# Background

The Australian Technical Advisory Group on Immunisation (ATAGI) advises the Australian Government on clinical recommendations for vaccinations. ATAGI is proposing changes to the recommendations for the use of pneumococcal vaccines.

The proposed changes reflect the current best clinical practice to prevent pneumococcal disease in adults and in people with conditions that increase their risk of disease. The revised recommendations will be published online in the [Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/).

In general, invasive pneumococcal disease (IPD) incidence is highest in very young people and older people. Pneumococcal disease surveillance shows there is a high disease burden in certain populations in Australia. Aboriginal and Torres Strait Islander people, and people with certain medical or lifestyle conditions continue to be at greatest risk of IPD.

2 vaccines are used to prevent pneumococcal disease:

13-valent pneumococcal conjugate vaccine (13vPCV), which protects against serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F

23-valent pneumococcal polysaccharide vaccine (23vPPV), which protects against serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F

Pneumococcal vaccination is recommended as part of the routine infant and adult schedules. It is also recommended for specific populations with an increased risk of pneumococcal disease.

# Rationale

ATAGI has proposed new recommendations for people with an increased risk of pneumococcal disease to:

optimise protection against the disease

simplify vaccination advice

ensure equitable access for those most at risk of disease

The current recommendations for people with an increased risk of pneumococcal disease are complex, and vary depending on:

the person’s age

whether they have a risk condition and when the condition was diagnosed

their Aboriginal and Torres Strait Islander status

their vaccination history

The changes to the recommended vaccines and the list of risk conditions will help to simplify this advice.

Note there are no proposed changes to the routine infant schedule. All children are recommended to receive 3 doses of 13vPCV at ages 2, 4 and 12 months.

## Children and adults with risk conditions

Pneumococcal disease incidence is higher in children and adults with risk conditions than in healthy children and adults.

A range of medical and behavioural conditions can increase the risk of IPD. ATAGI has reviewed the evidence and revised the list of conditions to ensure that people with the highest risk of disease are protected through vaccination.

The burden of IPD caused by serotypes that are included in 23vPPV but not included in 13vPCV (known as 23v-non-13v serotypes) is higher in non-Indigenous adults with risk conditions than those without risk conditions. To address this issue, ATAGI is recommending that people with specific risk conditions receive both 13vPCV and 23vPPV to maximise protection against disease.

## Aboriginal and Torres Strait Islander people

Compared with non-Indigenous adults, in Aboriginal and Torres Strait Islander adults:

IPD incidence starts to increase at a younger age

the prevalence of risk conditions for pneumococcal disease is higher at younger ages

the burden of IPD caused by 23v-non-13v serotypes is higher

To address these issues, ATAGI is recommending that all Aboriginal and Torres Strait Islander adults continue to receive pneumococcal vaccines from age 50, and that they receive both 13vPCV and 23vPPV to maximise protection against the serotypes that commonly cause disease in this group.

Aboriginal and Torres Strait Islander adults <50 years with risk conditions should receive pneumococcal vaccines according to the recommendations for people with risk conditions. Aboriginal and Torres Strait Islander adults <50 years without risk conditions do not need additional pneumococcal vaccines.

Aboriginal and Torres Strait Islander children aged ≤5 years living in certain states and territories (Queensland, Western Australia, South Australia and the Northern Territory) already receive 4 doses of 13vPCV as part of their routine schedule (at 2, 4, 6 and 12 months). ATAGI is also recommending 2 doses of 23vPPV in addition to these 4 doses of 13vPCV.

## Older adults without conditions associated with an increased risk of pneumococcal disease

In older adults, community-acquired pneumonia (CAP) is the most common form of pneumococcal disease. The current pneumococcal vaccination program for older adults uses 23vPPV, but 23vPPV is expected to have limited benefit against non-invasive pneumococcal CAP.

A large randomised controlled trial in adults aged ≥65 years in the Netherlands (the CAPiTA trial) showed that a dose of 13vPCV was effective against invasive as well as non-invasive pneumococcal CAP caused by vaccine serotypes. Informed by this evidence, ATAGI proposes that the dose of 23vPPV currently given to all non-Indigenous adults at age ≥65 years is replaced with a dose of 13vPCV.

This dose will also be moved to age ≥70 because pneumococcal disease is much more common in people over 70 years of age than in people aged 65–69 years. The incidence rate of IPD caused by 13vPCV serotypes in adults from 70 years of age is about 2-fold higher than that in people aged 65–69 years (unpublished estimates from National Notifiable Diseases Surveillance System notification data). Because the effectiveness of pneumococcal vaccines reduces over time, moving this dose to age 70 years will ensure protection as people move into older age groups with increasing IPD risk.

23vPPV includes 11 extra serotypes that are not included in 13vPCV. In healthy non-Indigenous older adults, the incidence of IPD caused by 23v-non-13v serotypes is too low to support the continued use of 23vPPV following 13vPCV in this group.

# New recommendations for people with risk conditions

## New list of risk conditions

The following list of conditions associated with an increased risk of invasive pneumococcal disease applies to all recommendations that are based on these risk factors.

List. Risk conditions for invasive pneumococcal disease

Children and adults with these risk conditions may be at increased risk of pneumococcal disease and may benefit from additional doses of pneumococcal vaccine.

Many children and adults with these risk conditions are eligible for funded doses of 13vPCV (13‑valent pneumococcal conjugate vaccine) and 23vPPV (23-valent pneumococcal polysaccharide vaccine) under the National Immunisation Program (NIP). However, some groups are not eligible to receive funded vaccine doses because the incidence of disease is not sufficient to meet cost-effectiveness thresholds.

Vaccine doses for people with the risk conditions in this list are funded under the NIP unless otherwise noted.

* Previous episode of invasive pneumococcal disease
* Functional or anatomical asplenia, including

– sickle cell disease or other haemoglobinopathies

– congenital or acquired asplenia (for example, splenectomy) or hyposplenia

* Immunocompromising conditions, including

 – congenital or acquired immune deficiency, including symptomatic IgG subclass or isolated IgA deficiency

– 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 therapya

 – non-haematological malignancies receiving chemotherapy or radiotherapy (currently or anticipated)a

* Proven or presumptive cerebrospinal fluid (CSF) leak, including

– cochlear implants

– intracranial shunts

* Chronic respiratory disease, including

– suppurative lung disease, bronchiectasis and cystic fibrosis

– chronic lung disease in preterm infants

* Chronic renal disease

– relapsing or persistent nephrotic syndrome

 – chronic renal impairment – eGFR <30 mL/min (stage 4 disease)b

* Cardiac disease, including

– congenital heart diseasec

– coronary artery diseasec

– heart failurec

* Children born less than 28 weeks gestationc
* Trisomy 21c
* Chronic liver disease, including

– chronic hepatitisa

– cirrhosisa

– biliary atresiaa

* Diabetesa
* Smoking (current or in the immediate past)a
* Harmful use of alcohola

**a** Not funded under the NIP

**b** Funded under the NIP for eGFR <15 mL/min only (including patients on dialysis)

**c** Funded under the NIP for children <5 years only

## Current list of risk conditions

ATAGI currently recommends a similar list that is split into Category A (highest increased risk) and Category B (increased risk). Vaccination recommendations differ depending on the risk category.

## Key differences

The revised list includes all the risk conditions listed in the current Handbook, but consolidates the previous Category A and Category B conditions into a single list. It includes ‘previous episode of invasive pneumococcal disease’ in adults as well as children.

