

Australian Technical Advisory Group on Immunisation (ATAGI) statement

Clinical advice for immunisation providers regarding the use of Menitorix[®] in delivering catch-up vaccinations, July 2013

Background

From 1 July 2013, the combined *Haemophilus influenzae* type b (Hib) and Meningococcal serogroup C (MenC) vaccine, Menitorix[®], will be added to the National Immunisation Program (NIP) schedule at 12 months of age. This combination vaccine will replace the single dose of monovalent meningococcal C conjugate vaccine (MenCCV) and booster dose of monovalent Hib vaccine previously scheduled at 12 months of age, which means one less injection is required at this schedule point. However, due to the use of the combination vaccine, issues may arise when planning catch-up vaccinations for either MenC or Hib. ATAGI recommends the following principles for planning catch-up vaccination schedules using the Hib-MenCCV combination vaccine, Menitorix[®]. Examples of acceptable approaches to a catch-up schedule for one catch-up scenario are provided in Table 1.

General principles for using Menitorix[®] in catch-up vaccination schedules, in children <10 years of age

- 1) *When required, Menitorix[®] can be used for catch-up vaccinations for either MenC or Hib in children <10 years of age.*

The product information (PI) for Menitorix[®] states that the vaccine is indicated for the prevention of invasive diseases caused by Hib and MenC. An upper age limit for administration is not stated in the indication for use however the PI does state that Menitorix[®] should be given in accordance with available official recommendations, usually from the age of 12 months onwards and before the age of 2 years. The ATAGI recommends that Menitorix[®] can be used for catch-up vaccinations for either MenC or Hib in children <10 years of age, if required. Although there is limited data on the use of the vaccine in children beyond the second year of life, Menitorix[®] is considered likely to be safe and effective when immunisation against Hib or MenC is required in children from 2 to <10 years. The number of doses and interval between catch-up vaccinations required for MenC and Hib in children <10 years of age are outlined in the 10th edition *Immunisation Handbook*. The use of Hib vaccine is not recommended in individuals who are ≥ 5 years of age, unless they have certain immunocompromising conditions (such as asplenia) and a Hib dose has not previously been given, or if the primary course of Hib vaccine is incomplete.

- 2) *When catching up either Hib or menC vaccinations using Menitorix[®], administering 'extra' (more than strictly required) dose(s) of the other antigen is acceptable.*

As stated in Section 2.1.5 *Catch-up*, 'Planning catch-up vaccination' on page 41 of the 10th edition *Immunisation Handbook*, the use of a combination vaccine(s) is acceptable in catch-up situations if it is the only available vaccine containing the antigens required. This remains the case even if use of the combination vaccine means the number of doses of one or more antigens administered exceeds the number strictly required. The justification for this is that the benefits of catch-up vaccination(s) are much greater than any potential increase in adverse events following administration of additional dose(s) of either Hib or MenCCV.

- 3) ***Priority should be given to administering due doses of Infanrix hexa[®], Prevenar 13[®] and measles-mumps-rubella (MMR) vaccines over menC vaccine in a child over 12 months of age who has had few or no prior vaccinations, particularly when considering the number of injections administered at one visit.***

In instances where multiple injections are required at a single visit, often in a child aged ≥ 12 months in whom few or no prior vaccine doses have been administered, local disease epidemiology and the degree of protection expected from the number of vaccine doses already provided are important factors in deciding the priority given to each required catch-up vaccination. Due to the current very low incidence of meningococcal serogroup C disease in children, priority should be given to catch-up vaccinations for other recommended infant vaccinations. Patients can be recalled at the next appropriate time point for administration of Menitorix[®]. Chapter 2.1 *Pre-vaccination*, in the 10th edition *Immunisation Handbook*, provides information and resources to assist in the planning of catch-up schedules, in particular *Table 2.1.7 Minimum acceptable dose intervals for children <10 years of age*, which outlines the minimum acceptable intervals between doses considered in special circumstances such as catch-up vaccination.

- 4) ***The administration of Menitorix[®] at the same time as another Hib-containing vaccine is not preferred, but considered acceptable in the context of delivering catch-up vaccinations if no alternative vaccine(s) or scheduling is suitable.***

As stated in the 10th edition *Immunisation Handbook*, Menitorix[®] can be administered simultaneously with other vaccines on the NIP schedule. The Menitorix[®] PI states that care should be taken not to administer Menitorix[®] concurrently with other vaccines containing either Hib or menC vaccine, which is appropriate for routine vaccination. However, the ATAGI considers that the co-administration of Menitorix[®] with other Hib-containing vaccines, such as Infanrix hexa[®] (DTPa-hepB-IPV-Hib), is acceptable in catch-up situations if there is no suitable alternative vaccine(s) or schedules, although ***it is not the preferred option***. This could occur, for example, if there is uncertainty about being able to successfully recall the patient for later administration of Menitorix[®] and assumes the number of injections offered at the current visit is acceptable. From first principles, ATAGI considers that the co-administration of Menitorix[®] with other Hib-containing vaccines is unlikely to result in any clinically important increase in adverse events or reduction in immunogenicity of concomitantly administered vaccine antigens, although this has not been assessed formally in clinical studies.

