Australian Immunisation Handbook 10th Edition

Responses to Public Consultation Submissions

Proposed changes to the infant pneumococcal vaccination schedule

Public consultation period: 1 September 2017 to 2 October 2017

Contents

1 Introduction

Public consultation on the proposed changes to the infant pneumococcal vaccination schedule in *The Australian Immunisation Handbook* 10th Edition (the Handbook) was conducted over a four-week period from 1 September 2017 to 2 October 2017, during which time the proposed changes were available on the Citizen Space website. The Immunisation Branch invited a range of stakeholders, committees, working groups and interested people to provide submissions. A list of organisations invited to comment on the draft recommendations is provided in **Appendix A**.

This report outlines the public consultation comments received specifically for the proposed changes. 14 submissions were received using the submission template provided on the Citizen Space website. Of these, 10 were on behalf of an organisation and four were as individuals (Table 1).

Table 1: List of respondents who made comment on the draft recommendations

Responder No.	Organisation
1.	Department of Health and Human Services, Victorian State Government
2.	Public Health Services, Tasmania
3.	Individual
4.	Department of Health and Human Services, Tasmanian State Government
5.	Individual
6.	Pius X Aboriginal Corporation
7.	Menzies School of Health Research
8.	Individual
9.	Health Protection NSW & NSW Chief Health Officer
10.	Communicable Disease Control Branch, SA Health
11.	Queensland Department of Health
12.	Professor of Paediatrics, UNSW Sydney
13.	Individual
14.	Royal Australian College of General Practitioners

The Australian Technical Advisory Group on Immunisation (ATAGI) considered all responses from the public consultation in October 2017 and, where necessary, revised the proposed changes in accordance with the submissions. Comments from the public consultation submissions and the ATAGI responses are summarised in the following section.

This report was submitted to the National Health and Medical Research Council (NHMRC) in October 2017 and was approved in November 2017.

2 Responses to public consultation submissions

2.1 Proposed changes to the infant pneumococcal vaccination schedule

	Comment	Proposed Action	Rationale
1a	Many children travel overseas just before they are 12 months old. Clear advice about the validity of the booster dose of Prevenar 13 if it is administered at 11 months or earlier is needed.	**Reviewed. No change in recommendation made.**	This comment relates to implementation and will be addressed in a review of the Australian Immunisation Register (AIR) due/overdue rules. Reference to this rule will be provided in the Handbook.
1b	Suggested sites for vaccine administration for a 12 month old for multiple injections e.g. anterolateral thigh and deltoids.	**Reviewed. No change in recommendation made.**	Already specified in the Handbook.
1c	Guidance for parents to pay for a booster dose for children who were not eligible for the free boost in the 2nd year of life.	**Reviewed. Change made to recommendation.**	Relevant scenario with a footnote added to Table 2b of submission indicating that an additional non-funded dose in the second year of life can maximise protection against Invasive Pneumococcal Disease (IPD) (although it is not routinely recommended).
1d	Vaccine software vendors are updated to implement the schedule in a timely manner.	**Reviewed. No change in recommendation made.**	This comment relates to implementation, specifically AIR updates, and will be managed by Department of Health (DOH) as per standard processes.
2	The schedule change will need to be well 'advertised' and promoted so as providers are aware.	**Reviewed. No change in recommendation made.**	This comment relates to implementation and will be managed by DOH as per standard processes.
3	I think parents will opt to have the immunisations over 2 visits if there are now 4 vaccines to be given. This may result in non-attendance for the 2nd visit and hence missed immunisations.	**Reviewed. No change in recommendation made.**	This comment relates to implementation and was noted as a potential risk in the public consultation document.
4a	Potential benefits/harms/consequences: Of interest, when the 7v valent pneumococcal vax was given to infants it virtually eliminated invasive disease due to these serogroups in all age groups in Tasmania, and it did so* without a 12 month dose. If it's the intrinsic (lower) immunogenicity of the additional strains in the13v vax that is the problem, the change in timing (from 6 to 12 months) may or may not help.	**Reviewed. No change in recommendation made.**	Issue already considered by ATAGI and discussed in public consultation document.