The specific increase in risk of pneumococcal disease varies widely with each risk condition (see Table 1). This revised list aims to simplify the current complex recommendations for people with risk conditions to improve compliance and reduce disease burden.

## New recommendation

**Children diagnosed with certain risk conditions at** ≤**12 months of age are recommended to receive 4 doses of 13vPCV and 2 doses of 23vPPV**

In addition to the 3 doses for all children ≤5 years of age, children ≤12 months of age with conditions that increase their risk of invasive pneumococcal disease (see List. Risk conditions for invasive pneumococcal disease) are recommended to receive:

* a dose of 13vPCV at 6 months of age
* a dose of 23vPPV at 4–5 years of age
* a 2nd dose of 23vPPV 5–10 years after the 1st dose of 23vPPV

This is because of the higher disease burden and the possibility of lower antibody responses in these children.1-3

Aboriginal and Torres Strait Islander children diagnosed with risk conditions at ≤12 months of age who live in the NT, Qld, SA or WA already receive these extra doses as part of their routine schedule.

Any child from 6 to 11 months with a **newly identified** medical condition who has not received an additional dose of 13vPCV at 6 months of age, should receive this at diagnosis. The exception is children who have received a haematopoietic stem cell transplant — these children are recommended to receive 3 doses of 13vPCV after transplantation. See [Table. Recommendations for revaccination after haematopoietic stem cell transplant in children and adults](https://immunisationhandbook.health.gov.au/resources/handbook-tables/table-recommendations-for-revaccination-after-haematopoietic-stem-cell).

See Catch-up vaccination for more details, including minimum intervals between doses.

See [Table. Recommended ages for pneumococcal vaccination in children aged ≤5 years](https://immunisationhandbook.health.gov.au/resources/handbook-tables/table-recommended-ages-for-pneumococcal-vaccination-in-children-aged).

## Current recommendation

ATAGI currently recommends the following:

Children aged ≤5 years with certain medical conditions are recommended to receive 4 doses of 13vPCV and 1 dose of 23vPPV

Children and adolescents aged ≥5 years to <18 years with pre-existing medical conditions in Category A who have previously received 4 doses of 13vPCV and a dose of 23vPPV at 4–5 years of age are recommended to receive further doses of 23vPPV

Children and adolescents aged ≥5 years to <18 years with pre-existing conditions in Category B who have previously received 4 doses of 13vPCV and a dose of 23vPPV at 4–5 years of age are recommended to receive another dose of 23vPPV

## Key differences

ATAGI proposes that children with conditions that increase their risk of pneumococcal disease receive an additional dose of 13vPCV and 2 doses of 23vPPV, and no further doses of 23vPPV during their lifetime.

## New recommendation

**Children and adolescents aged >12 months to <18 years with newly identified risk conditions are recommended to receive 1 dose of 13vPCV and 2 doses of 23vPPV**

All children and adolescents with newly identified risk conditions (see List. Risk conditions for invasive pneumococcal disease) (except Aboriginal and Torres Strait Islander children <5 years of age living in the NT, Qld, SA or WA) are recommended to receive:

* 1 dose of 13vPCV at diagnosis (at least 2 months after any previous doses of 13vPCV)
* 1 dose of 23vPPV 12 months after 13vPCV (2–12 months later is acceptable), or at ≥4 years of age, whichever is later
* a 2nd dose of 23vPPV 5–10 years later

Aboriginal and Torres Strait Islander children <5 years of age with risk conditions who live in the NT, Qld, SA or WA already receive these doses as part of their routine schedule.

The exception is people who have received a haematopoietic stem cell transplant — these people are recommended to receive 3 doses of 13vPCV after transplantation. See [Table. Recommendations for revaccination after haematopoietic stem cell transplant in children and adults](https://immunisationhandbook.health.gov.au/resources/handbook-tables/table-recommendations-for-revaccination-after-haematopoietic-stem-cell).

A minimum interval of 2 months between the last dose of 13vPCV and 23vPPV is recommended. This is based on a small number of studies in children of different ages with underlying conditions. These studies have shown that 23vPPV is more immunogenic if given approximately 2 months after a 7vPCV dose.4-7

See [Table. Recommended ages for pneumococcal vaccination in children aged ≤5 years](https://immunisationhandbook.health.gov.au/resources/handbook-tables/table-recommended-ages-for-pneumococcal-vaccination-in-children-aged).

## Current recommendation

Overall, for people with risk conditions, the current recommendation is for 3 lifetime doses of 23vPPV. This includes the following:

Children and adolescents aged ≥5 years to <18 years with newly identified medical conditions in Category A who have never received 13vPCV are recommended to receive 1 dose of 13vPCV at diagnosis and doses of 23vPPV

Children and adolescents aged ≥5 years to <18 years with newly identified conditions in Category B are recommended to receive doses of 23vPPV

Children and adolescents aged ≥5 years to <18 years with pre-existing conditions in Category A who received 23vPPV at 4–5 years of age but have never received 13vPCV are recommended to receive 1 dose of 13vPCV and further doses of 23vPPV

## Key differences

ATAGI proposes to simplify the current recommendations by:

consolidating Category A and Category B conditions into a single list of conditions that increase the risk of pneumococcal disease

recommending the same vaccines and number of doses – 1 dose of 13vPCV and 2 doses of 23vPPV – for all people >12 months of age, regardless of their age at diagnosis

limiting the number of lifetime doses of 23vPPV to 2 doses

## New recommendation

**Adults of any age ≥18 years with newly identified risk conditions are recommended to receive 1 dose of 13vPCV and 2 doses of 23vPPV**

All adults of any age with newly identified risk conditions (see List. Risk conditions for invasive pneumococcal disease) are recommended to receive:

* 1 dose of 13vPCV at diagnosis (at least 2 months after any previous doses of 13vPCV)
* 1 dose of 23vPPV 12 months after 13vPCV (2–12 months later is acceptable)
* a 2nd dose of 23vPPV 5–10 years later

Aboriginal and Torres Strait Islander adults aged ≥50 years already receive these doses, and they do not need to be repeated.

The exception is people who have received a haematopoietic stem cell transplant — these people are recommended to receive 3 doses of 13vPCV after transplantation. See [Table. Recommendations for revaccination after haematopoietic stem cell transplant in children and adults](https://immunisationhandbook.health.gov.au/resources/handbook-tables/table-recommendations-for-revaccination-after-haematopoietic-stem-cell).

A minimum interval of 2 months between the last dose of 13vPCV and 23vPPV is recommended. This is based on a small number of studies in children of different ages with underlying conditions. These studies have shown that 23vPPV is more immunogenic if given approximately 2 months after a 7vPCV dose.4-7

## Current recommendation

Overall, for people with risk conditions, the current recommendation is for 3 lifetime doses of 23vPPV. This includes the following:

Adults with newly identified medical conditions in Category A are recommended to receive 1 lifetime dose of 13vPCV and 3 doses of 23vPPV

Adults with newly identified conditions in Category B are recommended to receive 3 doses of 23vPPV

Adults with pre-existing medical conditions in Category A who have previously received 23vPPV are recommended to receive 1 dose of 13vPCV and 2 doses of 23vPPV

Adults with pre-existing medical conditions in Category A who have previously received 13vPCV are recommended to receive 3 doses of 23vPPV

Adults with pre-existing conditions in Category B are recommended to receive 3 lifetime doses of 23vPPV

## Key differences

ATAGI proposes to simplify the current recommendations by:

consolidating Category A and Category B conditions into a single list of conditions that increase the risk of pneumococcal disease

recommending the same vaccines and number of doses – 1 dose of 13vPCV and 2 doses of 23vPPV – for all people >12 months of age, regardless of their age at diagnosis

limiting the number of lifetime doses of 23vPPV to 2 doses

## Evidence for the new recommendations

### Higher burden of disease in people with risk conditions

Overall, the burden of pneumococcal disease has decreased significantly, driven mainly by the indirect protective effects of the 13vPCV schedule in infants. However, some population subgroups have an increased risk of pneumococcal disease due to underlying medical conditions and behavioural factors (Table 1). In these groups, the burden of disease remains substantial and involves a broad range of pneumococcal serotypes. People in these risk groups are likely to benefit from a pneumococcal schedule that uses both 13vPCV and 23vPPV.