The feasibility of using lower valency DTPa-containing vaccines, such as DTPa-IPV, in a catch-up schedule can be considered to prevent the co-administration of Menitorix[®] with Infanrix hexa[®]. However, this approach would require ready access to monovalent paediatric hepatitis B vaccine if subsequent hepatitis B doses are required that cannot be delivered via a combination vaccine.

It is considered inappropriate to deliver the un-reconstituted component of Infanrix hexa[®] (that is, the content of the pre-filled syringe which only contains DTPa-hepB-IPV antigens) in an effort to avoid administration of Hib PRP-T antigen.

Using Menitorix[®] in adolescents and adults

There is limited evidence on the use of Menitorix[®] in adolescents and adults. Vaccination of adolescents and adults against Hib and menC is not routinely recommended. As discussed above, catch-up for Hib vaccination is not generally required for children ≥ 5 years of age. In circumstances where a dose of MenCCV is required for a person ≥ 10 years of age, such as for an unimmunised household or sexual contact of a case of confirmed vaccine-preventable invasive meningococcal disease, Menitorix[®] is considered acceptable, until further evidence becomes available. Alternatively, the use of quadrivalent meningococcal conjugate vaccines (Menactra[®] and Menveo[®]) is also an option and has the advantage of providing protection against meningococcal serogroups A, W₁₃₅ and Y in addition to serogroup C. The use of quadrivalent meningococcal conjugate vaccines is preferred over quadrivalent meningococcal polysaccharide vaccines (Mencevax ACWY[®] and Menomune[®]). None of the available meningococcal vaccines are funded under the NIP for these uses.

Guidance on the use of meningococcal vaccines for the public health management of meningococcal disease outbreaks is provided in the *Guidelines for the early clinical and public health management of meningococcal disease in Australia*.

Additional information on the vaccination recommendations for meningococcal disease and Hib are outlined in the 10th edition of [The Australian Immunisation Handbook](#).

Table 1: Examples of acceptable catch-up schedules for a 12-month-old child* who has not previously received any infant vaccinations, applying the above general principles

Option	Visit 1	Visit 2	Visit 3	Visit 4 [†]	Rationale
1	Now	1 month after visit 1	1 month after visit 2	2 months after visit 3 [†]	
	Infanrix hexa [®] Prevenar 13 [®] MMR	Infanrix hexa [®]	Menitorix [®]	Infanrix hexa [®]	<i>This is the preferred catch-up schedule using Menitorix[®].</i> As the incidence of meningococcal C disease is currently low, the MenCCV catch-up dose as Menitorix [®] is delayed until visit 3, and the 3rd dose of Infanrix hexa [®] is delayed until visit 4 to meet the minimum interval requirements for hepatitis B-containing vaccines. This overcomes the need for co-administration of Menitorix [®] with another Hib-containing vaccine.
2	Now	1 month after visit 1	1 month after visit 2	3 months after visit 3 [†]	
	Infanrix IPV [®] Prevenar 13 [®] MMR Menitorix [®]	Infanrix hexa [®]	Infanrix hexa [®]	Monovalent paediatric hepatitis B	Infanrix IPV [®] given at visit 1 instead of Infanrix hexa [®] overcomes the need for co-administration of Menitorix [®] with another Hib-containing vaccine. This option delays the start of hepatitis B catch-up by 1 month and provides timely commencement of catch-up for other required vaccines. Access to monovalent paediatric hepatitis B at visit 4 is required, meeting the minimum interval requirements for hepatitis B-containing vaccines.
3	Now	1 month after visit 1	3 months after visit 2 [†]		
	Infanrix hexa [®] Prevenar 13 [®] MMR Menitorix [®]	Infanrix hexa [®]	Infanrix hexa [®]	N/A	Menitorix [®] can be administered with other Hib-containing vaccines. This option provides timely catch-up for all required vaccines and can be suitable for children who cannot make return visits in a timely way. This is not the preferred option, but is acceptable in catch-up situations if there is no suitable alternative vaccines or schedules.

N/A = not applicable

* Other catch-up schedules that are not listed in the above table may also be considered appropriate.

† Consider administering the required catch-up dose scheduled at this visit with measles-mumps-rubella-varicella (MMRV) vaccine, which is recommended on the NIP at 18 months of age as the second dose of measles-containing vaccine, but can be given earlier if there is concern about a timely return visit. The minimum interval between MMR-containing vaccines is 4 weeks.