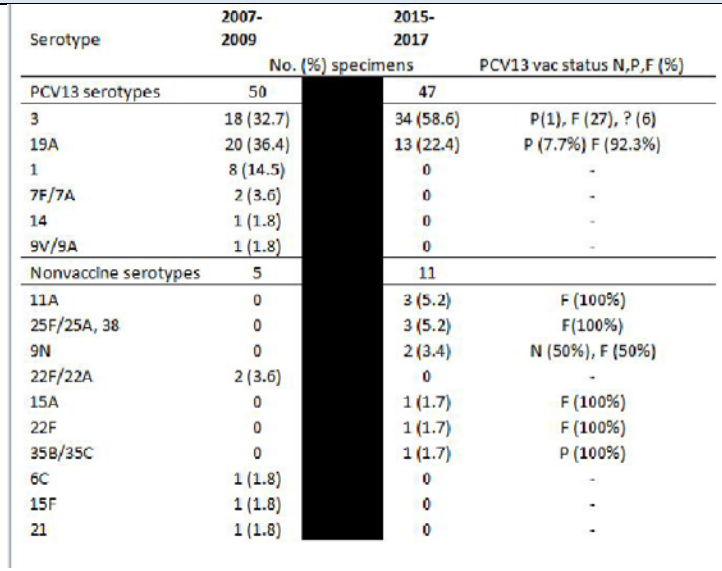
	Comment	Proposed Action	Rationale
	Other clinical/implementation considerations: As outlined, will require ongoing monitoring of the incidence of invasive disease across all age groups to check that by switching dose #3 to 12 months the direct and indirect protection against the 13v serogroups really does improve and that the burden of disease in 6-12 month old infants does not significantly increase.		
4b	As with any schedule change, significant warning, awareness raising and education will be required. Consider general practice software changes and prompts to assist. Consider 'baby book' reprinting/stickers to assist.	**Reviewed. No change in recommendation made.**	This comment relates to implementation and will be managed by DOH as per standard processes.
4c	Initially may cause confusion and increase in PHU workload due to increased phone calls.	**Reviewed. No change in recommendation made.**	This comment relates to implementation and was already discussed in public consultation document.
4d	Will mean that there is an extra vaccine at 12 months of age. Consider future consequences of replacing Menitorix with quadrivalent Mening vaccine and a separate Hib.	**Reviewed. No change in recommendation made.**	Issue of schedule crowding has been considered by ATAGI.
5	**Potential benefits/harms/consequences:** I think adding the pneumococcal vaccine to newborn is essentially, especially important to those vulnerable groups, pre-term babies as well as babies with some congenital medical conditions. **Other clinical/implementation considerations:** As i am not sure how likely the pneumococcal vaccine will cause the babies, I think after 6 months or do it around 1 year old could be helpful. Also prophylactics measurements recommended for parents could be helpful and help with vaccinated babies to overcome complications easily.	**Reviewed. No change in recommendation made.**	Comment noted with thanks. Pneumococcal vaccines are only studied and registered for use in infants from 6 weeks of age.
6	I agree with the recommended schedule adding the extra immunisation will give the 2 to 3 year olds coverage that seem to deplete in the present regime especially with Aboriginal children.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
7	**Further comments:** Re: Children who are currently recommended to receive four doses will continue to receive a dose at 6 months of age due to their increased risk of IPD. However, it is proposed that the fourth dose is given at 12 months of age rather than the currently recommended 12–18 months of age[1]. The ATAGI may be interested in data to come from our current RCTs, firstly PREVIX_COMBO[2] comparing the immunogenicity, nasopharyngeal carriage and otitis media in Aboriginal infants living in 5 remote regions of the NT and WA.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.