### Risk conditions are present across all age groups

There are no Australian-specific estimates for the prevalence of risk factors associated with an increased risk of IPD that specifically match the new list of pneumococcal risk conditions. However, data from 2 international studies8,9 and the Australian Bureau of Statistics national population health surveys show that conditions associated with an increased risk of IPD occur across all age groups.

### 13vPCV is likely to be effective in people with risk conditions

There is a lack of data on the efficacy and effectiveness of 13vPCV in people with risk conditions. However, immunogenicity data are available for several risk conditions, and these data indicate that the vaccine induces a protective response. Studies in people with risk conditions showed no major safety concerns after vaccination.

Immunogenicity and safety data are available for 13vPCV in people with HIV infection, people with chronic kidney disease, people who have had a haematopoietic stem cell transplant, people who have had a kidney transplant and people who are receiving immunosuppressive therapy for cancers.10-17

Post-hoc analysis of the CAPiTA trial18 assessed the efficacy of 13vPCV in people with certain risk conditions, including:

heart disease

lung disease

asthma

diabetes

liver disease

smoking

splenectomy

In these people, the efficacy of 13vPCV against vaccine-type IPD was 77.3%, and 40.3% against vaccine-type CAP.18 Although these point estimates were lower than for healthy trial participants, the confidence intervals overlapped, indicating a statistically similar response to the vaccine. Vaccine efficacy is expected to be the same or better in younger adults with these risk conditions.

### 23vPPV is likely to be effective in people with risk conditions

Studies of 23vPPV indicate that this vaccine can be effective in people with risk conditions. In people with HIV and other immunocompromising conditions, vaccine effectiveness against IPD is estimated to be 35–50%.19,20 In people with chronic conditions who are not immunocompromised, vaccine effectiveness against IPD is estimated to be 50–60%.19,21

Sequential administration of 13vPCV and 23vPPV in people with risk conditions is therefore likely to protect these people against 23v-non-13v serotypes. This is supported by immunogenicity studies that compared sequential administration of 7vPCV or 13vPCV and 23vPPV in varying combinations and dose intervals (2, 6, 12 months or 3–4 years) in adults from 50 years of age.22-28 In these studies, antibody levels were generally higher when PCV was given as the first dose.

The recommended interval between 13vPCV and 23vPPV of 2–12 months aims to harness the extended protection against 23v-non-13v serotypes in a short period of time.

Immunogenicity data support 1 repeat dose of 23vPPV 3–5 years later, but there is no substantial benefit in further doses of 23vPPV beyond this.29 Also, additional doses are associated with higher rates of adverse events, especially injection site reactions.30-32 It is unclear whether additional doses of 23vPPV may lead to immune hyporesponsiveness. Because of these factors, ATAGI recommends a total of 2 doses of 23vPPV for people with risk conditions.

The current schedule and funding for pneumococcal vaccines in people with risk conditions is complex and challenging for patients, providers and programs. By using the same recommendation for all those at risk and providing funded doses to large number of Australians with risk factors, the new recommended schedule is expected to simplify the recommendations and improve compliance.

Table 1 Summary of incidence rates of IPD and rate ratios in people with underlying risk conditions (compared with healthy people) from selected studies, in descending order of incidence or relative risk

Immunosuppressive conditions

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Stem cell transplant recipients | ≥18 years | 2250 | na | Clinically recommended to receive 3 doses of 13vPCV. Torda et al33 |
| Solid organ transplant recipients – any solid organ | ≥18 years  | 146 | na | Kumar et al34 |
| Solid organ transplant recipients – liver transplant | ≥18 years | 354 | na | Kumar et al34 |
| Asplenia, functional or anatomical | 5–17 years | 107.9 | 101.5 (60.1-171.5) | Pelton et al35 |
| Asplenia, functional or anatomical | 18–49 years | 59.9 | 32.6 (22.9‐46.4) | Shea et al36 |
| Asplenia, functional or anatomical | 50–64 years | 125.4 | 28.1 (22.1‐35.9) | Shea et al36 |
| Asplenia, functional or anatomical | ≥65 years | 116.3 | 14.0 (10.5‐18.7) | Shea et al36 |
| Congenital immunodeficiency | 5–17 years | 29.7 | 27.9 (11.5–67.8) | Pelton et al35 |
| Congenital immunodeficiency | 18–49 years | 68.8 | 37.5 (25.4‐55.4) | Shea et al36 |
| Congenital immunodeficiency | 50–64 years | 105.2 | 2.2 (1.5‐3.4) | Shea et al36 |
| Congenital immunodeficiency | ≥65 years | 118.1 | 14.2 (8.8‐23.1) | Shea et al36 |
| Neutropenia | 5–17 years | 123.6 | 116.3 (66.4–203.8) | Pelton et al35 |
| Neutropenia | 18–49 years | 52.1 | 28.4 (19.6‐41.1) | Shea et al36 |
| Neutropenia | 50–64 years | 68 | 15.3 (11.8‐19.6) | Shea et al36 |
| Neutropenia | ≥65 years | 110.9 | 13.3 (10.0‐17.8) | Shea et al36 |
| Haematological malignancy – all malignancies | All age groups | 50 | na | Lee et al37 |
| Haematological malignancy – leukaemia | All age groups | 52 | na | Lee et al37 |
| Haematological malignancy – lymphoma | All age groups | 28 | na | Lee et al37 |
| Haematological malignancy – myeloma | All age groups | 139 | na | Lee et al37 |
| HIV infection | 18–49 years | 40.3 | 22.0 (16.2‐29.8) | Shea et al36 |
| HIV infection | 50–64 years | 54.7 | 12.3 (9.1‐16.5) | Shea et al36 |
| HIV infection | ≥65 years | 27.4 | 3.3 (0.8‐13.2) | Shea et al36 |
| Other immunosuppressive drugs/conditions | 5–17 years | 46.3 | 43.6 (29.1–65.1) | Pelton et al35 |
| Other immunosuppressive drugs/conditions | 18–49 years | 15.5 | 8.4 (7.0‐10.1) | Shea et al36 |
| Other immunosuppressive drugs/conditions | 50–64 years | 28.9 | 6.5 (5.8‐7.2) | Shea et al36 |
| Other immunosuppressive drugs/conditions | ≥65 years | 36.4 | 4.4 (3.9‐5.0) | Shea et al36 |
| Solid tumour malignancy | All age groups | 11 | na | Lee et al37 |

