# Coversheet on evidence assessment by ATAGI using the GRADE framework for the use of 20-valent pneumococcal conjugate vaccine (20vPCV) in children

*Summary of key methods and decisions on evidence assessment using GRADE for developing ATAGI recommendations on the use of 20-valent pneumococcal conjugate vaccine (20vPCV) in children for the Australian Immunisation Handbook pneumococcal disease chapter.*

## Background

- 20vPCV was TGA approved on 5 January 2024 for children aged ≥6 weeks.
- ATAGI undertook GRADE assessment in 2023 to make relevant recommendations on its use in anticipation of the availability of this vaccine in Australia.
- In November 2023 PBAC recommended that 20vPCV be a designated vaccine for the purposes of the National Health Act 1953, for the prevention of pneumococcal disease in the following paediatric populations: all non-Indigenous infants and Aboriginal and Torres Strait Islander infants living in Australian Capital Territory (ACT), New South Wales (NSW), Victoria (Vic) and Tasmania (Tas) aged <12 months in a **2+1 schedule,** Aboriginal and Torres Strait Islander children living in Northern Territory (NT), Queensland (QLD), South Australia (SA) and Western Australian (WA) and children diagnosed with certain risk conditions (as per the AIH), aged <12 months in a **3+1 schedule.** Children aged ≥12 months with a NIP-funded risk condition.
- In 2024, when this GRADE assessment was undertaken, the ATAGI recommendations were 13vPCV or 15vPCV in a 2+1 schedule for all non-Indigenous infants and Aboriginal and Torres Strait Islander infants living in Australian Capital Territory (ACT), New South Wales (NSW), Victoria (Vic) and Tasmania (Tas)**.** 13vPCV or 15vPCV followed by up to a maximum of 2 doses of 23-valent pneumococcal polysaccharide vaccine (23vPPV) for Aboriginal and Torres Strait Islander children living in Northern Territory (NT), Queensland (QLD), South Australia (SA) and Western Australian (WA) and children diagnosed with certain risk conditions (as per the AIH).
- In 2025, ATAGI provided advice to the Department of Health, Disability and Ageing on the optimal pneumococcal vaccine schedule for children. As a result of this advice, the following changes were made to the childhood pneumococcal vaccine schedule: 20vPCV became the preferred vaccine over 13vPCV and 23vPPV, all Aboriginal and Torres Strait Islander children were recommended a 3+1 schedule (i.e. the schedule for those children in ACT, NSW, Vic and Tas changed from a 2+1 to a 3+1 schedule), and 23vPPV was no longer part of the recommended schedule. The GRADE assessment was updated to reflect these changes. These also became the National Immunisation Program funded recommendations.
- 20vPCV contains the following serotypes: 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F. 13 of these are shared with 13vPCV and 15 are shared with 15vPCV. The unique serotypes to 20vPCV that are not contained in either 13vPCV or 15vPCV are:  8, 10A, 12F, 15B.

## Research questions

1. Should Prevenar 20 (20-valent pneumococcal vaccine [20vPCV]) be recommended instead of 13vPCV for non-Indigenous infants without risk conditions to prevent pneumococcal disease?

**Table 1. PICO 1: 20vPCV vs. 13vPCV**

| | |
|---|---|
| Population | Non-Indigenous infants |
| Intervention | 20vPCV (2+1) |
| Comparator | 13vPCV (2+1) |
| Outcomes | *Critical*<br>• Serious adverse events (SAE)<br>*Important*<br>• Difference in proportion of participants with IgG response rate* (IgG GMCs ≥0.35 µg/mL) post dose 3<br>• Difference in proportion of participants with IgG response rate* (IgG GMCs ≥0.35 µg/mL) post dose 2<br>• IgG GMC ratios post dose 3<br>• IgG GMC rations post dose 2<br>• OPA response rate* post dose 3<br>• OPA response rate* post dose 2<br>• Local adverse events<br>• Systemic adverse events |

*Abbreviations:* 13vPCV=13-valent pneumococcal conjugate vaccine; 20vPCV=20-valent pneumococcal conjugate vaccine; AE=adverse event; CI=confidence interval; GMC=geometric mean concentrations; GMT=geometric mean titres; ID=identification; IgG=immunoglobulin G; LCI=lower confidence interval; NR=not reported; OPA=opsonophagocytic activity; PD=post dose; RCTs=randomised controlled trials; SAE=serious adverse events; ST=serotype; UCI=upper confidence interval.