	Comment	Proposed Action	Rationale
	Infants are randomised at 28 to 38 days of age to one of three groups: 1. Synflorix (PHiD-CV10) at 2,4,6 months of age 2. Prevenar13 (PCV13) at 2,4,6 months of age 3. Synflorix (PHiD-CV10) at 1,2,4 months of age and PCV13 at 6 months. Our hypothesis is that a combination schedule (group 3) will be superior to single vaccine formulation schedules (groups 1 or 2). Immunogenicity outcomes are at 2,4, and 7 months of age. Our analysis plan is to report the proportion of infants with IgG GMC above threshold of 0.35 microg/L, and the Geometric mean concentration (GMC) for 23 pneumococcal serotypes and for proteinD (HiD) of non-typeable Haemophilus influenzae (the carrier protein in Synflorix). We have randomised all 425 children to the PREVIX_COMBO trial, and have achieved our sample size of 339 sera at 7 months of age. Testing IgG concentrations will be completed by November 2017. We also have 392 sera from infants at 2 or 4 months of age (including post first dose of PCV13).		
8	**Potential harm:** 1) Some children -may- have a poor reaction to the aluminium salt adjuvant because they cannot clear the metal from the body very efficiently, leading to a build-up of aluminium in the blood, bones, resulting in a constantly stimulated immune system, and mental development delay. (https://www.ncbi.nlm.nih.gov/pubmed/22235057) 2) Children with a MTHFR gene weakness should be screened and either - NOT given the vaccine at all - or should be given additional nutritional support, IE glutathione, or L-Cysteine to provide/support metallothionines to help clear the aluminium adjuvant from their system. Otherwise they will definitely have a developmental delay problem.(https://www.ncbi.nlm.nih.gov/pubmed/22099159) (http://resqua.com/100005927200207/what-ismthfr-a1298c-gene-mutation) **Implementation consideration:** 1) Screen those with a MTHFR gene weakness, to either skip the vaccine, or provide additional nutritional support to boost natural metallothionine levels so that the Aluminium adjuvant does not build up. **Further comments:** There are fast gene screening services available now days to make MTHFR screening before vaccines possible.	**Reviewed. No change in recommendation made.**	Comments not applicable or supported by body of evidence.
9a	**Potential benefits, harms or consequences:** The small increase in infant cases of IPD is an expected harm. What is the marginal cost-benefit of adopting a 3+1 schedule?	**Reviewed. No change in recommendation made.**	Marginal cost-benefit of a 3+1 schedule already considered by ATAGI.

	Comment	Proposed Action	Rationale
9b	**Other clinical or implementation considerations:** NSW notes the difficulties inherent in implementing any change to the NIP Schedule, particularly for general practice, and particularly where the change is a move in an existing vaccine schedule point (rather than a new vaccine). There are likely to be errors, most likely inadvertent administration of 3+1 or continuation of 3+0. NSW also notes potential crowding of the 12-month schedule point, particularly if meningococcal ACWY replaces Menitorix, and suggests that the Hib booster could be moved to the 18 month schedule point. If all these changes were to occur it would be preferable to implement them at the same time - this would reduce the education burden, and the introduction of new vaccines along with moving pneumococcal to 12 months would be likely to create increased awareness of the change amongst providers and increase ompliance with the schedule.	**Reviewed. No change in recommendation made.**	Issue of schedule crowding has been considered by ATAGI.
10a	**Further comments:** Overall sounds like a good idea, but seems the impact of changing to 2+1 is not as great for severe IPD (particularly in children <12 months) compared to all IPD. Has there been an assessment of burden of disease in these different age groups? From a quick search it appears children <12 months of age have higher IPD mortality and meningitis (and presumably higher rate of meningitis-related long-term complications), compared to children >12 months. Does the small increase of severe IPD in kids <12 months on the 2+1 schedule outweigh the burden of disease in children >12 months on the current 3+0 schedule? I suspect not, but would be worth considering before making the change.	**Reviewed. No change in recommendation made.**	Issue already considered by ATAGI and discussed in public consultation document.
10b	The catch-up schedule for all other children (not including Aboriginal and Torres Strait Islander children living in QLD/NT/WA/SA or children at increased risk) does not include children who are ≥ 12 months old, but received x3 pneumococcal vaccines before 12 months (i.e. at 2, 4 and 6 months as per the current schedule). Should these children also be offered a single booster, i.e. at the 18 month schedule point, or at any time up to 24 or 36 months (based on table 3)?	**Reviewed. Change made to recommendation.**	Relevant scenario with a footnote added to Table 2b of submission indicating that an additional non-funded dose in the second year of life can maximise protection against IPD (although it is not routinely recommended).
11a	**Potential benefits/harms/ consequences:** In addition to the routine National Immunisation Program vaccines scheduled at the 12 month age point, Aboriginal and Torres Strait Islander children in Queensland are eligible to receive: • hepatitis A vaccine (with a booster dose given at 18 months of age) • hepatitis B vaccine for low birth weight or medical at risk children [1] • Japanese encephalitis (JE) vaccine (for children resident on the outer Torres	**Reviewed. No change in recommendation made.**	This comment relates to implementation. Issue of schedule crowding has been considered by ATAGI.

