Risks of omitting Hib when administering Infanrix-IPV+Hib

Issue
The NPSA is aware of continuing incidents of children not receiving the Haemophilus influenzae type b (Hib) component of a combined pre-school vaccine (Infanrix-IPV+Hib). This is part of the Hib Catch-up campaign, which applies to children born between March 2003 and September 2005.

Advice on the need to reconstitute the Hib component was issued by the Department of Health (DH) on 26 September 2008 [Gateway 10633], in Vaccine Update [July and October editions] and by the Welsh Assembly Government (WAG) on 1 October 2008. This Report reinforces that advice with specific actions for staff via the Central Alerting System (England) and directly to organisations in Wales.

Patient safety incidents
The NPSA is aware of 80 recently reported incidents (some involving multiple patients) of children not receiving the Hib component of the booster vaccine up to mid-October 2008 across England and Wales. The manufacturer also received 68 calls about the problem in September 2008 and a further 19 in early October 2008 and anecdotal information suggests further incidents which have not been reported.

Recent supplies of Infanrix-IPV+Hib have been imported from other European countries, with outer packaging overlabelled in English. The Patient Information Leaflets (PILs) and instructions for use in English are supplied alongside stocks, but these were not always available at point of use. Some staff may have not realised that there was a vial of Hib vaccine in the pack that needed to be reconstituted with the liquid DTP-IPV that was in a pre-filled syringe. Some have been familiar with an alternative single ready to use product (Pediacel), available during supply shortages, which did not require separate reconstitution of the Hib component.

For IMMEDIATE ACTION by Immunisation Leads in Primary Care Trusts/Local Health Boards, DATE FOR ACTION COMPLETE is 4 November 2008

Each practice or vaccination clinic should be able to demonstrate that:
• 008/1. All staff who prepare and administer childhood vaccines are aware of correct methods of preparation for all vaccines, including Infanrix-IPV+Hib where the powdered Hib needs to be reconstituted before administration, using contents of the pre-filled syringe.
• 008/2 They have checked that PILs and instructions for use in English are available with each dose at the time it is given.
• 008/3 They have procedures in place to review practice for administering Infanrix-IPV+Hib and for identifying all children in the current Hib Catch-up campaign at risk of not receiving the Hib component of this vaccine. These children should be invited back to receive a separate dose of Menitorix (Hib/MenC) before March 2009, in line with DH advice in the letter of 26 September 2008 [Gateway 10633] and WAG on 1 October 2008.
• 008/4 Local procedures and policies have been reviewed to incorporate the above and this is reflected in Patient Group Directions (or equivalent in Wales), where applicable.
• 008/5 Problems such as these are reported via local incident reporting systems.

Further information
For queries about the work of the NPSA, please contact Tara Lamont: rrr@npsa.nhs.uk
For clinical queries about this issue, please contact Dorian Kennedy: Dorian.Kennedy@dh.gsi.gov.uk