Chronic kidney disease

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Chronic renal failure, including end-stage renal failure, glomerulonephritis, nephrotic syndrome and dialysis | 5–17 years | 74.1 | 69.7 (37.0–131.6) | Pelton et al35 |
| Chronic renal failure, including end-stage renal failure, glomerulonephritis, nephrotic syndrome and dialysis | 18–49 years | 26.8 | 14.6 (10.3‐20.7) | Shea et al36 |
| Chronic renal failure, including end-stage renal failure, glomerulonephritis, nephrotic syndrome and dialysis | 50–64 years | 57.9 | 13.0 (10.8‐15.6) | Shea et al36 |
| Chronic renal failure, including end-stage renal failure, glomerulonephritis, nephrotic syndrome and dialysis | ≥65 years | 50 | 6.0 (5.0‐7.2) | Shea et al36 |
| Chronic renal failure – end-stage renal disease (GFR <15 mL/min) or requiring renal replacement therapy | ≥18 years | na | 18.5 | Baxter et al38 |

Previous invasive pneumococcal disease

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Previous IPD | 5–17 years | 90 | na | J Malo and S Lambert, Queensland Health, personal communication to ATAGI, January 2017 |
| Previous IPD | ≥18 years | 377 | na | J Malo and S Lambert, Queensland Health, personal communication to ATAGI, January 2017 |

Blood–brain barrier dysfunction

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Cochlear implant | 5–17 years | 50 | na | Weycker et al39 |
| Cochlear implant | ≥65 years | 87.4 | 10.5 (1.5–74.8) | Shea et al36 |

Chronic respiratory disease

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Chronic respiratory disease (not asthma) | 5–17 years | 3.8 | 3.6 (1.5–8.7) | Pelton et al35 |
| Chronic respiratory disease (not asthma) | 18–49 years | 11.6 | 6.3 (4.7‐8.5) § | Shea et al36 |
| Chronic respiratory disease (not asthma) | 50–64 years | 34.4 | 7.7 (6.8‐8.8) § | Shea et al36 |
| Chronic respiratory disease (not asthma) | ≥65 years | 51.1 | 6.2 (5.4‐7.0) § | Shea et al36 |
| Bronchiectasis | 18–49 years | na | 9.9 (3.4-28.3) | Inghammar et al40 |
| Bronchiectasis | 50–64 years | na | 2.5 (0.5-11.8) | Inghammar et al40 |
| Severe asthma | 5–17 years | na | 12.3 (5.4-28.0) | Klemets et al41 |
| Asthma (excluding severe asthma) | 5–17 years | 2.3 | 2.1 (1.4–3.2) | Pelton et al35 |
| Asthma (excluding severe asthma) | 18–49 years | 4.5 | 2.5 (1.9‐3.2) | Shea et al36 |
| Asthma (excluding severe asthma) | 50–64 years | 16.7 | 3.8 (3.2‐4.5) | Shea et al36 |
| Asthma (excluding severe asthma) | ≥65 years | 34.2 | 4.1 (3.4‐5.0) | Shea et al36 |
| Fibrotic lung disease/ pneumoconiosis | 50–64 years | na | 1.3 (0.2-10.0) | Shea et al36 |

Chronic liver disease

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Chronic liver disease | 18–49 years | 18.7 | 10.2 (6.7‐15.6) | Shea et al36 |
| Chronic liver disease | 50–64 years | 28.5 | 6.4 (4.8‐8.5) | Shea et al36 |
| Chronic liver disease | ≥65 years | 53.4 | 6.4 (4.4‐9.5) | Shea et al36 |
| Chronic hepatitis | 18–49 years | 2.0 | 3.5 (3.0- 4.1) | Wotton et al42 |
| Cirrhosis | 50–64 years | 7.2 | 7.2 (6.2-8.3) | van Hoek et al9 |

Down syndrome

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Down syndrome | 5–17 years | 14.6 | 13.7 (3.4–55.2) | Pelton et al35 |

Chronic heart disease

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Chronic heart disease | 5–17 years | 10.6 | 9.9 (4.7–21.1) | Pelton et al35 |
| Chronic heart disease | 18–49 years | 7.2 | 3.9 (3.0‐5.1) | Shea et al36 |
| Chronic heart disease | 50–64 years | 13 | 2.9 (2.6‐3.3) | Shea et al36 |
| Chronic heart disease | ≥65 years | 26.6 | 3.2 (2.8‐3.6) | Shea et al36 |
| Severe heart failure | 50–64 years | 5 | 5.2 (3.8-7.1) | Incidence rate calculated by taking the incidence of IPD in people with no recorded risk factors (from enhanced IPD surveillance data for 2014–16) and multiplying by the relative risk from Jackson et al43 |
| Ischaemic heart disease | 50–64 years | 3 | 2.9 (1.3-6.2) | Incidence rate calculated by taking the incidence of IPD in people with no recorded risk factors (from enhanced IPD surveillance data for 2014–16) and multiplying by the relative risk from Watt et al44 |

Other conditions

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Chronic use of oral steroids | 5–17 years | 6.0 | 5.7 (.8–40.5) | Pelton et al35 |
| Chronic use of oral steroids | 18–49 years | 6.2 | 3.4 (1.8‐6.5) | Shea et al36 |
| Chronic use of oral steroids | 50–64 years | 10 | 2.2 (1.3‐3.9) | Shea et al36 |
| Chronic use of oral steroids | ≥65 years | 15.2 | 1.8 (1.0‐3.4) | Shea et al36 |
| Diabetes | 5–17 years | 5.8 | 5.4 (2.2–13.2) | Pelton et al35 |
| Diabetes | 18–49 years | 5.5 | 3.0 (2.4‐3.7) | Shea et al36 |
| Diabetes | 50–64 years | 11.6 | 2.6 (2.3‐2.9) | Shea et al36 |
| Diabetes | ≥65 years | 21.1 | 2.5 (2.2‐2.9) | Shea et al36 |

Behavioural risk factors

| Condition | Age group | Rate per 100,000 | Rate ratio (95% CI) | Notes and references |
| --- | --- | --- | --- | --- |
| Smoking | 18–49 years | 6.5 | 3.6 (2.8‐4.5) | Shea et al36 |
| Smoking | 50–64 years | 19.2 | 4.3 (3.7‐5.0) | Shea et al36 |
| Smoking | ≥65 years | 34.9 | 4.2 (3.2‐5.5) | Shea et al36 |
| Harmful use of alcohol | 18–49 years | 14.1 | 7.7 (5.3‐11.2) | Shea et al36 |
| Harmful use of alcohol | 50–64 years | 29.6 | 6.6 (4.8‐9.1) | Shea et al36 |
| Harmful use of alcohol | ≥65 years | 41.8 | 5.0 (2.7‐9.4) | Shea et al36 |

# New recommendations for Aboriginal and Torres Strait Islander people

## New recommendation

**Aboriginal and Torres Strait Islander children aged ≤5 years living in certain states and territories are recommended to receive 4 doses of 13vPCV and 2 doses of 23vPPV**

In addition to the 3 doses for all children ≤5 years of age, Aboriginal and Torres Strait Islander children living in the following states and territories are recommended to receive an additional dose of 13vPCV at 6 months of age:

* Northern Territory
* Queensland
* South Australia
* Western Australia

This is because of the higher disease burden and the possibility of lower antibody responses in these children.45

These children are also recommended to receive 2 doses of 23vPPV:

* 1 dose at 4–5 years of age
* a 2nd dose 5–10 years later

This is because a considerable proportion of invasive pneumococcal disease in these children is caused by serotypes that are present in 23vPPV but not in 13vPCV.

