Australian Government
Department of Health

AUSTRALIAN TECHNICAL ADVISORY GROUP ON IMMUNISATION (ATAGI) | **CLINICAL ADVICE**

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ATAGI CLINICAL ADVICE TO SUPPORT CHANGES TO THE NATIONAL IMMUNISATION PROGRAM (NIP) FROM 1 JULY 2018

It is important to read this statement in conjunction with the current online version of The Australian Immunisation Handbook available on the Immunise Australia website (www.immunise.health.gov.au).

Overview of the key changes to the childhood immunisation schedule from 1 July 2018

13 valent pneumococcal conjugate vaccine (13vPCV; Prevenar 13®)

- Infants who do not have a medical condition that causes an increased risk of invasive pneumococcal disease (IPD) will be provided *Prevenar 13*® in a 3-dose schedule at 2, 4 and 12 months of age. This includes:
  - *non-Aboriginal and Torres Strait Islander children in all states; and*
  - *Aboriginal and Torres Strait Islander children in ACT, NSW, TAS or VIC.*

  This dosing schedule replaces the 2, 4 and 6 month schedule which has been used to date.
- A nationally consistent 4-dose schedule of 13vPCV at 2, 4, 6 and 12 months will be provided to all:
  - *Aboriginal and Torres Strait Islander children in the NT, QLD, SA and WA; and*
  - *children with a medical condition associated with an increased risk of IPD.*

  This dosing schedule replaces the 2, 4, 6 and 12-18 months schedule which has been used to date.

Meningococcal vaccines (Meningococcal ACWY, Nimenrix®)

- Infants 12 months of age will be provided the 4-valent meningococcal conjugate (MenACWY) vaccine (Nimenrix®).
  - *Nimenrix® replaces the meningococcal C (MenC) vaccine, adding protection against three additional meningococcal serogroups.*
  - *This vaccine is scheduled at the same time as the first dose of measles-mumps-rubella (MMR vaccine) and the 12-month dose of 13vPCV.*

Haemophilus influenzae type b vaccines (monovalent Hib, ActHIB®)

- Infants 18 months of age will be provided the monovalent *Haemophilus influenzae* type b (Hib) vaccine (ActHIB®).
  - *This is the 4th dose of Hib-containing vaccine on the NIP schedule.*
  - *This Hib booster vaccine dose was previously scheduled at age 12 months of age and given as the combined Haemophilus influenzae type b-meningococcal C conjugate vaccine (Hib-MenC, Menitorix®).*
  - *The Hib-MenC vaccine will no longer be given under the NIP. However it is safe and effective to use Menitorix® instead of ActHIB® at the 18 month schedule point until supplies are exhausted.*

New schedule cards showing the diseases covered and vaccines given at each schedule point are available at www.health.gov.au/immunisation.

ATAGI recommendations for changes to the infant NIP schedule

Background

- Vaccination with 13vPCV has been highly effective in reducing pneumococcal disease in children, as well as providing indirect herd immunity protection to older persons who are not vaccinated.
  - *There has however been an increasing number of cases of IPD occurring in Australian children who have been fully vaccinated according to the current '3+0' schedule.*

- *Evidence suggests protection of children in Australia beyond the first year of life can be further improved by giving a booster dose of 13vPCV at age 12 months. This change is anticipated to further improve protection against pneumococcal disease in children beyond age 12 months.*
- *Evidence also suggests that the primary dosing schedule before 12 months of age remains the most effective approach for protecting infants against pneumococcal disease.*

- For children with increased risk for pneumococcal disease, the 4-dose schedule (3 infant doses at ages 2, 4 and 6 months with a booster dose in the second year of life) is to be made nationally consistent.
  - *Administering the booster dose at age 12 months (instead of 12 or 18 months) is designed to shorten the interval between the completion of the primary course and the booster dose and improve protection in the second year of life.*

- A dose of MenACWY 4-valent meningococcal conjugate vaccine (Nimenrix®) will replace the dose of meningococcal C vaccine (which was given in a combination vaccine formulation that included the Hib vaccine, Menitorix®).
  - *This will broaden protection against meningococcal disease caused by serogroups A, W and Y in addition to serogroup C among young Australian children.*