* IgG response rate defined as: proportion of participants with IgG GMCs ≥0.35 ug/mL. OPA response rate defined as OPA titres ≥lower limit of quantitation (LLOQ)

1. Should 20vPCV be recommended instead of 13vPCV for Aboriginal and Torres Strait Islander infants and children diagnosed with certain risk conditions for the prevention of pneumococcal disease?

**Table 2. PICO 2: 20vPCVvs. 13vPCV+23vPPV**

| | |
|---|---|
| Population | Aboriginal and Torres Strait Islander infants and children diagnosed with certain risk conditions (as listed in the Australian Immunisation Handbook) |
| Intervention | 20vPCV (3+1) |
| Comparator | 13vPCV (3+1) + 23vPPV |
| Outcomes | *Critical*<br>• Serious adverse events (SAE)<br>*Important*<br>• Difference in proportion of participants with IgG response rate* (IgG GMCs ≥0.35 µg/mL) post dose 4<br>• Difference in proportion of participants with IgG response rate* (IgG GMCs ≥0.35 µg/mL) post dose 3<br>• Proportion of participants with IgG response rate* (IgG GMCs ≥0.35 µg/mL) post 1 dose<br>• IgG GMC ratios post dose 4<br>• IgG GMC rations post dose 3<br>• IgG GMCs post 1 dose PCV |

| | |
|---|---|
| | • IgG GMCs post PPV<br>• Local adverse events<br>• Systemic adverse events |

*Abbreviations:* 13vPCV=13-valent pneumococcal conjugate vaccine; 20vPCV=20-valent pneumococcal conjugate vaccine; 23vPPV=23-valent pneumococcal polysaccharide vaccine; AE=adverse event; CI=confidence interval; GMC=geometric mean concentrations; GMT=geometric mean titres; ID=identification; IgG=Immunoglobulin G; LCI=lower confidence interval; NR=not reported; OPA=opsonophagocytic activity; PD=post dose; RCTs=randomised controlled trials; SAE=serious adverse events; ST=serotype; UCI=upper confidence interval.

* IgG response rate defined as: proportion of participants with IgG GMCs ≥0.35 ug/mL

## Literature search

A literature search was performed on 3/5/2023 to identify studies assessing immunogenicity, efficacy and/or safety outcomes of the 20vPCV vaccine in children. Details of the search methods are presented in Appendix A. Citations were selected for review if they met the following criteria:

- *Study type:* Randomised controlled trial (RCT), observational study
- *Population:* Children aged <18 years
- *Intervention:* 20vPCV or 20vPCV+23vPPV
- *Comparator:* 13vPCV or 13vPCV+23vPPV
- *Outcomes:* Effectiveness, efficacy, immunogenicity, safety

Only 1 citation met these above criteria. In this study the comparison was between 20vPCV and 13vPCV in a 3+1 schedule. No published studies were found for the comparison was between 20vPCV and 13vPCV in a 2+1 schedule. No studies were done in Aboriginal and Torres Strait Islander infants nor in infants with risk conditions.

Two of the included studies did not have published journal articles at the time of the searches and of these, only one had results posted on clinical trials.gov. However, there were no statistical analysis plans for either and the reported outcomes in the GRADE were not all provided on clinical trials.gov. For these two unpublished studies the clinical study reports (CSRs) were not provided by the Sponsor, instead data tables were provided and were utilised for all outcomes for the GRADE assessment.

Prior to publication of the GRADE the known studies were checked for publicly available information and where relevant included corresponding publications, updates to results posted on clinicaltrials.gov, public data from the PBAC public summary document and TGA product information.

## Inclusion criteria and rationale

**Table 3. Rationale for PICO and inclusion criteria**

| Inclusion criteria | Rationale |
|---|---|
| Study type:<br>RCT, observational study | All study types comparing 20vPCV to 13vPCV in children were included. Single arm trials without a comparison to 13vPCV were excluded.<br>No efficacy or effectiveness studies with clinical outcomes were identified. |
| Population | The population groups were initially based on the groups recommended to receive pneumococcal vaccine but were updated to be based on the current groups recommended to receive pneumococcal vaccine in the Australian Immunisation Handbook following ATAGI optimal advice on pneumococcal vaccination in children.<br>PICO 2 incorporates Aboriginal and Torres Strait Islander children, infants diagnosed with certain risk conditions at ≤12 months of age as well as people diagnosed with certain risk conditions, aged ≥12 months to <18 years. This is because these populations receive a 3+1 schedule, although the timing of doses may differ depending on time of diagnoses. |
| Intervention<br>20vPCV | 20vPCV (2+1) alone or 20vPCV (3+1) |