## Current recommendation

ATAGI currently recommends the following:

Aboriginal and Torres Strait Islander children aged ≤5 years living in certain states and territories are recommended to receive 4 doses of 13vPCV

## Key differences

All Aboriginal and Torres Strait Islander children living in the NT, Qld, SA or WA are currently recommended to receive 4 doses of 13vPCV (3+1 schedule) due to their overall higher burden of pneumococcal disease. ATAGI proposes to add 2 doses of 23vPPV to the schedule for these children.

## Evidence for the new recommendation

A considerable proportion of IPD in Aboriginal and Torres Strait Islander children living in the NT, Qld, SA or WA is caused by 23v-non-13v serotypes (Table 2). ATAGI therefore considers that a schedule that includes both 13vPCV and 23vPPV will maximise protection for these children. This schedule also aligns with the schedule for children with medical risk factors.

Table 2 Proportion of IPD caused by different vaccine serotype groups in Aboriginal and Torres Strait Islander children in NT, Qld, SA and WA, 2015–2017

| Age group (years) | Serotype group 13vPCV, % (n) | Serotype group 23v-non-13v, % (n) | Serotype group other, % (n) | Total, % (n) |
| --- | --- | --- | --- | --- |
| <5 | 19.7 (15) | 27.6 (21) | 52.6 (40) | 100 (76) |
| 5–14 | 26.5 (9) | 35.3 (12) | 38.2 (13) | 100 (34) |

Data source: National Notifiable Diseases Surveillance System

## New recommendation

**Aboriginal and Torres Strait Islander adults aged** ≥**50 years are recommended to receive 1 dose of 13vPCV and 2 doses of 23vPPV**

Aboriginal and Torres Strait Islander adults without conditions that are associated with an increased risk of invasive pneumococcal disease are recommended to receive:

* a dose of 13vPCV at age 50 years
* a dose of 23vPPV 12 months later
* a 2nd dose of 23vPPV 5–10 years later

This is based on:

* the increased risk of invasive pneumococcal disease in Aboriginal and Torres Strait Islander adults compared with non-Indigenous adults
* the high prevalence of conditions associated with an increased risk of invasive pneumococcal disease (including tobacco smoking) in Aboriginal and Torres Strait Islander adults after 50 years of age compared with younger ages

Aboriginal and Torres Strait Islander adults who have previously received a dose of 23vPPV are recommended to receive:

* 1 dose of 13vPCV 12 months after their 23vPPV dose
* 1 dose of 23vPPV 12 months after their 13vPCV dose, or 5 years after their previous 23vPPV dose, whichever is later

Aboriginal and Torres Strait Islander adults who have previously received doses of 23vPPV are recommended to receive the dose of 13vPCV 12 months after their last 23vPPV dose. If they have already received at least 2 doses of 23vPPV, no further 23vPPV doses are recommended.

In all these scenarios, the interval between doses of 13vPCV and 23vPPV should be 12 months, but 2–12 months is acceptable. The interval between doses of 23vPPV should be 5 years.

Aboriginal and Torres Strait Islander adults with conditions that are associated with an increased risk of invasive pneumococcal disease are recommended to receive 1 dose of 13vPCV at diagnosis followed by 2 doses of 23vPPV (see recommendations for people with risk conditions).

## Current recommendation

ATAGI currently recommends the following:

Aboriginal and Torres Strait Islander adults aged 50 years without conditions associated with an increased risk of pneumococcal disease are recommended to receive 2 doses of 23vPPV

## Key differences

ATAGI proposes to add a dose of 13vPCV for Aboriginal and Torres Strait Islander adults aged 50 years.

## Evidence for the new recommendation

### Higher burden of disease in Aboriginal and Torres Strait Islander adults

The incidence of IPD among Aboriginal and Torres Strait Islander people is higher than that among non-Indigenous Australians for all age groups (Table 3). The incidence of IPD has continued to increase in Aboriginal and Torres Strait Islander adults, despite the high coverage of 13vPCV vaccination in infants and children. This is in contrast to the incidence of IPD in non-Indigenous adults, which has decreased. This widens the gap in disease burden between Aboriginal and Torres Strait Islander people and non-Indigenous people.46

Table 3 Notification rates (per 100,000) of invasive pneumococcal disease by age group in Aboriginal and Torres Strait Islander and non-Indigenous populations, and rate ratios, 2011–2014

| Population group | 0–4 years | 5–14 years | 15–24 years | 25–34 years | 35–49years | 50–64 years | ≥65 years |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Aboriginal and Torres Strait Islander (rate) | 51.6 | 22.7 | 16.0 | 35.8 | 64.3 | 80.3 | 98.9 |
| Non-Indigenous (rate) | 13.0 | 2.6 | 1.5 | 2.7 | 4.8 | 7.6 | 16.8 |
| Aboriginal and Torres Strait Islander:non-Indigenous (rate ratio) | 4.0 | 8.6 | 10.4 | 13.3 | 13.4 | 10.6 | 5.9 |

Data source: National Notifiable Diseases Surveillance System

Along with this higher disease burden, 26% of IPD cases in Aboriginal and Torres Strait Islander adults aged ≥50 years are due to 23v-non-13v types (Table 4).

Table 4 Proportion of IPD caused by different vaccine serotype groups in Aboriginal and Torres Strait Islander adults aged ≥25 years, 2011–2014

| Age group | Serotype group 13vPCV, % (n) | Serotype group 23v-non-13v, % (n) | Serotype group non-vaccine type, % (n) | Serotype group not typed, % (n) | Total, % (n) |
| --- | --- | --- | --- | --- | --- |
| 25–49 | 36.7% (138) | 30.1% (113) | 31.9% (120) | 1.3% (5) | 100% (376) |
| 50–64 | 33.7% (58) | 28.5% (49) | 34.3% (59) | 3.5% (6) | 100% (172) |
| ≥65 | 38.1% (24) | 19.0% (12) | 34.9% (3) | 7.9% (5) | 100% (63) |
| Total | 36% (220) | 28.5% (174) | 32.9% (201) | 2.6% (16) | 100% (611) |

Data source: National Notifiable Diseases Surveillance System

This epidemiology indicates that a schedule that includes both 13vPCV and 23vPPV will optimise protection for Aboriginal and Torres Strait Islander adults.

# New recommendation for healthy non-Indigenous adults

## New recommendation

**Non-Indigenous adults aged** ≥**70 years without conditions associated with an increased risk of pneumococcal disease are recommended to receive 1 dose of 13vPCV**

A single dose of 13vPCV is recommended for all non-Indigenous adults at 70 years of age.

Non-Indigenous adults aged ≥70 years who have previously received a dose of 23vPPV are recommended to receive a dose of 13vPCV at least 12 months after their 23vPPV dose.

Adults aged ≥70 years with conditions associated with an increased risk of pneumococcal disease are recommended to receive 13vPCV followed by additional doses of 23vPPV, as per the schedule for people with risk conditions.