- MenC disease has been well controlled since the meningococcal C vaccine was included in the NIP from 2003.
  - *Since 2013, the occurrence of meningococcal W disease has been increasing rapidly in Australia. A smaller yet steady rise in the occurrence of meningococcal Y disease has also been seen since 2016.*
  - *Together, these two serogroups cause close to half of all recently reported cases of meningococcal disease. Young children aged <2 years have the highest rates of new cases reported.*
- A 4th dose of Hib vaccine in the second year of life (in addition to the 3 doses given at ages 2, 4 and 6 months) is required, acting as a booster dose, to prevent Hib disease later in childhood and ensure long term protection.
  - *This dose was previously given at age 12 months as the combined vaccine, Menitorix®. The introduction of a MenACWY vaccine at age 12 months means the meningococcal C component of Menitorix® will no longer be required, and the 4th dose of Hib can be given in a monovalent formulation (i.e. containing only Hib).*
  - *Considering the number of vaccine doses and the epidemiology of the diseases with a vaccine scheduled at age 12 months, ATAGI recommends that this 4th dose of Hib vaccine can be moved to the 18-month schedule point.*
  - *Australian data on Hib disease, vaccination coverage, community immunity, and international comparisons indicate postponement of the Hib dose from age 12 months to 18 months is unlikely to lead to an increased number of Hib disease cases among children aged 12–18 months.*
  - *It is safe and effective to use available supplies of Menitorix® until they are exhausted.*

General recommendations

- At the 12- and 18-month NIP schedule points, most children will require three injections.
- Aboriginal and Torres Strait Islander children living in NT, QLD, SA and WA will require four injections, as they are also recommended to receive the 1st dose of hepatitis A vaccine at 12 months of age.
- At each visit, the vaccine dose more likely to cause injection site reactions (e.g. pain, redness or swelling) should be given last in a visit, at an arm rather than the leg, and in a different limb from the other vaccines.
  - *Vaccines most likely to cause injection site reactions are 13vPCV at age 12 months, and diphtheria, tetanus and acellular pertussis (DTPa) vaccine at age 18 months.*

- In rare situations, a child may require additional vaccines at 12 and 18 months of age.
  - *This includes children with certain medical conditions, such as preterm infants who require an additional dose of hepatitis B vaccine at age 12 months.*
  - *An additional visit to administer vaccine dose(s) may be necessary. Advice on which vaccine dose/s can be deferred to the later visit can be provided by state/territory health authorities on a case by case basis.*

Specific recommendations

A) 13-valent pneumococcal conjugate vaccine – schedule transition recommendations

- For all non-Indigenous children or Aboriginal and Torres Strait Islander children living in ACT, NSW, TAS or VIC without a medical condition:[a]

- *Those born since 01 January 2018: give a 3rd dose at age 12 months according to the new schedule. A third dose of 13vPCV at six months of age is no longer required in children not at increased risk of invasive pneumococcal disease.*
- *Those born between 01 July 2017 and 31 December 2017: give a booster dose of 13vPCV at age 12 months or 2 months after the previous dose, whichever is later, regardless of whether they have already received a 3rd dose of 13vPCV at age 6 months.*
- *Those born prior to 01 July 2017 and have received 3 doses of 13vPCV according to the previous schedule at ages 2, 4 and 6 months: no further doses of 13vPCV are required or funded under the NIP.*

- Children with a diagnosed medical condition[b] between the ages of 6–12 months who have previously received 2 doses of 13vPCV (scheduled at age 2 and 4 months) should receive a 3rd dose of 13vPCV at diagnosis, followed by a booster dose at age 12 months or 2 months after the third dose, whichever is later.

- For children who have missed 13vPCV doses at the recommended schedule points or have a newly diagnosed medical condition and require catch-up doses, refer to the Catch-up section for pneumococcal vaccines in the online Australian Immunisation Handbook.

B) Meningococcal ACWY conjugate vaccine

- A single dose of MenACWY vaccine, Nimenrix®, is to be given at age 12 months for all children born since 1 July 2017. This is recommended regardless of whether the child has previously received one or more privately purchased doses of any brand of MenACWY vaccine in infancy. If a dose has been previously given, there should be a minimum interval of 8 weeks since the last dose in infancy.

C) *Hib* vaccine booster dose in second year of life

- All children aged 18 months from 1 July 2018 will be offered a Hib vaccine. If a child has already received a Hib vaccine at or after 12 months of age, they are not required to have an additional dose; however it is safe for them to do so.

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[a] As outlined in the Pneumococcal Chapter of the Australian Immunisation Handbook.
[b] As above