| | |
|---|---|
| Comparator<br><br>13vPCV<br><br>13vPCV+23vPPV | Non-Indigenous infants and Aboriginal and Torres Strait Islander infants living in ACT, NSW, Vic and Tas were recommended to receive 13vPCV alone in a 2+1 schedule and Aboriginal and Torres Strait Islander infants living in NT, QLD, SA, WA and infants and children diagnosed with certain risk condition were recommended to receive 13vPCV in a 3+1 schedule followed by 2 doses of 23vPPV.<br>No studies were identified that included a 3+1 PCV schedule followed by 2 doses of 23vPPV (1 study identified where participants received 3 PCV doses + 1 23vPPV dose and had results post PPV dose). For PICO 2, majority of included studies assessed 20vPCV vs 13vPCV on a 3+1 PCV schedule alone (without 23vPPV). |
| Outcomes | The outcomes included are as stated above in Table 1 and Table 2. No studies were identified which included efficacy or effectiveness against clinical outcomes |
| | Each important or critical outcome was discussed iteratively and ranked based on the consensus of ATAGI. |
| | General framework (depending on outcomes measured in studies available):<br>*Critical*<br>• Mortality due to invasive pneumococcal disease<br>• Invasive pneumococcal disease<br>• Pneumococcal pneumonia<br>• Serious adverse events<br>*Important*<br>• Difference in IgG GMC response rate^<br>• IgG GMC ratio<br>• OPA GMT response rate^<br>• OPA GMT ratios<br>• IgG GMC ratios<br>• Local adverse events<br>• Systemic adverse events<br>Note: Some outcomes may be missing in GRADE projects due to absence of data from available studies. Additional outcomes specifically reported in studies were included due to relevance. |
| | Non-inferiority margins were consistent across studies. For the difference in IgG response rate outcome, all studies used a margin of LCI>-10% points for non-inferiority and LCI>10% points for superiority. IgG GMC ratio margins were non-inferiority LCI>0.5 and superiority LCI>2.0. OPA response rates did not have predefined margins but were assessed as to whether they had overlapping confidence intervals. |

*Abbreviations:* ACT=Australian Capital Territory; ATAGI=Australian Technical Advisory Group on Immunisation; EP=evidence profile; GMC=geometric mean concentration; GMT=geometric mean titres; IgG=immunoglobulin; IPD=invasive pneumococcal disease; LCI=lower confidence interval; NSW=New South Wales; NT=Northern Territory; OPA=opsonophagocytic activity; QLD=Queensland; SA=South Australia; Tas=Tasmania; Vic=Victoria, WA=Western Australia.

^IgG response rate defined as: proportion of participants with IgG GMCs ≥0.35 ug/mL. OPA response rate defined as OPA titres ≥LLOQ

## Risk of bias assessment

Risk of bias (RoB) was assessed for all selected studies using the standard GRADE criteria. Two assessors undertook this using the RoB 2.0 tool for randomised controlled trials (see Appendix B).

# Appendix A: Literature search strategy

**MEDLINE: 20 valent pneumococcal conjugate vaccine in children – immunogenicity, efficacy and safety (as at 03.05.23)**

Database: MEDLINE(R) All including Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946-current>
Search Strategy:

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1 exp Streptococcus pneumoniae/ (24596)
2 (streptococc$ adj5 pneumo$).tw. (28317)
3 exp Pneumococcal Infections/ (22431)
4 exp Pneumococcal Vaccines/ (8864)
5 pneumococc$.tw. (29487)
6 1 or 2 or 3 or 4 or 5 (54031)
7 (twenty valen$ or twenty-valen$ or 20 valen$ or 20-valen$ or 20valen$).tw. (65)
8 (20v or 20vPCV$ or PCV 20$ or PCV-20$ or PCV20$).tw. (208)
9 7 or 8 (240)
10 6 and 9 (93)
11 Apexxnar$.tw. (2)
12 ("prevnar 20" or prevnar-20 or prevnar20 or "prevenar 20" or prevenar-20 or prevenar20).tw. (4)
13 11 or 12 (5)
14 10 or 13 (95)
15 exp Immunogenicity, Vaccine/ (3289)
16 immunogen$.tw. (90510)
17 exp Antibodies, Bacterial/ (52336)
18 exp Antibody Formation/ (63582)
19 (antibod$ adj2 (respons$ or form$)).tw. (61860)
20 (immun$ adj2 (respon$ or protect$)).tw. (357134)
21 exp Seroconversion/ (1165)
22 seroconver$.tw. (21474)
23 seroprotect$.tw. (1964)
24 exp Treatment Outcome/ (1236700)
25 efficac$.tw. (1075292)
26 effective$.tw. (2483887)
27 exp Safety/ (88571)
28 exp Safety-Based Drug Withdrawals/ (416)
29 exp "Drug-Related Side Effects and Adverse Reactions"/ (131280)
30 exp Product Surveillance, Postmarketing/ (18104)
31 exp Drug Evaluation/ (42054)
32 exp Adverse Drug Reaction Reporting Systems/ (8771)
33 (adverse adj2 (effect$ or event$)).tw. (451659)
34 (safe or safety or aefi or aesi).tw. (1009355)
35 ((post marketing or post-marketing or postmarketing or post licensure or post-licensure or postlicensure) adj2 (surveillance or monitor$)).tw. (3582)
36 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 (5352845)
37 14 and 36 (38)
38 limit 37 to "all child (0 to 18 years)" (13)
39 exp Infant/ (1246560)
40 exp Child/ (2140276)
41 (baby or babies or infant$ or toddler$ or child$ or adolescen$ or pediatric$ or paediatric$).tw. (2324965)
42 39 or 40 or 41 (3525131)
43 37 and 42 (12)
44 38 or 43 (17)

**EMBASE: 15 valent pneumococcal conjugate vaccine in children – immunogenicity, efficacy and safety (as at 4.05.23)**

Database: Embase <1974 to 2023 May 02>
Search Strategy:

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1 exp Streptococcus pneumoniae/ (49349)
2 (streptococc$ adj5 pneumo$).tw. (35569)
3 exp pneumococcal infection/ (19444)
4 exp Pneumococcus vaccine/ (23328)
5 pneumococc$.tw. (36222)
6 1 or 2 or 3 or 4 or 5 (84905)
7 ("twenty valen$" or twenty-valen$ or 20 valen$ or 20-valen$ or 20valen$).tw. (80)
8 (20v or 20vPCV$ or PCV 20$ or PCV-20$ or PCV20$).tw. (436)
9 7 or 8 (462)
10 6 and 9 (135)
11 Apexxnar$.tw. (4)
12 ("prevnar 20" or prevnar-20 or prevnar20 or "prevenar 20" or prevenar-20 or prevenar20).tw. (16)
13 11 or 12 (19)
14 10 or 13 (149)
15 exp vaccine immunogenicity/ (6518)
20 (immun$ adj2 (respon$ or protect$)).tw. (471715)
21 exp seroconversion/ (29288)
22 seroconver$.tw. (28798)
23 seroprotect$.tw. (2550)
24 exp drug efficacy/ (1015863)
25 efficac$.tw. (1599595)
31 (adverse adj2 (effect$ or event$)).tw. (727431)
32 (safe or safety or aefi or aesi).tw. (1554641)
33 ((post marketing or post-marketing or postmarketing or post licensure or post-licensure or postlicensure) adj2 (surveillance or monitor$)).tw. (5644)
34 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 (6818769)
35 14 and 34 (64)
36 limit 35 to (infant <to one year> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>) (1)

16 immunogen$.tw. (121249)
17 exp bacterium antibody/ (26923)
18 exp antibody production/ (62351)
19 (antibod$ adj2 (respons$ or form$)).tw. (72087)
26 effective$.tw. (3280550)
27 exp drug safety/ (557999)
28 exp postmarketing surveillance/ (39145)
29 exp drug surveillance program/ (26702)
30 exp adverse drug reaction/ (633928)
37 exp infant/ (1131449)
38 exp child/ (3076933)
39 exp adolescent/ (1755874)
40 (baby or babies or infant$ or toddler$ or child$ or adolescen$ or pediatric$ or paediatric$).tw. (2973574)
41 37 or 38 or 39 or 40 (4702971)
42 35 and 41 (17)
43 36 or 42 (17)

**Cochrane Library Central Register of Controlled Trials (CENTRAL), Issue 2 of 12, February 2022: 15 valent pneumococcal conjugate vaccine in children – immunogenicity, efficacy and safety (as at 05.05.23)**