	Comment	Proposed Action	Rationale
	Strait Islands)[2] Therefore under the proposed pneumococcal vaccination schedule change, Aboriginal and Torres Strait Islander children in Queensland could potentially receive four to six vaccines at 12 months, depending on their location and medical history. This number of vaccines will create a crowded schedule at 12 months of age and has the potential to impact on the appropriate and timely vaccination of Indigenous children for the following reasons: • Aboriginal and Torres Strait Islander parents may be hesitant to agree to multiple vaccinations at one age point and this may cause vaccination delays • Provider comfort and confidence with administering multiple vaccines at one visit may also impact on the timeliness of vaccination, and • Deferring vaccination as a result of concerns from either the parent or provider may lead to missed vaccinations if families do not return to complete a vaccination schedule. It would be appreciated if ATAGI investigate options to reduce the number of vaccinations at the 12 month age point for Aboriginal and Torres Strait Islander children, as part of the proposed changes to pneumococcal vaccination schedule. [1] It is likely that a high proportion of Aboriginal and Torres Strait Islander children may require an additional dose of hepatitis B vaccine at 12 months of age. This is evidenced using data from the 2016 Queensland Health Close the Gap Performance Report which indicated that Aboriginal and Torres Strait Islander babies were 1.8 times more likely to be of "low birth weight" and therefore potentially medically at risk compared with non-Indigenous infants. [2] Queensland Health funds Japanese encephalitis (JE) for residents of the outer Torres Strait Islands. Children are vaccinated in a 2 dose schedule at 12 months and at 18 months of age.		
11b	**Other clinical or implementation considerations:** <u>Clear guidelines.</u> It will be essential that clear guidelines for providers about the scheduling requirements of pneumococcal vaccination during any transition period are made available. The catch up tables in the public consultation document use footnotes to provide further detail. It would be preferable if the use of footnotes could be avoided and that any additional detail could be displayed in an easy to follow format.	**Reviewed. No change in recommendation made.**	This comment also relates to implementation. Additional in text guidance will be included in the Handbook detailing some of the principles around catch up.

	Comment	Proposed Action	Rationale
11c	Catch up booster dose for young children. Our experience in Queensland has shown that approximately half of 13vPCV failures occur in the second year of life. To mitigate breakthrough disease, consideration should be given to providing a catch-up dose of 13vPCV to all children aged 12–23 months who have received their primary 3-dose schedule before 12 months of age.	**Reviewed. Change made to recommendation.**	Relevant scenario with a footnote added to Table 2b of submission indicating that an additional non-funded dose in the second year of life can maximise protection against IPD (although it is not routinely recommended).
11d	Children at high risk. Our experience in Queensland has highlighted that after an initial episode of invasive pneumococcal disease, both children and adults are at substantially higher risk of future disease. These individuals often do not have any predisposing medical conditions identified at the time of the first episode. Children who experience an episode of invasive pneumococcal disease in the first year of life should therefore be recognised as an at-risk group for future disease and should receive a 3-dose primary course with the booster dose at 12 months of age (3+1). Pneumococcal vaccination during this high-risk period should not be delayed for the purposes of clinical investigations into underlying medical conditions.	**Reviewed. Change made to recommendation.**	History of previous episode of Invasive IPD has been included as a risk factor for a subsequent episode of IPD (outlined in Attachment A of submission). Two key supporting references also added.
11e	**Further comments:** The Queensland Department of Health supports the proposed changes to the infant pneumococcal vaccination schedule given the evidence of breakthrough disease in the second year of life. Nevertheless, these changes if adopted should be considered in light of the impact they will make on the current National Immunisation Program schedule in Queensland.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
12	**Further comments:** I am the chief investigator of the current NHMRC funded TESTOV-Pneumo study -Evaluation Of The Effectiveness Of The 13-Valent Pneumococcal Conjugate Vaccine Against Pneumococcal Pneumonia In Children. We have preliminary data which we would be happy to share with ATAGI to help inform this consultation. Importantly we have pre and post 13vPCD data on pneumococcal serotypes causing severe pneumonia (empyema) in children. The pre-data have been published in: Strachan RE, Gilbert G, Martin A, McDonald T, Nixon G,Ranganathan S, Roseby R, Selvadurai H,Smith G,Soto-Martinez ME, Suresh S, Teoh L, Thapa K, Wainwright C, Jaffé A. Bacterial Causes of Empyema in Children, Australia, 2007– 2009. Emerging Infectious Diseases 2011; 17(10): 1839-1845. Our preliminary data on serotypes causing empyema (in preparation for a presentation to the Thoracic Society of Australia and New Zealand) are as follows:	**Reviewed. No change in recommendation made.**	Comment noted with thanks.