## Current recommendation

ATAGI currently recommends the following:

Non-Indigenous adults aged 65 years without conditions associated with an increased risk of pneumococcal disease are recommended to receive 1 dose of 23vPPV

## Key differences

ATAGI proposes to:

change the vaccine given to healthy non-Indigenous adults from 23vPPV to 13vPCV

change the age of vaccination from 65 years to 70 years

## Evidence for the new recommendation

### 13vPCV has higher efficacy than 23vPPV against common serotypes

The largest disease burden caused by pneumococcus in adults aged ≥65 years is non-bacteraemic CAP. The CAPiTA trial in adults aged ≥65 years showed that efficacy of 13vPCV was:47

45.6% (95% CI 21.8–62.4%) against a first episode of CAP (invasive or non-invasive) due to 13vPCV serotypes

75.0% (95% CI 41.4–90.8%) against a first episode of IPD due to 13vPCV serotypes

51.8% (95% CI 22.4–70.7%) against a first episode of IPD (vaccine type or non-vaccine type)

In contrast, estimates of efficacy and effectiveness for 23vPPV are lower and also vary, particularly against CAP outcomes:

Vaccine effectiveness against vaccine-type IPD is estimated at 61.1% (95% CI 55.1–66.9%), based on data from an Australian observational study, national notification data and adult health surveys48

Vaccine effectiveness against CAP outcomes ranges from 27% (95% CI 3–46%) to 51% (95% CI 16–71%) from observational studies49,50

Vaccine efficacy against CAP outcomes from randomised controlled trials was not statistically significant in a pooled analysis undertaken by ATAGI (unpublished data)

### IPD incidence is higher in people aged ≥70 years than in those aged 65–69 years

In pooled notification data for 2016 and 2017, the incidence of IPD due to 13vPCV serotypes was almost 2-fold higher among non-Indigenous adults aged ≥70 years (6.2 per 100,000) than in those aged 65–69 years (3.4 per 100,000). This substantially greater burden in adults from age 70 years and expected waning of pneumococcal protection with increasing age supports the recommendation of 13vPCV for all adults aged 70 years and above.

Of all IPD notifications in non-Indigenous adults ≥65 years of age, around 4% occurred in those without risk conditions as identified in notification data. Of those cases, only 20% were due to 23v-non-13v serotypes.

ATAGI therefore considers that the potential additional benefit of 23vPPV in all older adults without risk conditions is not substantial enough to recommend 13vPCV followed by 23vPPV.

In contrast, in Aboriginal and Torres Strait Islander people and people with risk conditions, it is justifiable to use 23vPPV as well as 13vPCV. This is because there is a higher burden of disease in these groups, including disease caused by 23v-non-13v serotypes.

# Additional information to be included in the Australian Immunisation Handbook – catch-up vaccination

## Catch-up vaccination for infants and children <5 years of age

Children living in ACT, NSW, Tas or Vic, and non-Indigenous children living in the NT, Qld, SA or WA, who have no underlying risk conditions and have not received 3 doses of 13vPCV are recommended to receive further doses of 13vPCV. The number of doses required depends on age at presentation (Table 5).

The recommended minimum interval between primary doses given at <12 months of age for catch-up is 4 weeks. For doses given at ≥12 months, the recommended minimum interval is 2 months.

Table 5 Catch-up schedule for 13vPCV for Aboriginal and Torres Strait Islander children living in ACT, NSW, Tas or Vic, and all children who do not have condition(s) associated with an increased risk of invasive pneumococcal disease, aged <5 years

| Number of doses received previously | Age at presentation | Age at 1st dose of PCV | Age at 2nd dose of PCV | Age at 3rd dose of PCV | Number of further primary doses needed | Number of booster doses needed at age ≥12 months |
| --- | --- | --- | --- | --- | --- | --- |
| None | <12 months | na | na | na | 2 | 1 |
| 12–59 months | na | na | na | None | 1 |
| 1 | <12 months | <12 months | na | na | 1 | 1 |
| 12–59 months | <12 months | na | na | None | 1 |
| 12–59 months | ≥12 months | na | na | None | None |
| 2 | <12 months | <12 months | <12 months | na | None | 1 |
| 12–59 months | <12 months | <12 months | na | None | 1 |
| 12–59 months | <12 months | ≥12 months | na | None | None |
| 3 | <12 months | <12 months | <12 months | <12 months | None | 1 |
| 12–59 months | <12 months | <12 months | <12 months | None | None (not routinely recommended but may be given to maximise individual protection) |

na = not applicable

Children with pre-existing medical conditions and Aboriginal and Torres Strait Islander children living in the NT, Qld, SA or WA who have not received 4 doses of 13vPCV are recommended to receive further doses of 13vPCV and 2 doses of 23vPPV. The number of 13vPCV doses required depends on age at presentation (Table 6).

The recommended minimum interval between primary doses given at <12 months of age for catch-up is 4 weeks. For doses given at ≥12 months, the recommended minimum interval is 2 months.

Table 6 Catch-up schedule for pneumococcal vaccines for Aboriginal and Torres Strait Islander children living in NT, Qld, SA or WA ONLY, and all children with any condition(s) associated with an increased risk of invasive pneumococcal disease, aged <5 years

These children are also recommended to receive 2 doses of 23vPPV:

1 dose at 4–5 years of age and a minimum of 2 months after a 13vPCV dose

a 2nd dose 5–10 years after the first 23vPPV dose

| Number of 13vPCV doses received previously | Age at presentation | Age at 1st dose of PCV | Age at 2nd dose of PCV | Age at 3rd dose of PCV | Number of further primary PCV dose(s) needed | Number of PCV booster doses needed at age ≥12 months |
| --- | --- | --- | --- | --- | --- | --- |
| None  | <12 months | na | na | na | 3 | 1 |
| 12–59 months | na | na | na | 1 | 1 |
| 1 | <12 months | Any age | na | na | 2 | 1 |
| 12–59 months | <12 months | na | na | 1 | 1 |
| 12–59 months | ≥12 months | na | na | None | 1 |
| 2 | <12 months | Any age | Any age | na | 1 | 1 |
| 12–59 months | <12 months | <12 months | na | 1 | 1 |
| 12–59 months | <12 months | ≥12 months | na | None | 1 |
| 12–59 months | ≥12 months | ≥12 months | na | None | None |
| 3 | <12 months | Any age | Any age | Any age | None | 1 |
| 12–59 months | <12 months | <12 months | Any age | None | 1 |
| 12–59 months | <12 months | ≥12 months | ≥12 months | None | None |

na = not applicable

## Catch-up vaccination for children ≥5 years of age and adults

All people with pre-existing medical conditions are recommended to receive 1 dose of 13vPCV (in addition to any doses received at <5 years of age) and 2 doses of 23vPPV. The recommended intervals between subsequent doses of pneumococcal vaccines are:

12 months between a dose of 23vPPV and a subsequent dose of 13vPCV

12 months between 13vPCV and the first subsequent dose of 23vPPV (2–12 months is acceptable)

5–10 years between any 2 doses of 23vPPV

# Future review of pneumococcal vaccine recommendations

The epidemiology of pneumococcal disease in Australia will continue to change. In July 2018, the National Immunisation Program (NIP) schedule for pneumococcal vaccines changed from a 3+0 schedule in infants (at 2, 4 and 6 months) to a 2+1 schedule (at 2, 4 and 12 months). This change is expected to further reduce the burden of pneumococcal disease in all age groups due to direct and indirect effects.

The successful vaccination program will reduce 13v serotypes, and there is potential for serotype replacement. This means the proportion of disease caused by non-13v serotypes may increase over time.

New pneumococcal vaccines that protect against more and different serotypes are in the pipeline. Implementing these vaccines will also affect pneumococcal epidemiology in ways that are not yet clear.

Because of these factors, ATAGI proposes that these recommendations for pneumococcal vaccination are reviewed within the next 5 years.

# Benefits of new recommendations

There are 5 key benefits from the new pneumococcal recommendations:

Simplifying the recommendations will reduce confusion for vaccine providers and vaccine recipients, particularly by creating a single list of risk conditions.