ID Search Hits
#1 MeSH descriptor: [Streptococcus pneumoniae] explode all trees 742
#2 (streptococc* NEAR/5 pneumo*):ti,ab,kw 1949
#3 MeSH descriptor: [Pneumococcal Infections] explode all trees 922
#4 MeSH descriptor: [Pneumococcal Vaccines] explode all trees 1170
#5 pneumococc*:ti,ab,kw 2827
#6 #1 OR #2 OR #3 OR #4 OR #5 3799
#7 ("twenty valen*" OR "twenty-valen*" OR "20 valen*" OR "20-valen*" OR 20valen*):ti,ab,kw 0
#8 (20v OR 20vPCV* OR "PCV 20*" OR "PCV-20*" OR PCV20*):ti,ab,kw 37
#9 #7 OR #8 37
#10 #6 AND #9 30
#11 Apexxnar*:ti,ab,kw 2
#12 ("prevnar 20" or "prevnar-20" or prevnar20 or "prevenar 20" or prevenar-20 or prevenar20):ti,ab,kw 5
#13 #11 OR #12 6
#14 #10 OR #13 31
#15 MeSH descriptor: [Immunogenicity, Vaccine] explode all trees 639
#16 immunogen*:ti,ab,kw 16293
#17 MeSH descriptor: [Antibodies, Bacterial] explode all trees 1864
#18 MeSH descriptor: [Antibody Formation] explode all trees 1103
#19 (antibod* NEAR/2 (respons* OR form*)):ti,ab,kw 5561
#20 (immun* NEAR/2 (respon* OR protect*)):ti,ab,kw 17081
#21 MeSH descriptor: [Seroconversion] explode all trees 333
#22 seroconver*:ti,ab,kw 4540
#23 seroprotect*:ti,ab,kw 1338
#24 MeSH descriptor: [Treatment Outcome] explode all trees 180401
#25 efficac*:ti,ab,kw 428362
#26 effective*:ti,ab,kw 406006
#27 MeSH descriptor: [Safety] explode all trees 18462
#28 MeSH descriptor: [Safety-Based Drug Withdrawals] explode all trees 11
#29 MeSH descriptor: [Drug-Related Side Effects and Adverse Reactions] explode all trees 5323
#30 MeSH descriptor: [Product Surveillance, Postmarketing] explode all trees 434
#31 MeSH descriptor: [Drug Evaluation] explode all trees 5966
#32 MeSH descriptor: [Adverse Drug Reaction Reporting Systems] explode all trees 157
#33 (adverse NEAR/2 (effect* OR event*)):ti,ab,kw 305901
#34 (safe OR safety OR aefi OR aesi):ti,ab,kw 326058
#35 (("post marketing" OR "post-marketing" OR postmarketing OR "post licensure" OR "post-licensure" OR postlicensure) NEXT/2 (surveillance OR monitor*)):ti,ab,kw 698
#36 #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 964970
#37 #14 AND #36 30
#38 MeSH descriptor: [Infant] explode all trees 41571
#39 MeSH descriptor: [Child] explode all trees 77718
#40 (baby OR babies OR infant* OR toddler* OR child* OR adolescen* OR pediatric* OR paediatric*):ti,ab,kw 334678
#41 #38 OR #39 OR #40 334678
#42 #37 AND #41 13

# Appendix B: Risk of bias – RoB 2.0

| Study ID<br>NCT number | Outcomes | Randomisation process | Deviation from intervention | Missing data | Measurement of outcomes | Selection of the reported results | Overall bias |
|---|---|---|---|---|---|---|---|
| B7471012<br>NCT4546425<br>CONFIDENTIAL CSR | Immunogenicity | Low | Low | Low | Low | Some concerns | Some concerns |
| | Safety | Low | Low | Low | Low | Low | Low |
| B7471011<br>NCT04382326<br>CONFIDENTIAL CSR | Immunogenicity | Low | Low | Low | Low | Some concerns | Some concerns |
| | Safety | Low | Low | Low | Low | Low | Low |
| Senders et al<br>B7471003<br>NCT03512288 | Immunogenicity | N/A | N/A | N/A | N/A | N/A | N/A |
| | Safety | Low | Low | Low | Low | Low | Low |

# References


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2. Hajdu G, Hughes T, Ouedraogo GL, et al. Safety of a 4-Dose 20-Valent Pneumococcal Conjugate Vaccine Series in Infants: A Randomized Trial. *Pediatrics* 2024;154:e2023065218. Available from: https://doi.org/10.1542/peds.2023-065218
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10. conjugate, 20-valent adsorbed) vaccine. The Australian Government. Available from: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-02385-1.
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