	Comment	Proposed Action	Rationale
	 Serotype / 2007-2009 / 2015-2017 / No. (%) specimens / PCV13 vac status N,P,F (%) PCV13 serotypes: 50 / 47 3: 18 (32.7) / 34 (58.6) / P(1), F (27), ? (6) 19A: 20 (36.4) / 13 (22.4) / P (7.7%) F (92.3%) 1: 8 (14.5) / 0 / - 7F/7A: 2 (3.6) / 0 / - 14: 1 (1.8) / 0 / - 9V/9A: 1 (1.8) / 0 / - Nonvaccine serotypes: 5 / 11 11A: 0 / 3 (5.2) / F (100%) 25F/25A, 38: 0 / 3 (5.2) / F(100%) 9N: 0 / 2 (3.4) / N (50%), F (50%) 22F/22A: 2 (3.6) / 0 / - 15A: 0 / 1 (1.7) / F (100%) 22F: 0 / 1 (1.7) / F (100%) 35B/35C: 0 / 1 (1.7) / P (100%) 6C: 1 (1.8) / 0 / - 15F: 1 (1.8) / 0 / - 21: 1 (1.8) / 0 / - We are currently analysing the data according to age but the data will not be available before the end of the consultation date- we would be happy to share these data with you once available. We also have surveillance data on serotype causes of less severe childhood pneumonia in Australia following the introduction of the 13vPCV which we are currently analysing. We also call on ATAGI to consider funding the TESTOV platform for ongoing surveillance given the likelihood of changes in the national pneumococcal vaccination schedule in the future. This platform gives a more accurate picture of serotypes causing pneumonia compared to the current national pneumococcal surveillance methods as we have previously demonstrated: Strachan RE, Cornelius A, Gilbert GL, Gulliver T, Martin A, McDonald T, Nixon G, Ranganathan S, Roseby R Selvadurai H, Smith G, Soto-Martinez ME, Suresh S, Teoh L, Thapa K, Wainwright C, Jaffé A. Pleural fluid nucleic acid testing enhances pneumococcal surveillance in children. Respirology 2012; 17, 114–119		
13	I believe that this document provides a comprehensive review of the clinical considerations	**Reviewed. No change in recommendation made.**	Comment noted with thanks.

	Comment	Proposed Action	Rationale
14	**Additional potential benefits, harms or consequences:** The RACGP is generally supportive of the proposed changes to infant pneumococcal vaccination recommendations to achieve longer lasting immunity. These changes to the pneumococcal vaccine schedule have implications for administration, and it will be important to clearly inform and support GPs and their practice teams through these changes. The RACGP believes a comprehensive implementation plan is needed to ensure both parents and providers clearly understand these changes. The RACGP is concerned that if these changes are not clearly communicated and understood by providers, there is a risk less children will receive the full vaccinations	**Reviewed. No change in recommendation made.**	This comment relates to implementation and will be managed by DOH as per standard processes.

3 Appendix A – Public consultation distribution list

An email was sent on 1 September 2017 to the following organisations/committees to advice of the consultation:

- Australian Health Ministers' Advisory Council
- Australian Health Protection Principal Committee
- Communicable Diseases Network Australia
- National Immunisation Committee
- Australian Technical Advisory Group on Immunisation
- Pharmaceutical Benefits Advisory Committee
- Advisory Committee on Vaccines
- General Practice Roundtable
- Royal Australasian College of Physicians
- Primary Health Networks
- Consumers Health Forum of Australia
- Australian Association of Practice Managers