Including a dose of 13vPCV for all adults is likely to improve protection against CAP. For people with risk conditions, a schedule that combines 13vPCV and 23vPPV will provide the greatest clinical benefits against both CAP and IPD.

Including both 13vPCV and 23vPPV for Aboriginal and Torres Strait Islander children and adults is likely to improve protection against pneumococcal disease. This will help reduce the disproportionately higher burden of disease in Aboriginal and Torres Strait Islander people.

Moving the recommended age for vaccination in older non-Indigenous people from 65 years to 70 years aligns with the age recommendation for zoster vaccine. This may help simplify communication messages about adult vaccinations.

Simplifying the vaccines recommended to individuals (particularly those with risk conditions) and increasing the number of Australians who can access funded doses of both 13vPCV and 23vPPV is expected to improve compliance.

# Potential risks of new recommendations

The potential risks that may arise from the new recommendations include the following:

Changing the vaccine recommendations for people with risk conditions means that some people may be improperly vaccinated due to an unclear medical history.

A person may present to an immunisation provider with pre-existing risk conditions but their medical and vaccination history are unclear. In these scenarios, the person is recommended to receive no more than 2 doses of 23vPPV after 13vPCV. This is the same as the recommendation for people who have never received a pneumococcal vaccine. The benefit of taking the opportunity to give a dose of 23vPPV outweighs the uncertain risk of harm of receiving a possible extra dose. This may lead to inadvertent administration of more doses of 23vPPV than currently recommended, but this situation is likely to be rare. This scenario also highlights the importance of immunisation providers recording all doses of vaccines given in the Australian Immunisation Register, so that vaccine histories are captured accurately.

There is a lack of high-quality efficacy data to inform the recommendation for 13vPCV in people with risk conditions.

There is little evidence for 13vPCV vaccine efficacy in people who are immunocompromised. Similarly, there are no Australian-specific estimates available for the prevalence of risk conditions associated with an increased risk of IPD that exactly match the new list of pneumococcal risk conditions. These recommendations have been based on extrapolation of the best available evidence.

# Preferences and values

The proposed changes to the use of pneumococcal vaccines are in line with best clinical advice. It is expected that the changes will result in additional protection for individuals most at risk of disease, and the wider community, including those who are not vaccinated. This is consistent with societal expectations of the best use of vaccines in Australia, including under the NIP.

These recommendations align with best clinical practice. Some of these recommendations are not funded under the NIP. Immunisation providers are recommended to check the current funding status for each person’s situation.

# Glossary

A [glossary of technical terms](https://immunisationhandbook.health.gov.au/technical-terms) is available on the Australian Immunisation Handbook website.

# References

1. Klugman K, Dagan R, Malley R, Whitney C. Pneumococcal conjugate vaccine and pneumococcal common protein vaccines. In: Plotkin S, Orenstein W, Offit P, Edwards K, eds. Plotkin's vaccines. 7th ed. Philadelphia: Elsevier; 2018.

2. Centers for Disease Control and Prevention. Pneumococcal disease. In: Hamborsky J, Kroger A, Wolfe C, eds. Epidemiology and prevention of vaccine-preventable diseases. Washington DC: Public Health Foundation; 2015.

3. Weinberger D, Harboe Z, Sanders E, et al. Association of serotype with risk of death due to pneumococcal pneumonia: a meta-analysis. Clinical Infectious Diseases 2010;51:692-9.

4. Abzug MJ, Pelton SI, Song LY, et al. Immunogenicity, safety, and predictors of response after a pneumococcal conjugate and pneumococcal polysaccharide vaccine series in human immunodeficiency virus-infected children receiving highly active antiretroviral therapy. Pediatric Infectious Disease Journal 2006;25:920-9.

5. Barton M, Wasfy S, Dipchand AI, et al. Seven-valent pneumococcal conjugate vaccine in pediatric solid organ transplant recipients: a prospective study of safety and immunogenicity. Pediatric Infectious Disease Journal 2009;28:688-92.

6. Vernacchio L, Neufeld E, MacDonald K, et al. Combined schedule of 7 valent pneumococcal conjugate vaccine followed by 23 valent pneumococcal vaccine in children and young adults with sickle cell disease. Journal of Pediatrics 1998;133.

7. Vernacchio L, Romero-Steiner S, Martinez J, et al. Comparison of an opsonophagocytic assay and IgG ELISA to assess respnses to pneumococcal polysaccharide and pneumococcal conjugate vaccines in children and young adults with sickle cell disease. Journal of Infectious Diseases 2008;181.

8. Kyaw M, Rose C, Fry A, et al. The influence of chronic illnesses on the incidence of invasive pneumococcal disease in adults. Journal of Infectious Diseases 2005;192:377-86.

9. van Hoek AJ, Andrews N, Waight PA, et al. The effect of underlying clinical conditions on the risk of developing invasive pneumococcal disease in England. Journal of Infection 2012;65:17-24.

10. Bhorat A, Madhi S, Laudat F, et al. Immunogenicity and safety of the 13-valent pneumococcal conjugate vaccine in HIV-infected individuals naive to pneumococcal vaccination. AIDS 2015;29:1345-54.

11. Lombardi F, Belmonti S, Fabbiani M, et al. Immunogenicity and safety of the 13-valent pneumococcal conjugate vaccine versus the 23-valent polysaccharide vaccine in unvaccinated HIV-infected adults: a pilot, prospective controlled study. PLoS ONE [Electronic Resource] 2015;11:e0156523.

12. Glesby M, Watson W, Brinson C, et al. Immunogenicity and safety of 13-valent pneumococcal conjugate vaccine in HIV-infected adults previously vaccinated with pneumococcal polysaccharide vaccine. Journal of Infectious Diseases 2015;212:18-27.

13. Cordonnier C, Ljungman P, Juergens C, et al. Immunogenicity, safety, and tolerability of 13-valent pneumococcal conjugate vaccine followed by 23-valent pneumococcal polysaccharide vaccine in recipients of allogeneic hematopoietic stem cell transplant aged ≥2 years: an open-label study. Clinical Infectious Diseases 2015;61:313-23.

14. Vandecasteele S, De Bacquer D, Caluwe R, Ombelet S, Van Vlem B. Immunogenicity and safety of the 13-valent pneumococcal conjugate vaccine in 23-valent pneumococcal polysaccharide vaccine-naive and pre-immunized patients under treatment with chronic haemodialysis: a longitudinal quasi-experimental phase IV study. Clinical Microbiology and Infection 2018;24:65-71.

15. Mitra S, Stein G, Bhupalam S, Havlichek D. Immunogenicity of 13-valent conjugate pneumococcal vaccine in patients 50 years and older with end-stage renal disease and on dialysis. Clinical and Vaccine Immunology 2016;23:884-7.

16. Dendle C, Stuart R, Polkinghorne K, et al. Seroresponses and safety of 13-valent pneumococcal conjugate vaccination in kidney transplant recipients. Transplant Infectious Disease 2018;20:e12866.

17. Hung T, Kotecha R, Blyth C, et al. Immunogenicity and safety of single-dose, 13-valent pneumococcal conjugate vaccine in pediatric and adolescent oncology patients. Cancer 2017;123:4215-23.

18. Suaya JA, Jiang Q, Scott DA, et al. Post hoc analysis of the efficacy of the 13-valent pneumococcal conjugate vaccine against vaccine-type community-acquired pneumonia in at-risk older adults. Vaccine 2018;36:1477-83.

19. Rudnick W, Liu Z, Shigayeva A, et al. Pneumococcal vaccination programs and the burden of invasive pneumococcal disease in Ontario, Canada, 1995-2011. Vaccine 2013;31:5863-71.

20. Breiman RF, Keller DW, Phelan MA, et al. Evaluation of effectiveness of the 23-valent pneumococcal capsular polysaccharide vaccine for HIV-infected patients. Archives of Internal Medicine 2000;160:2633-8.

21. Shapiro ED, Berg AT, Austrian R, et al. The protective efficacy of polyvalent pneumococcal polysaccharide vaccine. New England Journal of Medicine 1991;325:1453-60.

22. Greenberg RN, Gurtman A, Frenck RW, et al. Sequential administration of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine in pneumococcal vaccine-naïve adults 60–64 years of age. Vaccine 2014;32:2364-74.

23. Jackson LA, Gurtman A, van Cleeff M, et al. Influence of initial vaccination with 13-valent pneumococcal conjugate vaccine or 23-valent pneumococcal polysaccharide vaccine on anti-pneumococcal responses following subsequent pneumococcal vaccination in adults 50 years and older. Vaccine 2013;31:3594-602.

24. Musher DM, Rueda AM, Nahm MH, Graviss EA, Rodriguez-Barradas MC. Initial and subsequent response to pneumococcal polysaccharide and protein-conjugate vaccines administered sequentially to adults who have recovered from pneumococcal pneumonia. Journal of Infectious Diseases 2008;198:1019-27.

25. Goldblatt D, Southern J, Andrews N, et al. The immunogenicity of 7-valent pneumococcal conjugate vaccine versus 23-valent polysaccharide vaccine in adults aged 50-80 years. Clinical Infectious Diseases 2009;49:1318-25.

26. de Roux A, Schmole-Thoma B, Siber GR, et al. Comparison of pneumococcal conjugate polysaccharide and free polysaccharide vaccines in elderly adults: conjugate vaccine elicits improved antibacterial immune responses and immunological memory. Clinical Infectious Diseases 2008;46:1015-23.

27. Miernyk KM, Butler JC, Bulkow LR, et al. Immunogenicity and reactogenicity of pneumococcal polysaccharide and conjugate vaccines in Alaska native adults 55-70 years of age. Clinical Infectious Diseases 2009;49:241-8.

28. MacIntyre CR, Ridda I, Gao Z, et al. A randomized clinical trial of the immunogenicity of 7-valent pneumococcal conjugate vaccine compared to 23-valent polysaccharide vaccine in frail, hospitalized elderly. PLoS ONE [Electronic Resource] 2014;9:e94578.

29. Caya CA, Boikos C, Desai S, Quach C. Dosing regimen of the 23-valent pneumococcal vaccination: a systematic review. Vaccine 2015;33:1302-12.

30. Jackson L, Benson P, Sneller V, et al. Safety of revaccination with pneumococcal polysaccharide vaccine. JAMA 1999;281:243-8.

31. Musher DM, Manoff SB, McFetridge RD, et al. Antibody persistence 10 years after 1st and 2nd doses of 23 valent pneumococcal polysaccharide vaccine and immunogenicity and safety of 2nd and 3rd doses in older adults. Human Vaccines 2011;7:919-28.

32. Ohshima N, Nagai H, Matsui H, et al. Sustained functional serotype-specific antibody after primary and secondary vaccinations with a pneumococcal polysaccharide vaccine in elderly patients with chronic lung disease. Vaccine 2014;32:1181-6.

33. Torda A, Chong Q, Lee A, et al. Invasive pneumococcal disease following adult allogeneic hematopoietic stem cell transplantation. Transplant Infectious Disease 2014;16:751-9.

34. Kumar D, Humar A, Plevneshi A, et al. Invasive pneumococcal disease in solid organ transplant recipients--10-year prospective population surveillance. American Journal of Transplantation 2007;7:1209-14.

35. Pelton SI, Weycker D, Farkouh RA, et al. Risk of pneumococcal disease in children with chronic medical conditions in the era of pneumococcal conjugate vaccine. Clinical Infectious Diseases 2014;59:615-23.

36. Shea KM, Edelsberg J, Weycker D, et al. Rates of pneumococcal disease in adults with chronic medical conditions. Open Forum Infect Dis 2014;1:ofu024.

37. Lee Y, Huang Y, Kim S, et al. Trends in invasive pneumococcal disease in cancer patients after the introduction of 7-valent pneumococcal conjugate vaccine: a 20-year longitudinal study at a major urban cancer center. Clinical Infectious Diseases 2018;66:244-53.

38. Baxter R, Yee A, Aukes L, et al. Risk of underlying chronic medical conditions for invasive pneumococcal disease in adults. Vaccine 2016;34:4293-7.

39. Weycker D, Farkouh RA, Strutton DR, et al. Rates and costs of invasive pneumococcal disease and pneumonia in persons with underlying medical conditions. BMC Health Services Research 2016;16:182.

40. Inghammar M, Engstrom G, Kahlmeter G, et al. Invasive pneumococcal disease in patients with an underlying pulmonary disorder. Clinical Microbiology & Infection 2013;19:1148-54.

41. Klemets P, Lyytikainen O, Ruutu P, et al. Risk of invasive pneumococcal infections among working age adults with asthma. Thorax 2010;65:698-702.

42. Wotton CJ, Goldacre MJ. Risk of invasive pneumococcal disease in people admitted to hospital with selected immune-mediated diseases: record linkage cohort analyses. Journal of Epidemiology & Community Health 2012;66:1177-81.

43. Jackson ML, Nelson JC, Jackson LA. Risk factors for community-acquired pneumonia in immunocompetent seniors. Journal of the American Geriatric Society 2009;57:882-8.

44. Watt JP, O'Brien KL, Benin AL, et al. Risk factors for invasive pneumococcal disease among Navajo adults. American Journal of Epidemiology 2007;166:1080-7.

45. Naidu L, Chiu C, Habig A, et al. Vaccine preventable diseases and vaccination coverage in Aboriginal and Torres Strait Islander people, Australia 2006–2010. Communicable Diseases Intelligence 2013;37 Suppl:S1-95.

46. Ioannides S, Beard F, Larter N, et al. Vaccine preventable diseases and vaccination coverage in Aboriginal and Torres Strait Islander people, Australia, 2011-2015. Communicable Diseases Intelligence 2019;43:i-136.

47. Bonten MJM, Huijts SM, Bolkenbaas M, et al. Polysaccharide conjugate vaccine against pneumococcal pneumonia in adults. New England Journal of Medicine 2015;372:1114-25.

48. Menzies RI, Jayasinghe SH, Krause VL, Chiu CK, McIntyre PB. Impact of pneumococcal polysaccharide vaccine in people aged 65 years or older. Medical Journal of Australia 2014;200:112-5.

49. Ochoa-Gondar O, Vila-Corcoles A, Rodriguez-Blanco T, et al. Effectiveness of the 23-valent pneumococcal polysaccharide vaccine against community-acquired pneumonia in the general population aged ≥60 years: 3 years of follow-up in the CAPAMIS study. Clinical Infectious Diseases 2014;58:909-17.

50. Suzuki M, Dhoubhadel BG, Ishifuji T, et al. Serotype-specific effectiveness of 23-valent pneumococcal polysaccharide vaccine against pneumococcal pneumonia in adults aged 65 years or older: a multicentre, prospective, test-negative design study. The Lancet Infectious Diseases 2017;17:313-21.